Oiva Evaluation Guidelines for approved food establishments

Oiva Evaluation Guidelines include Evira's Guidelines 10205, 10232-10243, 10245,10249-10252, 10256-10322 and 10324-10333.

The headings of the Guidelines (KUTI lines), including the number of the heading, as well as the number, version and last-updated date of the Guideline are shown in the list below. If any changes are made in a Guideline, a new revised version is published. The last-updated date indicates the date the last version was made and approved. The most recent last-update dates are shown in bold. Lines indicated with orange colour refer to evaluations that are not included in the Oiva report, but only in the evaluation report.

Last updated on 3 July 2017

	Number and name of topical area and matter to be evaluated	No. of Guideline / version / last updated on
00	**Evaluation scale for evaluation guidelines of control results**	
0.1	General evaluation criteria for grading in the Oiva evaluation scale	10205 / 1 / 12.1.2015
01	**Compliance with requirements for approval**	
1.1	Approval of facilities, structures and equipment	10263 / 2 / 18.12.2015
1.2	Approval of activities	10264 / 2 / 18.12.2015
1.3	Approval of TSE activities	10265 / 2 / 18.12.2015
1.4	Compliance of water intended for human consumption with requirements	10266 / 1 / 1.5.2015
1.5	Compliance of clean water with requirements	10267 / 1 / 1.5.2015
1.6	General compliance of own-check with requirements	10268 / 2 / 18.12.2015
Annex:	Adequacy and suitability of own-check	1.5.2015
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05	**Hygiene of food production**	
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08	**Specific requirements for food production**	
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14.1	Packaging materials and other food contact materials	**10245 / 5 / 3.7.2017**
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16.4	Traceability of fish and fishery products under dioxin regulations	10251 / 2 / 11.1.2016
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18.1	Display of the Oiva report	10262 / 2 / 1.1.2017
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19.6	Spreadable fats	10332 / 2 / 1.1.2017
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0. Evaluation Scale for the Evaluation Guidelines of Control Results

0.1 General Evaluation Criteria for Grading in the Oiva Evaluation Scale

The common criteria for the Oiva evaluation scale are presented in this guideline which together with the substance-based Oiva evaluation guidelines comprise the overall set of Oiva evaluation guidelines.

To be taken into consideration:

- This guideline presents general descriptions of the Oiva evaluation scale, in which the risk-based aspects have been taken into account. The risk-based approach is discussed in more detail in the Oiva evaluation guidelines pertaining to specific substance areas.
- Oiva grades apply to approved food establishments or registered food premises.
- The general descriptions of the grades in the evaluation scale pertain to all evaluation guidelines of control results and all areas subject to control.
- The guidelines are all based on the statutes of the Food Act with which Eviras interpretation guidelines can be utilised.
- The Oiva evaluation guidelines, which are published separately, provide more precise and particular guidelines for the application of the evaluation scale.

EXCELLENT

Operations comply with requirements.

The inspector concludes that the inspected areas comply with the requirements of the legislation.

The inspector is satisfied that the operator is capable of dealing with sudden and random shortcomings and rectifying them through the in-house control system.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The inspector issues a written open notice to the operator of the detected shortcomings.

The inspector is satisfied that the operator is capable of dealing with sudden and random shortcomings and rectifying them through the in-house control system.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

As a rule, the inspector shall make use of the administrative coersive measures

referred to in the Food Act to ensure compliance with legislation.
However, the inspector may issue a written notice for corrective action with a set period of time, if there is a justified reason for this.

The areas covered by the inspection as specified in the guidelines do not cause a direct reduction in food safety. In this case, the grade "To Be Corrected" can however be given provided that the grade "Good" has been given repeatedly.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The inspector orders the operator to take corrective actions immediately. In cases like this, the inspector must always make use of the administrative coersive measures referred to in the Food Act to ensure compliance with legislation.

The areas specified in the guidelines do not immediately jeopardise food safety. In this case, the grade "Poor" can however be given, provided that the grade "Good" has been given repeatedly and the shortcomings have not been rectified within the set period of time.

1 Compliance with Requirements for Approval

1.1 Approval of Facilities, Structures and Equipment

To be taken into consideration:

- This Guideline is applied to all establishments.
- Evira maintains a register of approved establishments. The web address to the register of the establishments is provided at the end of this Guideline
- The food business operator is responsible for the compliance of the establishment with regulatory requirements and requirements for approval, also when operations are carried out in rented facilities.
- The evaluation carried out in this point concerns compliance with the structural requirements for approval of the establishments, including the compliance of facilities, structures and equipment with approval documents and compliance with regulatory requirements.
- In addition, this point covers the evaluation of whether the plant has applied for and been granted approval for any fundamental changes implemented in the facilities, structures or equipment.
- Facilities, structures and equipment are considered to include, for example, ceilings, walls, floors, water supply points, washing and disinfection systems, systems for draining of condensation water, washing water and wastewater as well as waste disposal systems, ventilations systems, and comparable matters. In this point, attention is paid to their availability, arrangement, materials and uses as well as hygiene.
- In some cases the operator may reduce the risk caused by minor structural shortcomings by means of operational arrangements, if food safety can be ensured through the arrangements (an example provided under the grade Good).
- A situation where the approval procedure has not been carried out in accordance with good governance or the approval decision fails to meet the requirements laid down in Decree 420/2011 on food control shall be taken into consideration in the evaluation. The operator is not responsible for shortcomings of this kind and they must be excluded from the evaluation.
- Compliance with operational requirements for approval is evaluated in point 1.2.
- The general compliance of the own-check plan with requirements is evaluated in point 1.6.
- The compliance of water intended for human consumption with requirements is evaluated in point 1.4 and the compliance of clean water in point 1.5.
- The approvals of OHSE activities (Occupational Health, Safety & Environment) are evaluated in point 1.3.

Matters to be controlled:

- The availability of approval documents and reports accompanying them for control at the establishment.
- The compliance of the availability, arrangement, implementation, materials and use of facilities, structures and equipment with the approval documents.
- The compliance of the availability, arrangement, implementation, the materials used and the application of facilities, structures and equipment with the valid regulatory requirements.
- Compliance with the structural conditions laid down in the approval decision.
- Implementation of fundamental structural changes arising from changes in legislation, and approvals applied for them.
- Implementation of fundamental structural changes arising from the operator, and approvals applied for them.

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- Approval documents and reports accompanying them are up-to-date and available for control at the establishment, and the valid approvals of the establishment regarding facilities, structures and equipment can be verified from them.
- The arrangement and the uses of the facilities comply with approval documents.
- Structures and surfaces are made from materials that are easy to keep clean.
- Drain systems for condensation water and wastewater are in place and comply with requirements.
- The number and arrangement of water supply points comply with approval documents and regulatory requirements.
- The structural conditions laid down in the approval decision are fulfilled.
- Approval has been applied and granted for fundamental structural changes prior to the start of operation.
- Needs for fundamental structural changes arising from changes in legislation have been implemented.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in the availability of approval documents for control.
- Structures and surfaces and in some parts made from a material that is difficult to keep clean; it is in good condition, but in order to ensure food safety, surfaces have been protected or the cleaning of surfaces is carried out especially thoroughly, for example. In a case like this, the grade Good can be awarded, depending on the nature of the shortcoming.
- There is no drain for washing water in a room where one should be provided pursuant to legislation, but the draining of washing water has been implemented in a hygienic manner.
- The deadlines for the conditions laid down in the approval decision have not been kept, but activities are under progress.
- The layout plan of the establishment is not up-to-date, but this shortcoming does not impair food safety.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- The facilities, structures and equipment, and their arrangement and uses differ substantially from those approved according to the approval documents.
- There is no drain for washing water in a room where one should be provided pursuant to legislation, and the draining of washing water has not been implemented in a hygienic manner, and the shortcoming impairs food safety.
- The facilities, structures and equipment, and their arrangement and uses comply with what is indicated in the approval documents, but some essential changes of legislation have not been taken into consideration as regards them.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- The establishment uses facilities for which no approval has been applied and granted, and the risks related to operation are not under control.
- It has become known since the approval was granted that the material or substance used in the structures or equipment of the establishment jeopardises food safety, and the operator has failed to take corrective actions.
- The establishment has failed to fulfil the structural conditions laid down in the approval decision to verify food safety.
- The operator has failed to execute the orders issued with the grade to be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 882/2004 on official controls
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Finnish Food Act 23/2006
- Government Decree on food control 420/2011
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on actions related to TSE diseases concerning slaughterhouses and cutting plants
- Evira's Guide 16033: Approval of an establishment
- Evira's Guide 16011: TSE actions at establishments
- Register maintained by Evira of approved establishments and storage facilities in meat, fish, milk and egg business: http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/elintarvikehuoneistot+/hyvaksytyt+laitokset+/laitokset/

Updates in version 2:

The responsibilities of the operator and the control authority as concerns the evaluation of approval decisions clarified in the point To be taken into consideration.

1 Compliance with Requirements for Approval

1.2 Approval of Activities

To be taken into consideration:

- This Guideline is applied to all establishments.
- For the purposes of this Guideline, activities refer to the activities recorded in the register of establishments maintained by Evira; the approval of the control authority is required for these activities. The web address to the register of the establishments is provided at the end of this Guideline
- Only matters related to the approval of activities are evaluated in this point, e.g. do the activities carried out at the establishment comply with the activities for which an approval has been granted to the establishment.
- The food business operator is responsible for the compliance of the operations with regulatory requirements and requirements for approval, also when the establishment carries out in their facilities operations that are not related to its actual own food production (for example, washing of food containers that are not the establishment's own containers).
- In addition, compliance with any operational conditions laid down in the approval decision is to be evaluated in this point. For example, the approval of the establishment may be granted on the condition that activities or work stages requiring different levels of hygiene that are carried out in the same production facility must be separated in time and the production facility must be thoroughly cleaned between them.
- The compliance of activities with the requirements for approval laid down in valid legislation and, for example, with the limits specified for production volumes (low-capacity slaughterhouses) is also evaluated in this point. For example, even if the facilities, structure and equipment of the establishment meet requirements as such, it is possible that the production volumes of the establishment have become too high in relation to the production facilities, equipment or number of personnel, and it is no longer possible to produce foodstuffs in a hygienic manner.
- In addition, this point covers the evaluation of whether the plant has applied for and been granted approval for any fundamental changes implemented in its activities.
- A situation where the approval procedure has not been carried out in accordance with good governance or the approval decision fails to meet the requirements laid down in Food Control Decree 420/2011 shall be taken into consideration in the evaluation. The operator is not responsible for shortcomings of this kind and they must be excluded from the evaluation.
- The compliance of practical implementation of production with requirements and the compliance of operation with requirements not related to approvals are evaluated in each specific evaluation point.
- The approvals of OHSE activities (Occupational Health, Safety & Environment) are evaluated in point 1.3.

Matters to be controlled:

- The compliance of the activities carried out at the establishment in practice with the activities approved according to the approval documents.
- The legality of the approvals of activities with respect to valid legislation.
- The proportioning of operations to the capacity and permitted production volumes of the establishment so as to ensure the hygiene of operations.
- Compliance in practice with the operational conditions laid down in the approval decision.

- Approvals applied for the implementation of fundamental changes arising from the operator.
- Implementation of fundamental needs for changes arising from changes in legislation, and approvals applied for them.

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- Approval documents and reports accompanying them are up-to-date and available for control at the establishment, and the valid approvals of the establishment regarding activities can be verified from them.
- The activities carried out at the establishment comply with those approved according to approval documents.
- The activities carried out at the establishment comply with the requirements laid down in valid legislation.
- Approval has been applied and granted for fundamental changes prior to the start of the activity.
- Any operational conditions laid down in the approval decision have been complied with in practice.
- Needs for fundamental structural changes arising from changes in legislation have been implemented.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- The activities carried out at the establishment comply, in essence, with those approved according to approval documents.
- The activities carried out at the establishment comply, in essence, with the requirements laid down in valid legislation, but there may be some minor shortcomings which do not, however, impair food safety.
- Approval has not been applied and granted for a fundamental change prior to the start of the activity, but this shortcoming does not impair food safety (a fundamental change may also increase food safety).
- There are some minor shortcomings in compliance with the operational conditions laid down in the approval decision, but these do not impair food safety, however.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time

For example:

- The activities carried out at the establishment do not comply with the activities for which the establishment has approval, and this shortcoming impairs food safety. For example, the establishment only has approval for cutting meat, but the establishment also produces minced meat.

- The activities carried out at the establishment do not comply with the requirements laid down in valid legislation, or the operational conditions laid down in the approval decision have not been complied with.
- Approval has not been applied and granted for a fundamental change prior to the start of the activity, and this shortcoming impairs food safety.
- The activities comply with those indicated in the approval documents, but the operator has failed to take notice of regulatory requirements that have changed fundamentally.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- The activities carried out at the establishment do not comply with the activities for which the establishment has approval, and this shortcoming jeopardises food safety.
- The activities carried out at the establishment do not comply with the requirements laid down in valid legislation, and this shortcoming jeopardises food safety.
- The operational conditions laid down in the approval decision have not been complied with.
- Approval has not been applied and granted for a fundamental change prior to the start of the activity, and this shortcoming jeopardises food safety. For example, the establishment only has approval to slaughter swine, but the establishment has started to slaughter also sheep, and has failed to apply for approval for this change.
- The operator has failed to execute the orders issued with the grade To be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 882/2004 on official controls
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on hygiene rules for food of animal origin
- Finnish Food Act 23/2006
- Government Decree on food control 420/2011
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on actions related to TSE diseases concerning slaughterhouses and cutting plants
- Evira's Guide 16033: Approval of an establishment
- Evira's Guide 16011: TSE actions at establishments
- Register maintained by Evira of approved establishments and storage facilities in meat, fish, milk and egg business: http://www.evira.fi/portal/fi/elintarvikkeet/valmistus+ja+myynti/elintarvikehuoneistot+/hyvaksytyt+laitokset+/laitokset/

Updates in version 2:

The responsibilities of the operator and the control authority as concerns the evaluation of approval decisions clarified in the point To be taken into consideration.

1 Compliance with Requirements for Approval

1.3 Approval of TSE Activities

To be taken into consideration:

- This Guideline is applied to cutting plants which are required to have specific approval as an establishment that separates TSE risk material.
- The purpose of this point is to control that the cutting plant has approval for activities for which specific TSE approval is required.
- The up-to-date status of the own-check plan and its compliance with the approval decision are also evaluated in this point.
- The separation of material of animal origin from wastewater in the facilities of slaughterhouses and cutting plants where TSE risk material is being separated is evaluated in point 1.1.
- The implementation of TSE operations in practice as well as the adequacy and suitability of the own-check plan are evaluated in point 8.1.

Matters to be controlled:

- TSE approval documents are available for control at the establishment.
- The establishment has applied for approval for all the TSE activities carried out at the establishment for which approval is required pursuant to legislation.
- Any conditions laid down in the TSE approval decision as regards facilities, structures, utensils or equipment are complied with (compliance with operational conditions is controlled in point 8.1).

EXCELLENT

Operations comply with requirements.

The establishment has applied for approval for all the TSE activities carried out at the establishment for which approval is required pursuant to legislation.

The facilities, structures and utensils etc. used in TSE activities comply with the approval documents and legislation.

Approval has been applied and granted for fundamental changes in operation prior to the implementation of the change.

Approval documents are available for control.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings as concerns the availability of the approval documents of the establishment for control.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:
- Approval documents are not available for control.
- TSE activities do not comply with the approval decision or the conditions laid down in the decision.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:
- The establishment has not applied for the specific approval required to carry out TSE activities.
- The establishment has not applied for approval for a fundamental change in TSE activities.

Legislation and guidelines (with any amendments) pertaining to the subject:
- Regulation (EC) No 999/2001, rules regarding TSEs
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on meat controls 590/2014
- Decree of the Ministry of Agriculture and Forestry on actions related to TSE diseases concerning slaughterhouses and cutting plants 7/EEO/2009
- Evira's Guide 16011: TSE actions at establishments
- Evira's Guide 16033: Guide for approval of an establishment

Updates in version 2:

Added in the point To be taken into consideration: The separation of material of animal origin from wastewater in the facilities of slaughterhouses and cutting plants where TSE risk material is being separated is evaluated in point 1.1.

1 Compliance with Requirements for Approval

1.4 Compliance of Water Intended for Human Consumption with Requirements

To be taken into consideration:

- This point is to be controlled in all establishments that use water intended for human consumption.
- Matters related to the own-check activities of water intended for human consumption are controlled in point 17.3 Own-check Testing of Water and Ice
- If part or all of the water used in production is clean water, matters related to it are evaluated in point 1.5 Compliance of Clean Water with Requirements.
- The purpose of this point is to control that the water intended for human consumption used at the plant comes from a plant that supplies water intended for human consumption or from the establishment's own source of water intended for human consumption from which samples are taken on a regular basis as required by the Decree on water intended for human consumption.
- It is also to be controlled that any recycled water used at the establishment does not cause any risk of contamination.

Matters to be controlled:

- The source/sources of water intended for human consumption used at the establishment are a plant that supplies water intended for human consumption as referred to in the Health Protection Act, or the establishment's own source of water intended for human consumption from which samples are taken on a regular basis as required by the Decree on water intended for human consumption.
- Any recycled water used at the establishment does not cause any risk of contamination. Recycled water meets the same requirements as water intended for human consumption, unless the competent authority is of the view that the quality of the water does not affect the safety of finished food products.

EXCELLENT

Operations comply with requirements.

- The source/sources of water intended for human consumption used at the establishment are a plant that supplies water intended for human consumption as referred to in the Health Protection Act, or the establishment's own source of water intended for human consumption from which samples are taken on a regular basis as required by the Decree on water intended for human consumption. This can be demonstrated e.g. by presenting a contract related to water management, or the matter is described in the own-check plan.
- The use of recycled water is arranged so as to ensure it causes no risk of contamination.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- The source/sources of water intended for human consumption used at the establishment are a plant that supplies water intended for human consumption as referred to in the Health Protection Act, or the establishment's own source of water intended for human consumption from which samples are taken on a regular basis as required by the Decree on water intended for human consumption, but the establishment is unable to demonstrate this e.g. by presenting a contract related to water management, or it has not been described in the own-check plan.
- There are some minor shortcomings in the use of recycled water which do not impair food safety.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- There are some shortcomings in the use of recycled water which impair food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- The water intended for human consumption used at the plant does not come from a plant that supplies water intended for human consumption or from the establishment's own source of water intended for human consumption from which samples are taken on a regular basis as required by the Decree on water intended for human consumption.
- The recycled water used at the establishment jeopardises food safety.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Government Decree on food control 420/2011
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

1 Compliance with Requirements for Approval

1.5 Compliance of Clean Water with Requirements

To be taken into consideration:

- This Guideline is applied to establishments in the fish sector.
- Matters related to the sampling of clean water (clean seawater or comparable fresh water) at the establishment are controlled in point 17.3 Own-check Testing of Water and Ice.
- If part or all of the water used in production is water intended for human consumption, matters related to it are evaluated in point 1.4 Compliance of Water Intended for Human Consumption with Requirements.
- The purpose of this point is to control that the intake of clean water has been arranged in a manner and from a source that makes it possible to assess the use of water to be safe.
- It is also controlled in this point that the areas of production and the activities in which clean water is used are suitable for it and food safety is not compromised.
- It is also controlled in this point that the microbiological and chemical quality of the source of clean water complies with regulatory requirements and recommendations.

Matters to be controlled:

- The intake of clean water, and the purification of the water, if any, is technically arranged in a manner that ensures risks are under control.
- The quality of the source of clean water has been assessed to allow it to be used in the specified activities at the relevant establishment in fish sector.
    - The water must not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the safety of food.

EXCELLENT

Operations comply with requirements.

- The quality of the source of clean water has been assessed to allow it to be used, purified or non-purified, in the specified activities at the relevant establishment.
- The purification of water, if any, is technically arranged in a manner that ensures the safety of foodstuffs is not impaired.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- The quality of the source of clean water has been assessed to allow it to be used, purified or non-purified, in the specified activities at the relevant establishment.
- The activities in which clean water is used have been deficiently defined in some respects, but the use of the water in them does not impair food safety.
- The technical suitability of the water purification system, if any, has been deficiently assessed, but the use of the system does not impair food safety.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- The quality of the source of the clean water used has been assessed to allow it to be used in the activities permitted by legislation at an establishment in the fish sector, but variations in the quality of non-purified water, for example, may impair food safety.
- The activities in which clean water is used have been deficiently defined, or the use of the water in them may impair food safety.
- The technical suitability of the water purification system, if any, has been deficiently assessed, and the use of the system may impair food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The clean water used does not meet quality criteria and may jeopardise food safety.
- Clean water is used in activities in which its use jeopardises food safety.
- The water purification system, if any, jeopardises food safety.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002/EC on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, Annex III, Section VIII
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Annex 2, Chapter 10.2
- Evira's Guide 16023, Control of fishery products

1 Compliance with Requirements for Approval

1.6 General Compliance of Own-check with Requirements

To be taken into consideration:

- The purpose of this point is to assess on a general level the controllability, basic structure, coverage and up-to-date status of the own-check plan, the risk assessment included in it, and any other HACCP procedures.
- The own-check plan and its execution, adequacy and suitability are evaluated specifically for each topical area and the evaluation is included in the grade of the topical area.
- In small companies (1-2 employees), the descriptions of all the programmes included within the scope of the prerequisite programmes need not necessarily be in written form.
- In some cases, a good practical guideline evaluated by Evira can replace the operator's own risk assessment.
- The own-check plan can be part of the quality system.
- The own-check plan shall be readily available for control. For the control of extensive own-check plans, the assistance of personnel familiar with the plan at the establishment should be taken advantage of. The evaluation result may not be reduced in case the controlling inspector is not able to identify the required matters in the own-check plan without assistance.
- Critical control points are not necessary, if the decision on their exclusion has been made based on a risk assessment.

Matters to be controlled:

- Availability of the own-check plan for control
- Coverage of the prerequisite programmes
- Assessment of risks
- Critical control points, if any, critical limits, monitoring procedures and corrective actions
- Verification practices
- Up-to-date status of the own-check plan, and the initial assessment, and if necessary re-assessment (validation)
- The laboratory (laboratories) used for the analysis of own-check samples required by legislation to be tested

EXCELLENT

Operations comply with requirements.

The own-check plan is available for control.

The own-check plan covers all the required prerequisite programmes.

The own-check plan covers all the facilities and activities of the establishment.

A risk assessment has been carried out for all processes and product groups.

Control points and good practices have been defined.

Critical control points, if any, critical limits, monitoring procedures and corrective actions have been defined.

Verification practices have been defined.

The own-check plan has been updated after any fundamental changes, the effectiveness of own-check has been validated before adoption and has been re-validated, where necessary.

Own-check samples required by legislation to be tested are analysed by a laboratory approved by Evira.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in the prerequisite programmes.
- There are some inaccuracies in the descriptions of monitoring procedures or corrective actions.
- There are some minor shortcomings in the updating of the own-check plan after fundamental changes.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- The own-check plan is not available for control.
- The prerequisite programmes does not include all the required programmes.
- A risk assessment has not been carried out for all processes and product groups and the shortcomings may impair food safety.
- Corrective actions have not been defined for deviations from critical limits.
- Verification practices have not been defined.
- The own-check plan has not been updated after fundamental changes, and the plan is not consistent with current operations.
- An initial validation and/or re-validation, where necessary, of the effectiveness of the own-check plan has not been conducted.
- Own-check samples required by legislation to be tested are analysed by a laboratory that is not approved by Evira.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- The majority of the required parts of the prerequisite programmes are missing.
- A risk assessment has not been carried out for processes or product groups of such a nature that shortcomings in them may jeopardise food safety.
- Critical limits have not been defined for critical control points.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002/EY on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Article 4
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Section 5
- Evira's Guide 16043: Risk-based control of the own-check of food establishments

Updates in version 2:

- The text about the availability of the own-check plan for control made more specific in the point To be taken into consideration.

Adequacy and Suitability of Own-check

General evaluation

To be taken into consideration:

- The Guideline pertains to the evaluation of the adequacy and suitability of the own-check of each topical area, i.e. the plan and the execution (including the prerequisite programmes and HACCP, if any).
- The Guideline also covers the evaluation of the records related to own-check activities and the storage of such records.
- The grade based on this Guideline is **NOT** included in point 1.6 General Compliance of Own-check with Requirements.
- The evaluation is included in the grade of each specific topical area.
- The evaluation is primarily carried out on the basis of execution and the records; the plan is to be controlled, as appropriate.

Matters to be controlled:

- Suitability and adequacy of the execution of own-check, including corrective actions.
- Adequacy, suitability and up-to-date status of the own-check plan.
- Records of monitoring and execution related to the prerequisite programmes.
- Records of the monitoring of critical control points, if any.
- Records of deviations and corrective actions (e.g. temperature deviations, shortcomings in chain information, deviations in sampling results).
  a deviation refers to a monitoring result that is outside the set limit, an unacceptable monitoring result
  monitoring refers to observations or measurements made according to plans to assess if the matter to be monitored is under control

EXCELLENT

Operations comply with requirements.

The risks related to the topical area are under control through the execution of own-check activities.

The execution of own-check activities complies with the plan.

The own-check plan is adequate and suitable in relation to operations, and it is up-to-date.

Records have been made of the monitoring of critical control points.

Corrective actions have been adequate and appropriate. Deviations and corrective actions have been recorded.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in the execution of own-check activities.
- The execution of own-check activities does not comply with the plan in all respects.
- There are some minor inaccuracies in the own-check plan or it is not quite up-to-date.
- As a rule, records have been made of the monitoring of critical control points, but in some individual cases a record has not been made.
- Corrective actions have been adequate and appropriate. There are some minor shortcomings in the records of deviations and corrective actions related to the support system.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- The risks related to the topical area are not under control through the execution of own-check activities and food safety is impaired. There are major shortcomings in the monitoring of critical control points, for example.
- The execution of own-check activities deviates significantly from the plan.
- There are major shortcomings in the own-check plan, or there is no own-check plan for a topical area. Evaluation depends on the topical area.
- There are major shortcomings in the monitoring of critical control points.
- Corrective actions related to the support system have not been made or they have been inadequate. Food safety is impaired.
- There are major shortcomings in the records of deviations and corrective actions related to the support system.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- The risks related to the topical area are not under control through the execution of own-check activities and food safety is jeopardised. Critical control points are not monitored, for example.
- There is no own-check plan for a topical area. Evaluation depends on the topical area.
- Corrective actions related to critical control points have not been made or they have been inadequate.
- Corrective actions related to the support system have not been made or they have been inadequate. Food safety is jeopardised.

2 Maintenance of Facilities and Equipment

2.2 Maintenance of Facilities and Structures

To be taken into consideration:

- This Guideline is applied to all establishments.
- The maintenance of facilities and structures refers to the functionality, integrity and maintenance of e.g. ceiling, floor and wall surfaces and structures, and the ventilation system. For example, cleaning of ventilation ducts, maintenance of floor drain traps, finishing of various pipe penetrations and appropriateness of directions of air flow. The cleanliness of the outer surfaces, stop ends or protective enclosures/grilles of ventilation pipes is evaluated in connection with the cleanliness of structures in point 3.1.
- The maintenance of fixtures, equipment, water equipment and utensils is evaluated in point 2.3.
- The cleanliness and order of facilities and structures is evaluated in point 3.1, and the cleanliness of surfaces, fixtures, equipment and utensils in point 3.2.
- The forming of condensation water is evaluated in point 5.4 when it occurs during the chilling of foodstuffs and in point 5.6 when it occurs during the storage and warehousing of foodstuffs.

Matters to be controlled:

- Functionality and maintenance of facilities and structures as well as the ventilation system.
- The adequacy and suitability of own-check activities, and the own-check control plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The facilities and structures (floors, walls, ceilings, windows, doors) of the establishment are in good condition and function appropriately and can be appropriately cleaned. Ventilation is functional and adequate, and the maintenance of the ventilation system is looked after.

The establishment identifies areas in need of improvement in its own own-check activities, prepares an appropriate repair plan and executes repairs timely. Where necessary, the operator introduces adequate special arrangements for the execution of the repair plan.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

There are some minor shortcomings in the maintenance or functionality of facilities, structures or the ventilation system, but food safety is not impaired. For example:

- There is visible corrosion, peeling, or wear in staff facilities and other facilities where no unpackaged foodstuffs are handled.

- There is considerable wear in facilities where unpackaged foodstuffs are handled, but food safety is not impaired, however.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The maintenance of facilities, structures or the ventilation system has been deficient. The establishment does not have an appropriate repair plan in place or the repair plan is not complied with. For example:

- There is visible corrosion, peeling, mould or considerable wear in facilities where unpackaged foodstuffs are handled. For example, there is corrosion on the walls of a cold store where unpackaged foodstuffs are stored, or mould on silicon seals or broken door seals in a high-hygiene area.
- Inoperability of ventilation results in heavy formation of condensation water on structures.
- Incorrectly adjusted ventilation produces wrong pressure relations causing air to flow from contaminated areas to clean areas (e.g. from a waste room to production facilities), which results in impaired food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to rectify the issues within the set deadline.

The maintenance of facilities or structures has been neglected. No repair plan has been drawn up at the establishment or the establishment repeatedly fails to follow the repair plan. For example:

- In facilities where unpackaged foodstuffs are handled, peeling paint or plaster can fall onto unpackaged foodstuffs.
- Due to the inoperability of ventilation, condensation water is formed on the structures in production facilities and may then run onto unpackaged foodstuffs.
- The window structures of the production facilities are not tight, allowing pests and vermin to gain access into the production facilities.
- There is mould on ceiling structures or wall surfaces in a high-hygiene area.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

Updates in version 2

- The requirement for the introduction of special arrangements for the execution of repairs added under the grade Excellent.

2 Maintenance of Facilities and Equipment

2.3 Maintenance of Fixtures, Equipment, Water Equipment and Utensils

To be taken into consideration:

- This Guideline is applied to all establishments.
- Water equipment refers primarily to water equipment directly related to the manufacture of foodstuffs, such as water tanks, water pipes, tap filters, ice machines, water chilling equipment and disinfection equipment that uses water.
- Maintenance refers to the equipment functioning as planned, their functioning is controlled on a regular basis, maintenance is carried out timely and the condition (also the condition of their surfaces, i.e., easiness of cleaning) and calibration of the equipment are looked after.
- This point also covers the evaluation of the fulfilment of standardisation requirements regarding the measuring equipment and temperature-recording systems used in the storage of quick-frozen products, and the functionality of measuring equipment used for the temperature management of frozen foodstuffs.
- The maintenance of the facilities and structures of the establishment is evaluated in point 2.2.
- The cleanliness and order of facilities and structures is evaluated in point 3.1, and the cleanliness of surfaces, fixtures, equipment and utensils in point 3.2.
- The hygiene of water supply points (e.g. hand washing points) and equipment that uses water (e.g. disinfection equipment) is evaluated in point 5.3.
- The calibration of equipment used for monitoring of temperature in the carriage of foodstuffs is evaluated in point 5.4.

Matters to be controlled:

- The functionality, maintenance, and calibration, if appropriate, of fixtures, equipment (including measuring equipment, such as thermometers), water equipment and utensils.
- The adequacy and suitability of own-check activities, and the own-check control plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The maintenance of fixtures, equipment, water equipment and utensils is looked after. Fixtures, equipment, water equipment and utensils function as planned, they can be appropriately cleaned, their functioning is controlled on a regular basis and maintenance is carried out timely.

The establishment identifies areas in need of improvement in its own own-check activities, prepares an appropriate repair plan and carries repairs out timely.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

There are some minor shortcomings in the maintenance of fixtures, equipment, water equipment and utensils, but food safety is not impaired. For example:

- There is wear on the frames (not on surfaces in contact with foodstuffs) of fixtures or equipment causing difficulties in cleaning in facilities where unpackaged foodstuffs are handled.
- Fixtures, equipment, or utensils are extremely worn in facilities where unpackaged foodstuffs are not handled, or in staff facilities.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The maintenance of fixtures, equipment, water equipment or utensils has been deficient. The establishment does not have an appropriate repair plan in place or the repair plan is not complied with. For example:

- A conveyor belt that comes into contact with unpackaged foodstuffs is frayed to the extent that it is difficult to keep clean.
- Work counters in a cutting plant are worn to the extent that they are difficult to keep clean.
- The condition or age of tap filters or water hoses impairs food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The maintenance of fixtures, equipment, water equipment or utensils has been neglected. No repair plan has been drawn up at the establishment or the establishment repeatedly fails to follow the repair plan. For example:

- A conveyor belt that comes into contact with unpackaged foodstuffs is extremely frayed and its surface is worn to the extent that it cannot be cleaned anymore.
- The circulating flushing system used to wash piping does not function appropriately and food safety is jeopardised.
- A water cooling basin or equipment is badly corroded.
- The maintenance/calibration of a thermometer or an automatic temperature monitoring system has been neglected and food safety is jeopardised.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

Updates in version 2:

- The text concerning the evaluation of the maintenance of disinfection equipment that uses water and the calibration of the equipment has been made more specific in the Guideline.

- An item added in the point To be taken into consideration: This point also covers the evaluation of the fulfilment of standardisation requirements regarding the measuring equipment and temperature-recording systems used in the storage of quick-frozen products, and the functionality of measuring equipment used for the temperature management of frozen foodstuffs.

3 Cleanliness of Facilities, Surfaces and Equipment

3.1 Cleanliness and Order of Facilities and Structures

To be taken into consideration:

- This Guideline is applied to all establishments.
- This point pertains to the evaluation of the cleaning of food production facilities and structures in these facilities. Facilities and structures are usually not in direct contact with foodstuffs.
- The cleanliness and order of cleaning equipment store rooms and staff facilities are also evaluated in this point.
- The maintenance of the facilities and structures of the establishment is evaluated specifically in point 2.2.
- Structures refer to e.g. ceiling, floor, and wall surfaces as well as ceiling, floor, and wall structures, such as piping, wiring, and ceiling tracks.
- The cleanliness of structures also refers to the cleanliness of e.g. the outer surfaces and stop ends or protective enclosures/grilles of various piping and wiring (the internal cleanliness of ventilation ducts is evaluated in connection with maintenance in point 2.2), the cleanliness of ceiling tracks, and door and window surfaces, as well as the cleanliness of floor drains and their strainers.
- The order of facilities refers to the order of raw materials, finished products and other items maintained in production facilities, as well as the order maintained in the corridors of production facilities, for example.
- The cleanliness of water supply points is evaluated in point 5.3 Hygiene of Water Supply Points and Equipment Using Water.
- The microbiological monitoring of cleanliness is evaluated in point 17.1.

Matters to be controlled:

- Cleanliness and order of ceiling, wall, and floor surfaces and structures in the food establishment.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".
- As concerns own-check activities, the following matters, for example:
    - The plan/programmes cover all facilities and structures
    - Sensory monitoring of cleanliness
    - Instructions for cleaning and disinfection
    - Detergents and disinfectants used

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- The facilities and structures of the establishment are clean and in orderly condition.
- Own-check activities are adequate at the establishment to ensure the cleanliness and order of the facilities and structures.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:
- Items not used in production are stored in corridors where they gather dust and dirt, but food safety is not impaired, however.
- The surfaces of facilities or structures are covered with dirt or mould in staff facilities and other facilities where no unpackaged food is handled.
- Own-check activities do not cover all the facilities or surfaces or the cleaning interval is too long, but food safety is not impaired, however.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:
- The surfaces of facilities or structures are covered with dirt or mould in a high-hygiene area and this shortcoming impairs food safety.
- In facilities where no unpackaged food is handled, the surfaces of ceiling structures (such as ventilation pipes or ceiling tracks) are covered with dust or dirt (e.g. track grease) which may fall onto food.
- The maintenance of the facilities or structures, for example, has not been effective due to the presence or amount of items which should not be in the production facilities.
- Staff facilities or other facilities where no unpackaged food is handled are dirty and in disorderly condition, which impairs working hygiene and the safety of foodstuffs.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:
- The surfaces of facilities or structures are covered with grime or mould in high-hygiene areas and this shortcoming jeopardises food safety.
- Ceiling structures, for example, are extremely dirty or extremely dusty in the facilities where unpackaged food is handled and dirt or dust falls onto unpackaged food.
- The operator has failed to fulfil the orders issued with the grade To be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:
- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 882/2004 on official controls
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

Updates in version 2:

- Examples in grades Good, To Be Corrected and Poor have been specified

3 Cleanliness of Facilities, Surfaces and Equipment

3.2 Cleanliness of Surfaces, Fixtures, Equipment and Utensils

To be taken into consideration:

- This Guideline is applied to all establishments.
- The cleanliness of surfaces, fixtures, equipment and utensils need not be verified through sampling; instead, evaluation can be carried as a sensory inspection. Microbiological monitoring is evaluated in point 17.1 Sampling and Own-check Test.
- In this point, surfaces refer to e.g. work surfaces that are in direct contact with unpackaged or packaged foodstuffs. Not to wall surfaces.
- When evaluating the cleanliness of cleaning equipment, their intended use is to be taken into account; are they intended for public areas or used for surfaces on which unpackaged perishable foodstuffs are handled.
- The maintenance of the facilities and structures is evaluated in point 2.2.
- The maintenance of fixtures, equipment, water equipment and utensils is evaluated in point 2.3.
- The cleanliness and order of facilities and structures are evaluated in point 3.1.

Matters to be controlled:

- The cleanliness of the work surfaces, fixtures, equipment (excluding water equipment, including ovens and heating equipment) and utensils (including cleaning equipment) used at the establishment.
- Daily cleaning of water chilling equipment for poultry.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

- Surfaces, fixtures, equipment, and utensils are clean at the establishment.
- Own-check activities are adequate at the establishment to ensure the cleanliness of surfaces, fixtures, equipment, and utensils.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- Surfaces, fixtures, equipment, and utensils that are in contact with unpackaged foodstuffs are clean.
- There are some minor shortcomings in the cleanliness of other surfaces, fixtures, equipment, and utensils, such as uncleaned dirt or dust, but this does not impair food safety, however.
- There are some minor shortcomings in the cleanliness of cleaning equipment, but they are not so dirty, taking their intended purpose into account, as to have an adverse effect on food safety.

- Own-check does not cover all the surfaces, fixtures, equipment, and utensils at the establishment or the cleaning interval is too long, but food safety is not impaired, however.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There are shortcomings in the cleanliness of surfaces, fixtures, equipment, or utensils at the establishment which may impair food safety.
- Surfaces that are not in direct contact with foodstuffs are covered with grime or mould, for example.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The cleaning of surfaces, fixtures, equipment, or utensils has clearly been neglected.
- The surfaces, fixtures, equipment, or utensils of the production facilities are covered with grime or mould.
- Unpackaged foodstuffs are handled using surfaces, fixtures, equipment, or utensils that are dirty or mouldy and this jeopardises food safety.
- The cleaning equipment is so dirty that it is no longer appropriate for the intended purpose and needs to be urgently replaced.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

3 Cleanliness of Facilities, Surfaces and Equipment

3.5 Vermin Control

To be taken into consideration:

- This Guideline is applied to all establishments. The responsibility for appropriate vermin control lies with the establishment, even if vermin control has been outsourced.
- The products used for vermin control are authorised by the Finnish Safety and Chemicals Agency Tukes (www.tukes.fi). Authorised control products are listed in the biocide register of Tukes (http://biosidit.tukes.fi).

Matters to be controlled:

- The compliance ofown check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "General Compliance of Own-check with Requirements".
- Can vermin (such as rodents, insects, birds) or indications of vermin (such as droppings or materials damaged by rodents) be found in the facilities of the establishment.
- The products used for vermin control do not contaminate foodstuffs, raw materials and/or packaging materials.

EXCELLENT

Operations comply with requirements.

The own-check plan of the establishment for vermin control complies with requirements, the plan is complied with, and records are kept of control measures. There are no vermin or indications of the presence of vermin.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in the following cases where:

- There are some minor shortcomings in the own-check plan; for example, if bait boxes or traps are used, the map showing their locations is not updated.
- There are some minor shortcomings in the implementation of the own-check plan; for example, if traps are used, they are not controlled as frequently as planned.
- There are shortcomings in the records.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There is no own-check plan at all, or there is no plan for the control of a specific group of vermin, such as flies.
- Vermin, such as insects, or indications of vermin are found in the facilities of the establishment and the control measures are not adequately effective.
- Vermin control measures are only implemented on a random basis, although vermin, such as insects, or indications of vermin can be found in the facilities of the establishment.
- Records are deficient.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- Own-check does not include a vermin control plan, or several vermin groups are missing from the plan.
- No vermin control is implemented, and vermin or indications of vermin can be found in the production facilities.
- There are no records at all of vermin control.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Rodent control and use of rodenticides in feed and food production, Guideline by Evira and Tukes (Finnish Safety and Chemicals Agency) for producers, 10.12.2015 http://www.evira.fi/files/attachments/fi/elaimet/rehut/ohjeet/jyrsijatorjuntaohje_2015.pdf

Updates in version 2:

- Text in the point To be taken into consideration made more specific as concerns the authorisation of vermin control products.
- Added in the point To be taken into consideration: The products used for vermin control do not contaminate foodstuffs, raw materials and/or packaging materials.
- Examples given for evaluation made more specific.
- The guideline of Evira and Tukes on rodent control added in the list of legislation and guidelines.

3 Cleanliness of Facilities, Surfaces and Equipment

3.6 Disposal of Wastes and Wastewater

To be taken into consideration:

- The hygiene and adequacy of the disposal of food wastes, other wastes and wastewater are evaluated according to this Guideline only to the extent that the establishment is responsible for the disposal.
- By-products at establishments are evaluated in point 5.7 Hygiene of Handling and Storage of By-products.
- The working hygiene of the personnel is evaluated in point 4.1.

Matters to be controlled:

- Storage of food wastes and other wastes.
- Disposal of food wastes and other wastes from the establishment.
- Compliance with transfer routes specified for wastes at the establishment.
- Suitability of waste containers for collection of wastes. Closed containers or other suitable containers, or a disposal system. Waste containers are clearly distinguishable from containers designed for storage of foods.
- Washing and cleanliness of waste containers and waste management facilities.
- Hygiene of waste management activities for which the establishment is responsible.
- Monitoring of general cleanliness and order of waste treatment facilities for which a waste management company or some other external service provider is responsible, and submittal of complaints to the responsible service provider, in case a shortcoming related to the waste management facilities causes a risk to food safety.
- Suitability and functionality of drainage systems in the food processing area.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

- Food wastes and other wastes are stored adequately separated from manufacture and handling of food.
- Food wastes and other wastes are transferred to waste management areas as soon as possible, during the following production break or at the end of the production shift.
- The cleanliness of waste containers is looked after and the waste containers are suitable for their intended use.
- The general cleanliness and order of the waste management facilities is on a good level.
- The drainage system does not cause any risk of contamination to foodstuffs.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are some minor shortcomings in the transfer of food wastes and other wastes to the waste management facilities.
- There are some minor shortcomings in the cleanliness of waste containers, but the waste containers are suitable for their intended use.
- There are some minor shortcomings in the general cleanliness and order of waste management facilities.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- Food wastes and other wastes are stored at the establishment in a manner that impairs food safety.
- Waste containers are dirty and/or waste containers are not suitable for their intended use.
- The general cleanliness or order of the waste management facilities is not looked after.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- Food wastes and other wastes are stored at the establishment in a manner that jeopardises food safety. For example, wastes are transferred from the production facilities to the waste management facilities only once a week.
- Waste in partly or completely open drain troughs runs from a contaminated area towards or into a clean area, particularly to an area where foodstuffs exposed to contamination are handled.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

4 Actions and Training of Personnel

4.1 Working Hygiene of Personnel

To be taken into consideration:

- This Guideline is applied to all establishments.
- The use of protective gloves is evaluated in point 4.3 Working Clothes and Protective Clothing of Personnel.
- The temperature monitoring of the knife disinfection unit is evaluated in point 6.7.

Matters to be controlled:

- Own-check is adequately extensive at the establishment in relation to the scope of operations to ensure hygienic work practices.
- Work practices, such as hand hygiene, as well as hygienic working methods, such as the correct use of the two-knife system.
- Hygienic use of and disinfection instructions for working utensils, and utensils are only used for their intended use.
- Instructions for hand hygiene.
- Compliance with clean area division and defined routes.
- Smoking.
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

- Operational guidelines regarding hand hygiene are adequate and cover all operations.
- Good working hygiene is complied with in operation; for example, working utensils, such as knives, vessels, ladles and other utensils that come into contact with foods and raw materials of foods are replaced, cleaned and disinfected on a regular basis.
- The personnel looks after hand hygiene, also between work stages.
- Employees who handle perishable unpackaged foodstuffs do not have visible cuts, or artificial nails or piercing jewellery or any other jewellery. The same also applies to employees who handle other unpackaged foods, if the factors referred to could jeopardise food safety.
- The clean area division and the rules issued regarding the routes used by personnel, raw materials and materials are complied with.
- Rules issued regarding smoking are complied with.
- Compliance with guidelines related to working hygiene is monitored.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- Operational guidelines regarding working hygiene do not cover all operations. Some minor shortcomings are found, but they do not impair food safety, however.
- The own-check plan includes descriptions of the hygienic handling of the most important raw materials and foodstuffs. Some minor shortcomings are found.
- Guidelines do not cover all aspects of hygienic use of working utensils, but good practices are complied with. For example, working utensils, such as knives, vessels, ladles and other utensils that come into contact with foods and raw materials of foods are replaced, cleaned and disinfected on a regular basis.
- The personnel observe hand washing procedures, also between work stages.
- Employees who handle perishable unpackaged foodstuffs do not have visible cuts or artificial nails, but some of them have piercing jewellery and some other jewellery. The same also applies to employees who handle other unpackaged foods, if the factors referred to could jeopardise food safety.
- The clean area division and the rules issued regarding the routes used by personnel, raw materials and materials are complied with as far as the clean area is concerned.
- Rules issued regarding smoking are complied with fairly well. Some minor deviations are found in the control.
- A plan has been prepared for the monitoring of compliance with guidelines related to working hygiene, but the plan is not complied with. However, there do not appear to be any shortcomings in personal hygiene or work practices.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- Operational guidelines regarding working hygiene do not cover all operations. Shortcomings are found that may affect food safety.
- The own-check plan includes some descriptions of the hygienic handling of raw materials and foodstuffs. Several shortcomings are found.
- Guidelines have not been provided for hygienic use of working utensils, but some good practices are complied with. For example, there are clear shortcomings in the replacement, cleaning, and disinfection of working utensils, such as knives, vessels, ladles and other utensils that come into contact with foods and raw materials of foods.
- The personnel observes hand washing procedures inconsistently.
- Employees who handle perishable unpackaged foods have visible cuts or artificial nails. Some employees also have piercing jewellery and other jewellery.

- Compliance with the clean area division and the rules issued regarding the routes used by personnel, raw materials and materials is poor.
- Rules issued regarding smoking are complied with inconsistently.
- A plan has been prepared for the monitoring of compliance with guidelines related to working hygiene, but the plan is not complied with. Shortcomings are found in personal hygiene or working practices.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- There are no operational guidelines regarding working hygiene. The shortcomings affect food safety.
- The own-check plan does not include descriptions of the hygienic handling of raw materials and foodstuffs.
- Guidelines have not been provided for hygienic use of working utensils, and good practices appear to be complied with hardly at all. For example, there are several serious shortcomings in the replacement, cleaning, and disinfection of working utensils, such as knives, vessels, ladles and other utensils that come into contact with foods and raw materials of foods.
- The personnel observes hand washing procedures inconsistently.
- Employees who handle perishable unpackaged foods have infected cuts or artificial nails. The indifference of the personnel about hand hygiene is noticeable and jeopardises food safety. Some employees also have piercing jewellery and other jewellery.
- There is no clean area division in place and no rules have been issued regarding the routes used by personnel, raw materials and materials.
- Compliance with rules issued regarding smoking is poor.
- There is no plan in place for the monitoring of compliance with guidelines related to working hygiene and no monitoring is implemented.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene in registered food premises, 1367/2011
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

4 Actions and Training of Personnel

4.3 Working Clothes and Protective Clothing of Personnel

To be taken into consideration:

- This Guideline is applied to all establishments.

Matters to be controlled:

- The protective clothing worn by the personnel at work (work uniform, headwear and footwear, and protective gloves, as appropriate) as concerns employees who handle perishable unpackaged foodstuffs and other unpackaged foodstuffs.
- Cleanness of protective clothing
- Any visible cuts covered and piercing jewellery and other jewellery (e.g. necklaces, earrings, bracelets) removed.

EXCELLENT

Operations comply with requirements.

- Employees who handle perishable unpackaged foods wear adequate and appropriate protective clothing.
- Employees who handle perishable unpackaged foodstuffs do not have visible cuts, piercing jewellery or any other jewellery. The same also applies to employees who handle other unpackaged foods, if the factors referred to could jeopardise food safety.
- As a rule, the personnel wear work uniforms and clothes that are suitable for their work, clean and neat.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

- Almost all of the employees who handle perishable unpackaged foods wear adequate and appropriate protective clothing.
- Employees who handle perishable unpackaged foodstuffs do not have visible cuts, piercing jewellery or any other jewellery. The same also applies to employees who handle other unpackaged foods, if the factors referred to could jeopardise food safety.
- Not quite all employees wear work uniforms and clothes that are suitable for their work, and clean and neat, and/or there are some minor shortcomings in the clothing of some employees.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

- There are some shortcomings in the protective clothing of employees who handle perishable unpackaged foods.
- Employees who handle perishable unpackaged foodstuffs have visible cuts, piercing jewellery or some other jewellery. The same also applies to employees who handle other unpackaged foods, if the factors referred to could jeopardise food safety.
- Not quite all employees wear work uniforms and clothes that are suitable for their work, and there are shortcomings that impair food safety in the clothing of some employees.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

- There are serious shortcomings in the protective clothing of employees who handle perishable unpackaged foods.
- Employees who handle perishable unpackaged foodstuffs have visible cuts, piercing jewellery or some other jewellery. The same also applies to employees who handle other unpackaged foods. Food safety is jeopardised.
- There are serious shortcomings in the suitability and cleanness of the work uniforms and clothing of the personnel which jeopardise food safety.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Annex II, Chapter VIII
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

4 Actions and Training of Personnel

4.4 Monitoring of Employees' Health Status

NOTE! The legislation on the monitoring of employees' health status has been renewed with regard to the Infectious Diseases Act. This guideline will be updated when more detailed instructions are available from the Health and Welfare Institute (THL). Before the new guidelines from THL have been published, Oiva inspections according to guideline 4.4. are recommended to be carried out at a later time if possible.

To be taken into consideration:

- The purpose of this point is to evaluate how the operator establishes that the employees are fit to work in the food sector.

Matters to be controlled:

- Establishment of the health status of employees who handle foodstuffs, and where necessary, the monitoring of their health status.
- Own-check records related to the monitoring programme of the employees' health status

EXCELLENT

Operations comply with requirements.

- The food establishment ensures that employees known or suspected to be carriers of a foodborne disease do not handle foodstuffs.
- A health status check has been carried out on employees who handle unpackaged perishable foodstuffs.
- The records of the monitoring of the health status of the employees required under the Food Act are appropriate.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

- The food establishment ensures that employees known or suspected to be carriers of a foodborne disease do not handle foodstuffs.
- A health status check has been carried out on employees who handle unpackaged perishable foodstuffs.
- There are some shortcomings in records of the monitoring of the health status of the employees required under the Food Act.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

- The food establishment ensures that employees known or suspected to be carriers of a foodborne disease do not handle foodstuffs.
- Health status checks have not been carried out on employees who handle unpackaged perishable foodstuffs or there are some shortcomings in the performance of the checks.
- The records of the monitoring of the health status of the employees required under the Food Act are not maintained.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

- The food establishment has not ensured that employees known or suspected to be carriers of a foodborne disease do not handle foodstuffs.
- A health status check has not been carried out on all the employees who handle unpackaged perishable foodstuffs.
- The shortcomings related to the records of the monitoring programme of the employee's health status do not cause a direct risk to food safety. For this reason, the grade Poor is only awarded in case the grade To be corrected has been awarded repeatedly and the shortcomings have not been rectified within the set period of time.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Annex II, Chapter VIII
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Section 4
- Finnish Communicable Diseases Act 583/1986; Section 20
- Finnish Communicable Diseases Decree 1383/2003

Updates in version 2:

- Added Note!

4 Actions and Training of Personnel

4.5 Instruction, Guidance and Training of Personnel

To be taken into consideration:

- This point is evaluated at all establishments.

Matters to be controlled:

- Instruction provided to the personnel in own-check in the manner required for their work duties.
- Direction and training of employees who handle foods in matters related to food hygiene in the manner required for their work duties.
- Guidance and training provided to the personnel after any fundamental changes implemented in operations.
- The adequacy of the instruction provided to the personnel, particularly as concerns personnel with high turnover as well as high-risk activities.

EXCELLENT

Operations comply with requirements.

Instruction has been provided to the personnel in own-check in the manner required for their work duties.

Employees who handle foods have been provided with direction and training in matters related to food hygiene in the manner required for their work duties.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in providing instruction to the personnel in own-check according to their duties.
- There are some minor shortcomings in the direction and training of employees who handle foods in matters related to food hygiene in the manner required for their work duties.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- Instruction has not been adequately provided to the personnel in own-check in the manner required for their work duties.
- Direction and training has not been provided to employees who handle foods in matters related to food hygiene in the manner required for their work duties, and the employees carry out duties of such a nature that wrong work practices impair food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- Direction and training has not been provided to employees who handle foods in matters related to food hygiene in the manner required for their work duties, and the employees carry out duties of such a nature that wrong work practices jeopardise food safety.

Legislation and guidelines (with any amendments) pertaining to the subject:

- 852/2004/EC; Annex II Chapter XII
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Section 5 and Annex 3

4. Actions and Training of Personnel

4.6 Verification of Hygiene Proficiency

Matters to be controlled:

- Proficiency certificates of personnel handling unpackaged perishable foodstuffs
- Own-check activities records related to proficiency certificates

EXCELLENT

Operations comply with requirements.

It has been verified in the food establishment or food premises that every employee who handles unpackaged perishable foodstuffs has the proficiency certificate according to Evira's model.

The recordkeeping of the hygiene proficiency of the personnel required by the Food Act is in order.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

It has been verified in the food establishment or food premises that every employee who handles unpackaged perishable foodstuffs has the proficiency certificate according to Evira's model.

There are some minor shortcomings in the recordkeeping of the hygiene proficiency of the personnel required by the Food Act.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

It has not been verified in the food establishment or food premises that employees who handle unpackaged perishable foodstuffs have the proficiency certificate according to Evira's model.

There is no recordkeeping of the hygiene proficiency of the personnel as required by the Food Act.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The shortcomings related to proficiency certificates do not immediately endanger food safety. For this reason, the grade “Poor” is only given in case the grade “To be corrected” has been given repeatedly and the shortcomings have not been rectified within the set period of time.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation of the European Parliament and of the Council on the Hygiene of Foodstuffs, 852/2004/EC; Annex II, Chapter XII
- Finnish Food Act 23/2006, Section 27
- Evira's Guide for risk-based control of food establishments and food premises 16044

Updates in version 3:

- Legislation and guidelines pertaining to the subject: Evira's Guide on food hygiene in registered food premises 16025 has been replaced with Evira's Guide for risk-based control of food establishments and food premises 16044

5 Hygiene of Food Production

5.1 General Hygiene of Food Production

To be taken into consideration:

- This Guideline is applied to all establishments.
- Only matters not included in any specific/other evaluation point are evaluated in this point. For example:
  - Management of physical hazards and risks (e.g. broken glass, fragments of metal).
  - Washing operations of the food containers of other food establishments (not owned by the establishment itself).
  - Handling hygiene, washing operations and verification of cleanliness regarding the receptacles for by-products returned to the establishment.
  - Other matters that are controlled, but are not included in any specific evaluation point.
- The prevention of cross contamination at the various stages of production is evaluated in point 5.2 "Separation of Activities Requiring Different Hygiene Level".
- The establishment is also responsible for compliance of any outsourced activities with legislation and requirements (for example, cleaning and vermin control which are often outsourced).

Matters to be controlled:

- Management of physical hazards and risks.
- Other matters that are controlled, but are not included in any specific evaluation point.
- The adequacy and suitability of own-check activities regarding the controlled matters, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- Good hygiene is maintained, requirements are complied with and risks are under control as regards the controlled matter.
- Own-check activities are adequate and suitable as regards the controlled matters.
- The operator has sudden and random shortcomings under control through own-check activities.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in the own-check plan as regards the controlled matter.

- Corrective actions have not been recorded, but shortcomings have been rectified, however.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:
- There are shortcomings in the own-check plan as regards the controlled matter which impair food safety.
- Corrective actions have not always been taken and the shortcoming impairs food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:
- There are shortcomings in the own-check plan as regards the controlled matter which jeopardise food safety.
- Corrective actions have not always been taken and the shortcoming jeopardises food safety.
- The operator has failed to fulfil the orders issued with the grade To be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 882/2004 on official controls
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

5 Hygiene of Food Production

5.2 Separation of Activities Requiring Different Hygiene Levels

To be taken into consideration:

- This Guideline is applied to all establishments.
- The purpose of this point is to evaluate the separation, either in time or through operational arrangements, of activities requiring different hygiene levels (e.g. manufacture of meat preparations and meat products) during production.
- However, compliance with the conditions laid down in the approval decision is always evaluated in point 1.2 "Approval of Activities", even when the condition applies to the separation of activities requiring different hygiene levels.
- Matters to be evaluated in this point also include the separation of areas, production stages and foodstuffs of different hygiene levels, as well as the prevention of cross-contamination. For example:
  - Areas of different hygiene levels
  - Separation of raw materials and finished products.
  - Separation of uncooked and cooked finished products.
  - Separation of unpackaged and packaged foodstuffs.
  - Separation of meat specified to be heated (the actual heating procedure is evaluated in point 6.5 "Temperature Control in Food Production Processes").
  - Separation of pigs kept under controlled housing conditions from regular pigs to verify that *Trichinella* samples are taken from regular pigs.
  - Prevention of cross-contamination at various production stages, for example in the slaughter line.
- The approvals of activities are evaluated in point 1.2.
- The separation of materials and products other than foodstuffs from foodstuffs is evaluated in point 5.6 "Hygiene in Storage and Warehousing of Foodstuffs".
- Separation of TSE risk material is evaluated in point 8.1.
- Separation of by-products of categories 2 and 3 from foodstuffs is evaluated in point 5.7.

Matters to be controlled:

- The separation of activities requiring different hygiene levels in practice, in time or through structural or operational arrangements.
- The prevention of cross-contamination in practice between activities requiring different hygiene levels.
- For example, the separation of meat specified to be heated.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".
- A description in the own-check plan of how activities requiring different hygiene levels are separated in time or through operational arrangements, and compliance with the operational practices described in own-check.

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- Activities requiring different hygiene levels are separated in time or through structural or operational arrangements.
- Cross-contamination between activities is prevented.
- Own-check activities are adequate and suitable as regards separation.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- Activities, areas, etc. requiring different hygiene levels are mostly separated in time or through structural or operational arrangements.
- The possibility of cross-contamination between activities is mostly prevented.
- There are some minor shortcomings in the separation of activities requiring different hygiene levels; for example, the transfer routes of products of different hygiene levels (raw materials/finished products/unpackaged/ packaged), but the shortcoming does not impair food safety.
- Activities related to handling of cooked and uncooked foods in the same facilities or using the same equipment are separated from each other.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- Activities requiring different hygiene levels are not adequately separated in time or through structural or operational arrangements, and the shortcoming impairs food safety.
- For example, activities requiring different hygiene levels are carried out using the same utensils, but the cleaning of equipment and utensils between the activities is inadequate, and the shortcoming impairs food safety.
- Cooked and uncooked foods are handled in the same facilities at the same time, which exposes cooked products to a contamination risk.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- Activities requiring different hygiene levels are not separated in time or through structural or operational arrangements, and cross-contamination between activities is not prevented, and the shortcoming jeopardises safety.
- Cooked foods are handled using the same equipment previously used to handle uncooked foods (separated in time) and the equipment has not been

cleaned between these activities, which causes a direct risk of contamination to the foods.
- The operator has failed to fulfil the orders issued with the grade to be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 882/2004 on official controls
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Finnish Food Act 23/2006
- Government Decree on food control 420/2011
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

5 Hygiene of Food Production

5.3 Hygiene of Water Supply Points and Equipment Using Water

To be taken into consideration:

- This Guideline is applied to all establishments.
- The purpose of this point is to evaluate water supply points and equipment using water in terms of their cleanliness and hygienic suitability in connection with various activities. The maintenance of water supply points and water equipment is evaluated specifically in point 2.3 "Maintenance of Fixtures, Equipment, Water Equipment and Utensils".
- Water supply points and equipment using water refer to, for example, water taps, tap filters, water hoses, water basins and tanks, cleaning and disinfection equipment using water or steam, or e.g. a recycled water system. Disinfection equipment refers to, for example, equipment designed for the disinfection of working utensils used for hide removal, splitting of carcasses or cutting of meat.
- The production of ice as well as chilling carried out using water and ice are evaluated in point 5.4 "Hygiene in Thawing, Chilling and Freezing".
- Temperature monitoring of hot water used for disinfection is evaluated in point 6.7 "Temperature Control of Water Used for Disinfection of Working Utensils".

Matters to be controlled:

- Cleanliness of water supply points
- Cleanliness of equipment using water
- Items provided at hand washing points
- Hygienic suitability of water supply points and equipment using water, for example
  - functionality and cleaning effectiveness of touch free hand washing points
  - the manner in which the disinfection equipment is used and the length of the cleaning time to ensure that working utensils are clean
- Volume and exchange of hot (minimum +82°C) water used for disinfection are adequate
- Cleanliness, hygienic suitability and hygienic effectiveness of disinfection equipment using hot (minimum +82°C) water
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- Water supply points are clean.
- Items provided at hand washing points and the functionality of the points are adequate.
- Water taps, hoses and other equipment using water are hygienic.
- Disinfection equipment is clean and hygienic, and the desired disinfection result is achieved with it.
- Corrective actions have been adequate and appropriate. Deviations and corrective actions have been recorded.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:
- There are some minor shortcomings in the cleanliness of water supply points.
- There are some minor shortcomings in the items provided at hand washing points. However, food safety is not impaired.
- There are some minor shortcomings in the hygiene of water taps and hoses, but food safety is not impaired.
- There are some minor shortcomings in the records of deviations and corrective actions. Corrective actions have been adequate and appropriate.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:
- There are shortcomings in the cleanliness of water supply points which impair food safety.
- There are several shortcomings in the items provided at hand washing points, or there are shortcomings in the hygiene of water taps and hoses which impair food safety.
- There are shortcomings in the cleanliness of disinfection equipment or in the use of hot water which impair food safety.
- Deviations have not been recorded although it becomes known that deviations have occurred or corrective actions taken because of deviations have been inappropriate or inadequate.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:
- There are serious shortcomings in the cleanliness of water supply points which jeopardise food safety.
- At several hand washing points, the items provided are completely inadequate.
- There are serious shortcomings in the hygiene of water taps and hoses.
- There are serious shortcomings in the cleanliness of disinfection equipment or in the use of hot water which jeopardise food safety.
- Corrective actions are not taken when deviations are detected and the shortcomings jeopardise the safety of foods.
- The operator has failed to fulfil the orders issued with the grade To be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:
- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004/EY on hygiene rules for food of animal origin

- Regulation (EC) No 854/2004/EY on official controls on products of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Evira's (previously EVI) old guideline "In-house control of water for human consumption and of ice in establishments referred to in Hygiene Act" (EVI, 3565/41/02) can be utilised in applicable parts, where necessary.

Updates in version 2:

- Matters related to maintenance have been removed from the Guideline.

5 Hygiene of Food Production

5.4 Hygiene in Thawing, Chilling and Quick-freezing

To be taken into consideration:

- The purpose of this point is to evaluate hygiene in thawing, chilling, quick-freezing, freezing and ice production, as well as the production and storage of ice.
- Hygiene in thawing refers to e.g. the hygiene of the water used or produced in the thawing process.
- Chilling refers to chilling by means of air, water, or ice. Hygiene in air chilling refers to e.g. the management of condensation water. Hygiene in water chilling refers to e.g. the hygiene of the water chilling systems and the chilling water used for the chilling of poultry meat and fishery products.
- As concerns ice, the Guideline pertains to the hygiene of the ice water systems and ice at the establishments.
- Hygiene in quick-freezing and freezing is evaluated both as concerns foodstuffs quick-frozen/frozen for own production and foodstuffs intended for marketing as quick-frozen/frozen products.
- The compliance of water intended for human consumption with requirements is evaluated in point 1.4.
- The compliance of clean water with requirements is evaluated in point 1.5.
- Prevention of cross-contamination is evaluated in point 5.2 "Separation of Activities Requiring Different Hygiene Levels".
- Quick-freezing of products and temperature management in cold stores is evaluated in point 6.6 "Temperature Management of Quick-frozen and Frozen Foodstuffs, and Ice Cream".
- The freezing treatment carried out due to the parasite risk in fish is evaluated in point 8.8 "Parasite Controls and Freezing Treatment of Fishery Products".
- Own-check testing of water and ice is evaluated in point 17.3.

Matters to be controlled:

- Hygiene in the thawing, chilling, quick-freezing and freezing of foodstuffs
- Method of use of water used for thawing
- Hygienic draining of water produced in thawing
- Visible presence of condensation water
- Hygiene of water chilling equipment for poultry
- Production, storage and use of ice
- The adequacy and suitability of own check activities, and the own check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-Check".

EXCELLENT

Operations comply with requirements.

Thawing based on the use of water is implemented in a hygienic manner and the water produced in thawing is drained in a hygienic manner.
Water chilling is implemented in a hygienic manner and in compliance with regulatory requirements.

No condensation water is produced in air chilling, or the production and draining of a small volume of condensation water is under control so that condensation water cannot run onto products or along floors, and the contamination of foodstuffs is prevented.
The production and storage of ice for use in the production of foodstuffs is organised in a hygienic and appropriate manner. The use of ice water is hygienic and appropriate.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are some minor shortcomings in thawing hygiene based on the use of water, and food safety is not impaired.
- The draining of water produced in thawing is implemented in a manner that ensures food safety is not impaired.
- Water chilling is mostly implemented in a hygienic manner and in compliance with regulatory requirements, and food safety is not impaired.
- Some condensation water is produced in air chilling, but the production and draining of condensation water is under control so that condensation water cannot run onto products, and the contamination of foodstuffs is prevented.
- The production and storage of ice for use in the production of foodstuffs is as a rule organised in a hygienic and appropriate manner and food safety is not impaired. There may be some minor shortcomings in the use of ice water which do not impair food safety.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There are shortcomings in thawing based on the use of water which result in impaired food safety. There are shortcomings in the draining of water produced in thawing and food safety is impaired.
- There are shortcomings in water chilling which result in impaired food safety. There are shortcomings in hygiene during the chilling of water chilling equipment for poultry which impair food safety.
- Condensation water is produced in air chilling and the production and draining of the condensation water are not adequately under control. There is a possibility of condensation water running onto unpackaged foodstuffs causing a contamination risk to the foodstuffs and impairing food safety.
- There are shortcomings in the production and/or storage of ice used for food production, and food safety is impaired. There are shortcomings in the use of ice water resulting in impaired food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- There are shortcomings in thawing based on the use of water which result in food safety being jeopardised. There are shortcomings in the draining of water produced in thawing which result in food safety being jeopardised.
- There are shortcomings in water chilling which result in food safety being jeopardised. There are shortcomings in the cleaning of water chilling equipment for poultry which result in food safety being jeopardised.
- Condensation water is produced in air chilling and the production and draining of the condensation water are not adequately under control, or condensation water is drained in a manner that does not prevent the contamination of foodstuffs. Condensation water runs onto unpackaged foodstuffs, which jeopardises food safety. For example: condensation water accumulates onto the dirty surface structure and from there runs onto unpackaged foodstuffs, and contaminates them.
- There are shortcomings in the production and/or storage of ice used for food production, and food safety is jeopardised. There are shortcomings in the use of ice water which result in food safety being jeopardised.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Own-Check of Water for Human Consumption and of Ice in Establishments Referred to in Hygiene Act (EVI, 3565/41/02)

5 Hygiene of Food Production

5.5 Hygiene in Wrapping and Packing

To be taken into consideration:

- This Guideline is applied to all establishments where foodstuffs are wrapped and/or packed.
- Good hygiene practices are complied with in the operations of the establishment to ensure the hygiene and compliance with requirements of wrapping and packaging materials as well as the wrapping and packing processes.
- As a process, "wrapping" refers to the packing of a foodstuff in a wrapping or packaging that is in direct contact with the foodstuff, and as a material, to the actual wrapping or packaging material.
- "Packing" refers to the packing of one of several wrapped foodstuffs in another container, and "outer packaging" to the actual container.
- The suitability of materials for the wrapping and packing of foodstuffs is evaluated in point 14.1 "Packaging Materials and Other Food Contact Materials".
- Hand hygiene related to packing is evaluated in point 4.1 "Working Hygiene of Personnel".

Matters to be controlled:

- Cleanness and intactness of wrapping and packaging materials.
- Handling and storage of wrapping and packaging materials. Wrapping and packaging materials are to be stored in a manner that prevents them from being contaminated, e.g. excessive amounts of packaging material brought into production facilities. Materials shall be stored in a facility reserved for them, under conditions that are suitable for the material concerned.
- Hygiene in packing operations. Wrapping and packing shall be carried out in a manner that prevents the contamination of products. Matters to be taken into consideration include the hygiene of packing equipment and e.g. dust production from materials during the packing operation. Where cans and glass jars are concerned, the structural integrity and the cleanness of the materials shall be controlled, as well as the tightness of joints or lids.
- Any wrapping and packaging materials reused for packing of foodstuffs shall be easy to clean, and where appropriate, easy to disinfect.
- Suitability of the wrapping and packing facility for the operation, and hygiene level of the facility. During wrapping and packing, there may be no other traffic/operations in nearby facilities that disturb the wrapping/packing operation and jeopardise the hygiene level of the operation (increased risk of cross-contamination).
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

- Wrapping and packaging materials are clean and intact.
- Wrapping and packaging materials are handled and stored in a hygienic manner.
- Wrapping and packing is carried out in a facility of a suitable hygiene level and in a manner based on the requirements related to the foodstuff concerned.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are some minor shortcomings in the cleanness or integrity of packaging materials; for example, the materials are slightly wet or dusty.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There are shortcomings in the cleanness or integrity of packaging materials that impair food safety.
- There are shortcomings in the handling or storage of packaging material or in the packing of foodstuffs which impair the safety of food.
- Wrapping and packing of foodstuffs is carried out in production facilities not intended for wrapping and packing of foodstuffs.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- No efforts at all or not adequate efforts are taken to ensure the cleanness and integrity of wrapping and packaging materials. For example, wrapping and packaging materials are visibly dirty or damaged.
- Wrapping and packaging materials are stored under unhygienic conditions.
- Wrapping and packing of foodstuffs is carried out in facilities not suitable for these operations and conditions are unhygienic to the extent that the safety of foodstuffs is jeopardised.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs

5 Hygiene of Food Production

5.6 Hygiene in Storage and Warehousing of Foodstuffs

To be taken into consideration:

- This Guideline is applied to all establishments.
- The purpose of the Guideline is to evaluate hygiene in storage and warehousing of foodstuffs as concerns raw materials and foodstuffs to be delivered to the market or used by the operator itself.
- Temperature management in storage facilities is evaluated in point 6.2 "Temperature Control in Chilled Facilities".
- The cleanliness and order of surfaces and facilities is evaluated in point 3.1 "Cleanliness and Order of Facilities and Structures" and in point 3.2 "Cleanliness of Surfaces, Fixtures, Equipment and Utensils".

Matters to be controlled:

- Warehousing and storage conditions for foodstuffs.
- Stock rotation of foodstuffs.
- Separation of materials, articles and products other than foodstuffs from foodstuffs.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

- Foods and raw materials are stored in facilities reserved for them under suitable conditions in compliance with legislation.
- The warehousing and storage of articles and products other than foodstuffs does no result in impaired food safety with respect to foodstuffs.
- Products are in order in storage and stock rotation is effective, i.e., older products are taken from storage before newer products.
- Outdated materials or products are removed from storage.
- Condensation water is not produced onto raw materials and finished foodstuffs.
- Packaging materials are stored under cover.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are some minor shortcomings in stock rotation which do not impair or jeopardise food safety, but leave room for improvement.
- There are some minor shortcomings as concerns order in storage which do not impair or jeopardise food safety, but leave room for improvement.
- There are outdated materials in storage.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- Foodstuffs are stored and warehoused in facilities and under conditions that impair food safety; for example, there is a lot of ice in the freezer stores and doors cannot be closed.
- There are outdated foodstuffs in storage.
- Materials, articles or products that can impair food safety are stored in storage facilities.
- Dirty storage pallets are used in storage facilities.
- Foodstuffs that should be packaged are stored unpackaged.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- Foodstuffs are stored and warehoused in facilities and under conditions that jeopardise food safety.
- There are outdated foodstuffs in storage, e.g. foodstuffs not fit for use as food.
- The warehousing and storage of products other than foodstuffs jeopardises food safety, e.g. TSE risk material and detergents.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

5 Hygiene of Food Production

5.7 Hygiene in Handling and Storage of By-products

To be taken into consideration:

- This Guideline is applied to all approved establishments.
- The production of by-products as part of normal production processes at the establishment is included within the scope of the approval of the establishment as referred to in the Food Act, and within the scope of food control. Other by-product operations are covered by legislation and control pertaining to the by-product or feed sector.
- This Guideline is applied to the collection, handling, classification, sorting, storage, and identification of animal by-products at food establishments.
- The purpose of this point is to evaluate hygiene in the handling and storage of by-products in as far that it may cause a risk to food safety. This means that the separation of different categories of by-products from each other or the storage of by-products outside food production facilities are not evaluated, for example.
- Operations carried out at the establishment that are included within the scope of the by-product legislation and control, such as the separation of different categories of by-products from each other, as well as operations carried out in the by-product department are as a whole evaluated in point 5.8. The results of the evaluations based on Guideline 5.8 are not presented in the Oiva report, but only in the inspection report.
- Handling of TSE risk material is evaluated in point 8.1.
- Dispatching of by-products, commercial documents, and transport conditions and temperatures are evaluated in point 15.5.

Matters to be controlled:

- The collection, handling, classification, sorting, storage, warehousing, and identification of animal by-products in food production facilities.
- The separation of by-products from foodstuffs and the prevention of cross-contamination of foodstuffs.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- The establishment has a hygienic system in place for removal of by-products. By-products not fit for use as food are removed as quickly as possible, particularly from food production facilities where unpackaged foodstuffs are handled.
- By-products are identifiable (marked at the establishment in an identifiable manner) and kept separate from foodstuffs during collection and storage.
- Containers and utensils intended for the collection, handling, and storage of by-products are not used for the collection, handling, and storage of foodstuffs.

- The handling and storage of animal by-products is in food businesses carried out under conditions that prevent cross-contamination, and if appropriate, in a dedicated part of the establishment.
- Facilities intended for storage of by-products are adequate, hygienic, and adequately separated from the storage of foodstuffs.
- Own-check activities are adequate and suitable.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are occasionally some minor shortcomings in the identification of storage containers; however, there is no risk of confusion with foodstuffs at any stage.
- There are some minor shortcomings in the records of corrective actions, but corrective actions have been appropriate and adequate.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- By-product containers are damaged or they leak, or they are over-filled or not kept adequately clean, resulting in impaired hygiene and food safety at the establishment.
- Identification of by-products is deficient or missing from some containers in a manner that results in impaired food safety.
- Cross-contamination is not prevented in an adequate manner, and the handling and storage of by-products impairs food safety.
- Corrective actions have not been recorded although it becomes known that deviations have occurred, or corrective actions taken because of deviations have been inappropriate or inadequate.
- Category 3 by-product containers are used for the storage of foodstuffs, or vice versa, and food safety is impaired.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- Containers and utensils intended for the collection, handling, and storage of category 1 or 2 by-products are used for the collection, handling, and storage of foodstuffs, or vice versa, and food safety is impaired.
- Cross-contamination is not prevented, and the handling and storage of by-products jeopardises food safety; for example, category 1 or 2 by-products and unpackaged foodstuffs are stored in the same premises.
- Corrective actions have not been recorded even when records are required, or corrective actions have not been taken, or they have been inadequate, and food safety is jeopardised.

- The operator has failed to fulfil the orders issued with the grade to be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 882/2004 on official controls
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Annex II
- Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, Annex III, Section I, Chapter IV, and Section II, Chapter IV
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Finnish Food Act 23/2006, Section 10
- Government Decree on food control 420/2011
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments, 795/2014, Sections 4 and 5, Annex 1, Chapters 1 and 2, and Annex 3, Chapter 1
- Regulation (EC) No 1069/2009 on by-products, Articles 4, 7-10, 21, 25-26 and 29
- Evira's Guide 16010: Handling and control of by-products at food establishments

Updates in version 3:

- Example in grade Excellent has been specified.

5 Hygiene of Food Production

5.8 Production and Traceability of By-products

This evaluation is not presented in the Oiva report, but only in the inspection report.

To be taken into consideration:

- This Guideline is applied to all approved food establishments.
- The production of by-products as part of normal production processes at the establishment is included within the scope of the approval of the establishment as referred to in the Food Act, and within the scope of food control. Other by-product operations are covered by legislation and control pertaining to the by-product and/or feed sector.
- This Guideline is applied to the collection, handling, classification, sorting, storage, identification, and transport of animal by-products to the extent that operations are covered by legislation pertaining to by-product and/or feed sector and the operations do not cause a risk to food safety.
- The purpose of this point is to evaluate the separation of different by-product categories from each other, and the operations carried out in the by-product department or in establishments of the type referred to in the Regulation on by-products that are operated in conjunction with the food establishment. In addition, operations related to transports and covered by legislation pertaining to by-product and/or feed sector are evaluated. The results of these evaluations are not presented in the Oiva report, but only in the inspection report.
- An establishment that handles or delivers for feed use by-products produced in their own food production shall be registered as a feed business operator. If the establishment receives by-products from other food establishments for delivery as raw material for feed for fur animals, the establishment shall be registered as a collection centre. If the establishment manufactures pet food in primary packaging, the approval of a pet food establishment is required.
- An establishment that dispatches by-products is always responsible for delivering by-products for transport to an appropriately registered or approved carrier. The dispatching establishment is also responsible for the dispatch of by-products to a permitted destination, even if transport is outsourced. Also the drafting of a commercial document and making sure it includes all information required by the legislation, is the responsibility of the sender.
- Regardless of whether the establishment arranges the transport of by-products itself or outsources transport, the dispatching establishment shall always have records of the dispatched by-products.
- Where the by-product operations of the establishment can cause a risk to food safety at the establishment, the operations are evaluated in point 5.7 "Hygiene in Handling and Storage of By-products".
- Where the by-product operations of the establishment can cause a risk to food safety during transport, the operations are evaluated in point 15.5 "Dispatch of By-products, Commercial Documents and Transport Conditions".

Matters to be controlled:

- Separation of different categories of by-products at all stages of operation.
- Collection, handling, classification, sorting, storage, warehousing and identification of animal by-products in the by-product department.
- The usability as feed of by-products delivered for feed use, and verification of this.
- Identification markings of by-product categories in transport.

- Commercial documents in transport of by-products (transport documents), including the traceability of by-products.
- Monitoring of dispatched quantities of by-products.
- By-products are dispatched to a destination where they are permitted to be dispatched according to legislation.
- If the handling of by-products has been outsourced, by-products are delivered to an appropriately registered or approved carrier for transport.

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- By-products of different categories are separated from each other during collection and storage. If different by-product categories are combined, the whole batch is handled as the lower category by-product.
- Dispatched by-products (packaging, container or vehicle) are provided with identification marking as specified in the Regulation on by-products (by-product category and marking text) and there is no risk of confusion between categories.
- Dispatched by-products are accompanied by a commercial document filled out in compliance with the requirements laid down in the Regulation on by-products to verify traceability and identifiability.
- The establishment maintains records of dispatches and quantities of different categories of by-products and stores the associated commercial documents and health certificates for at least two years.
- By-products are only dispatched from the establishment to a destination permitted by legislation, such as an operator registered or approved pursuant to the Regulation on by-products (for example to a processing plant or a fur animal feed manufacturer).
- The establishment is registered as a feed business operator, if it delivers by-products for feed use. The operation is covered by the own-check plan.
- Any establishments of the type referred to in the Regulation on by-products that are operated in conjunction with the food establishment are approved/ registered and included in Evira's lists of by-product establishments. An own-check system is in place for them.
- If by-products to be used as feed are not delivered immediately after collection, they are chilled / frozen / acidified without undue delay. The microbiological quality and usability as feed of by-products to be delivered for feed use are monitored.
- The labelling of acidified feed intended for fur animals and finished pet food (not raw material for feed) complies with requirements.
- The carrier who transports by-products is an appropriately registered or approved operator.

GOOD

There are minor issues with operations.

For example:

- The sorting of by-products and the mixing of different categories of by-products is in practice carried out appropriately and the identification markings are correct, but the own-check plan does not include a description specifying the categories of the mixed ingredients based on the risk category referred to in the Regulation of by-products.
- There are occasionally some minor shortcomings or inaccuracies in identification markings or commercial documents. However, by-products are traceable and identifiable, and there is no risk of confusion between different categories of by-products.
- By-products are delivered for feed use accompanied by appropriate documents and in a manner that ensures their usability as feed is not reduced, but feeds are not covered by the own-check plan.
- There are some minor shortcomings in the own-check plan of an establishment of the type referred to in the Regulation on by-products which is operated in conjunction with the food establishment, or the plan is not up-to-date in all respects.
- The labelling of acidified feed for fur animals and finished pet food does not comply with requirements in all respects.
- The operator does not have in place a system for verifying that by-products delivered for feed use are usable as feed.

TO BE CORRECTED

There are clear issues with operations.

For example:

- There are shortcomings of such a nature in commercial documents and identification markings that by-products are not completely traceable and there is a possibility of risk of confusion between different categories of by-products.
- No records are kept of dispatched quantities of by-products.
- The establishment is not registered as a feed business operator, although it delivers by-products for feed use.
- There are clear shortcomings in the own-check plan of an establishment of the type referred to in the Regulation on by-products which is operated in conjunction with the food establishment.
- There are clear shortcomings in the microbiological quality of by-products delivered for feed use.

POOR

There are severe issues with operations, or the operator has failed to rectify the issues within the set period of time.

For example:

- The operator has failed to fulfil the orders issued with the grade to be corrected.

- The commercial documents or transport containers/packages do not present any of the information referred to in the Regulation on by-products, and by-products are not traceable because of this.
- The destination of dispatched by-products is not allowed in the Regulation on by-products.
- The carrier who transports by-products is not an appropriately registered or approved operator.
- An establishment of the type referred to in the Regulation on by-products is operated in conjunction with the food establishment, such as a collection centre or an establishment manufacturing pet food, but it has not been registered / approved as specified in the Regulation on by-products.
- An establishment of the type referred to in the Regulation on by-products does not have an own-check system in place.
- No labelling is provided on acidified feed for fur animals / finished pet food.
- Spoiled by-products or by-products that based on their category are not usable as feed are delivered for feed use.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 1069/2009 on by-products, Articles 4, 7-10, 21-23
- Regulation (EU) No 142/2011 implementing the Regulation on by-products; Article 17, Annex VIII
- Animal By-Product Act 517/2015
- Decree of the Ministry of Agriculture and Forestry 783/2015, Section 5, Annex 3
- Finnish Feed Act 86/2008, Sections 6-7, 15, 18-19, 21
- Evira's Guide 16010: Handling and control of by-products at food establishments
- Evira’s Guide 12514: Sivutuotteiden toimittaminen rehukäyttöön liha-alan laitoksista (in Finnish)

Updates in version 3:

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- The establishments of the type referred to in the Regulation on by-products that are operated in conjunction with the food establishment and the responsible quarter in drafting of the commercial document has been specified in To be taken into consideration.
- Evira’s Guide 12514 has been added.

6 Food Temperature Management

6.2 Temperature Management in Chilled Facilities

To be taken into consideration:

- The purpose of this point is to evaluate temperature management in all chilled handling and storage facilities.
- Quick-freezing of products and temperature management in cold stores is evaluated in point 6.6 "Temperature Management of Quick-frozen and Frozen Foodstuffs, and Ice Cream".
- The maintenance and calibration of thermometers is evaluated in point 2.3 "Maintenance of Fixtures, Equipment, Water Equipment and Utensils".

Matters to be controlled:

- Temperatures in chilled facilities and effectiveness of chilling in practice.
- Adequacy of the chilling of chilling equipment and the appropriateness of the equipment in other respects in relation to operations and conditions, e.g. adequacy of chilling in the summer.
- Temperatures of chilled foodstuffs, if appropriate.
- Temperature records in own-check
- Records of automatic temperature monitoring system, if any, monitoring of results and limit values for alarms.
- Deviations in temperatures, corrective actions and records of corrective actions
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own Check".

EXCELLENT

Operations comply with requirements.

The temperatures in chilled facilities and the adequacy of chilling are appropriate and ensure that food temperatures remain within the range specified in regulatory requirements.
Temperatures are monitored and recorded in compliance with the own-check plan and results are monitored.
The records of automatic temperature monitoring system, if any, are stored, results are monitored and the limit values for system alarms are appropriately set.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- The temperatures in chilled facilities are appropriate and ensure that food temperatures comply with regulatory requirements. There have been some minor shortcomings in temperatures in chilled facilities, such as brief increases in temperature; the operator has not reacted to them, but they have not impaired food safety.
- There have been some minor shortcomings in the performance of temperature measurements; for example, measurements specified in the own-check plan have occasionally been neglected.

TO BE CORRECTED

There are issues with the operations that are not in compliance with legislation or impair food safety or mislead consumers. These issues must be rectified within a set time of period.

The grade can be To be corrected e.g. in cases where:

- Temperatures are too high in chilled facilities and food temperatures do not comply with regulatory requirements. There are shortcomings in the temperatures of chilled facilities and products that impair food safety.
- Temperature measurements have not been carried out in compliance with the own-check plan.
- There has been a malfunction in the automatic temperature recording equipment which has not been detected.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to rectify the issues within the set time of period. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- Temperatures are too high in chilled facilities and food temperatures do not comply with regulatory requirements. There are shortcomings in the temperatures of chilled facilities and products that jeopardise food safety.
- Temperature measurements have not been performed at all, or the measurement results of automatic equipment have not been recorded or monitored.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002/EC on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

Updates in version 2:

- The Finnish title of the Guideline has been changed.

Updates in version 3:

- The titles of “To be corrected” and “Poor” have been edited.

6 Food Temperature Management

6.5 Temperature Management in Food Production Processes

To be taken into consideration:

- This Guideline is applied to all establishments with temperature controlled production processes (excluding establishments that only engage in quick-freezing operations).
- The purpose of this point is to evaluate, for example, heating (e.g. pasteurisation), thawing and chilling of foodstuffs. Temperature control in the production of cut meat, minced meat and mechanically separated meat is also evaluated in this point.
- Temperatures are either regulatory requirements or specified in the own-check plan e.g. on the basis of a hazard analysis.
- The temperature-time combinations do not guarantee the microbiological safety of the products in all processes, e.g. in connection with cold smoking. In these cases it is evaluated if compliance with the temperature-time combination ensures fulfilment of the criteria specified for the shelf life of the product.
- Freezing of products and temperature control in cold stores are evaluated in point 6.6.
- The freezing treatment carried out due to the parasite risk in fish is evaluated in point 8.8 "Parasite Controls and Freezing Treatment of Fishery Products".

Matters to be controlled:

- Management of food heating, chilling and thawing processes
- The heating temperatures and heating time of foods
- Effectiveness of the heating of carcases for which heating treatment is a requirement (salmonella, EHEC)
- The chilling temperatures and chilling time of foods, particularly perishable foods
- The thawing temperatures of foods, and the thawing time, if appropriate
- Management of food temperatures during production
- Temperature records
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-Check Activities".

EXCELLENT

Operations comply with requirements.

The time and temperature combinations and the monitoring frequencies are specified for temperature controlled production processes in the own-check plan.

The temperatures and temperature-time combinations of processes and products comply with the requirements laid down in legislation and in own-check. The operator has verified the achievement or maintenance of the target temperatures of processes and products.

Temperatures are monitored and monitoring data are recorded in compliance with the own-check plan.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- The temperatures of processes and products comply with the requirements laid down in legislation and in own-check. There have been some minor shortcomings in the temperatures of processes and products, but they have not impaired food safety.
- There are some minor shortcomings in the time and temperature combinations of temperature controlled production processes specified in the own-check plan.

TO BE CORRECTED

There are issues with the operations that are not in compliance with legislation or impair food safety or mislead consumers. These issues must be rectified within a set time of period.

The grade can be To be corrected e.g. in cases where:

- The temperatures of processes and products do not comply with the requirements laid down in legislation and in own-check. There are shortcomings in the temperatures of processes and products that impair food safety.
  - For example, minced meat is not chilled adequately quickly after production to max. 2°C.
- Time and temperature combinations have not been specified in the own-check plan for all temperature controlled production processes.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to rectify the issues within the set time of period. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The temperatures of processes and products do not comply with the requirements laid down in legislation and in own-check. There are shortcomings in the temperatures of processes and products that jeopardise food safety.
  - For example, canned food is placed on the market although the required temperature or temperature-time combination has not been achieved during its manufacture.
- Time and temperature combinations have not been specified in the own-check plan for temperature controlled production processes, or the specified combinations jeopardise food safety.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Finnish Food Act 23/2006

- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments, 795/2014; Annex I, Chapter 3 and Annex 2, Chapter 10

Updates in version 3:

- The example concerning minced meat under the grade To be corrected has been changed to refer to chilling after production.

Updates in version 4:

- The titles of “To be corrected” and “Poor” have been edited.

6 Food Temperature Management

6.6 Temperature Management of Quick-frozen and Frozen Foodstuffs, and Ice Cream

To be taken into consideration:

- This Guideline is applied to establishments where foodstuffs are quick-frozen or frozen, or quick-frozen or frozen foodstuffs are stored. The Guideline pertains to both foodstuffs quick-frozen/frozen for purposes of own production, and foodstuffs intended to be delivered or marketed as quick-frozen/frozen products. This Guideline is in applicable parts also applied to the freezing of ice cream at establishments.
- This Guideline is not applied to establishments where fish only undergo the freezing treatment required due to the parasite risk.
- This Guideline is used to evaluate the temperature management of quick-frozen and frozen foodstuffs and their storage and warehousing conditions.
- The demonstration of the fulfilment of standardisation requirements regarding the measuring equipment and temperature-recording systems used in the storage of frozen products, and the functionality and calibration of measuring equipment used for the temperature management of frozen food are evaluated in point 2.3 "Maintenance of Fixtures, Equipment, Water Equipment, and Utensils".
- Hygiene in quick-freezing and freezing is evaluated in point 5.4 "Hygiene in Thawing, Chilling and Freezing".
- Temperature management of the warehousing and storage conditions of chilled foodstuffs is evaluated in point 6.2.
- Temperature management in other temperature controlled processes than quick-freezing and freezing is evaluated in point 6.5 "Temperature Management in Food Production Processes".
- The freezing treatment carried out due to the parasite risk of fishery products is evaluated in point 8.8.
- Temperature management during transport of quick-frozen and frozen foodstuffs is evaluated in point 15.4.

Matters to be controlled:

- Quick-freezing or freezing is started without undue delay after the chilling of products intended to be quick-frozen or frozen. However, the preceding manufacturing process of the food product may contain various intermediate stages, such as maturation of meat.
- Temperature management during storage of quick-frozen/frozen foodstuffs.
- Maintenance of a cold chain for quick-frozen/frozen foodstuffs
- Appropriateness of temperature records
- Time and temperature limits for quick-freezing/freezing of mechanically separated meat and for storage of quick-frozen/frozen mechanically separated meat.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- The quick-freezing/freezing of the foodstuffs is systematically started without undue delay after the manufacture and chilling of products intended to be quick-frozen/frozen.
- It is ensured in the quick-freezing and freezing process that the quick-freezing or freezing medium (such as air) is effectively brought into contact with the foodstuffs or packaging of foodstuffs. For example, space is left between the foodstuffs and the walls, and between piles of foodstuffs in the freezing tunnel.
- The cold chain for foodstuffs works well. For example, quick-frozen/frozen foodstuffs are transferred to temperatures suitable for their storage directly from the equipment used for quick-freezing/freezing.
- Temperature deviations of quick-frozen and frozen foodstuffs are brief (less than 24 hours) and do not exceed the deviation limits laid down in legislation (the temperature of foodstuffs sold or otherwise delivered as frozen products may show a brief increase to at most -15°C).
- The records of automatic temperature monitoring system, if any (mandatory for foodstuffs sold or otherwise delivered as frozen products), are stored, results are monitored, deviations have been reacted to appropriately and the limit values for system alarms are appropriately set.
- Where the establishment needs to quick-freeze or freeze foodstuffs unexpectedly due to e.g. failure of the production line or equipment, the actions taken by the establishment in that situation ensure that food safety is not jeopardised.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example

- The quick-freezing/freezing of the foodstuffs is occasionally delayed, but delays are not common or frequent or so long that they would affect the food safety of the products.
- The temperature of a foodstuff sold or otherwise delivered as a frozen product has shown an individual and brief (less than 24 hours) increase above the deviation limit permitted by legislation (i.e. to more than -15°C); however, food safety has not been jeopardised and the product has not started to melt.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- The quick-freezing/freezing of the foodstuffs is frequently started several days after the end of the other stages of the manufacturing process. Delays are common and frequent, although not completely systematic.

- As concerns mechanically separated meat that is not to be processed within 24 hours after it has been chilled, the freezing process is not started within the time laid down in legislation (within 12 hours after production).
- The deviation limit set for foodstuffs sold or otherwise delivered as frozen products (the temperature of these products may show a brief increase to at most -15°C) has been exceeded repeatedly, or on an individual occasion but for a long period of time, and the operator has failed to take necessary actions.
- Based on the temperature records of the storage facilities, it is clear that the temperatures of quick-frozen/frozen foodstuffs have systematically been higher than the target temperatures (most commonly -18°C), and the operator has failed to take necessary actions. However, the increase in temperature has not resulted in the melting of the foodstuffs.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- The quick-freezing/freezing of the foodstuffs is systematically started at least several days after the end of the other stages of the manufacturing process causing a significant delay in the start of quick-freezing or freezing.
- There are shortcomings in the cold chain of quick-frozen/frozen foodstuffs which result in the melting of the foodstuffs, but the operator has failed to take necessary actions.
- Products that have melted have been quick-frozen/frozen again.
- Temperature measurements have not been carried out at all or no records have been made of manual temperature monitoring, or the measurements results of automatic equipment have not been recorded.

Legislation and guidelines (with any amendments) pertaining to the subject:

Applied to both quick-frozen and frozen foodstuffs

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Annex I, Chapter 3
- Evira's Guide 16049: Evira's Guide on quick-freezing and freezing of foodstuffs in food establishments

Applied only to quick-frozen foodstuffs

- Commission Regulation 37/2005/EC on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption
- Council Directive 89/108/EEC on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption
- Commission Directive 92/2/EEC laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption
- Decree of the Ministry of Agriculture and Forestry on quick-frozen products, 818/2012

6 Food Temperature Management

6.7 Temperature Management of Carcasses Dispatched from Establishment

To be taken into consideration:

- This Guideline is applied to establishments that slaughter ungulates. Such establishments include slaughterhouses, low-capacity slaughterhouses, reindeer slaughterhouses, slaughterhouses for farmed game and game handling establishments.
- The purpose of this point is to evaluate temperature management during the transport of the carcasses of domestic ungulates dispatched from the establishment
    - when the carcasses have reached the required temperature before transport, and
    - when carcasses are dispatched from the slaughterhouse or a cutting plant connected to slaughter facilities to another establishment before they have reached the required temperature (referred to as carcasses dispatched warm).
- The temperature control of carcasses received at the establishment is evaluated in point 15.1 "Reception of Foodstuffs and Commercial Documents".

Matters to be controlled:

- Verification that the temperature of carcasses during transport complies with requirements
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: " General Compliance of Own-check With Requirements ".
- As concerns carcasses dispatched warm:
    - Compliance with requirements specified for transport
    - Removal of carcasses from slaughterhouse or cutting plant connected to slaughter facilities
    - Verification of the maximum duration of transport
    - Verification of continuous chilling during transport
    - Informing the receiver of carcasses of the transport temperature of the carcasses and the need for continued chilling.

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- The compliance of the temperature of carcasses with requirements is verified before transport.
- The compliance with requirements of the temperature of carcasses during transport is verified by verifying parameters during transport with e.g. recording equipment (temperature in load compartment and any air flow).
- Own-check is adequate and suitable.

Carcasses dispatched warm:

- Transport takes place in compliance with requirements specified by the competent authority.
- Carcasses are removed immediately from the slaughterhouse or a cutting plant connected to slaughter facilities.
- The duration of transport is at most two hours.

- Chilling is continued during transport.
- The receiver of the carcasses is informed of the transport temperature of the carcasses and the need for continued chilling.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- The temperatures of carcasses exceed temperature limits occasionally and briefly.
- Own-check is adequate and suitable, and corrective actions have been appropriate and adequate.

Carcasses dispatched warm:

- There are some minor shortcomings in the compliance of transport with requirements, but they do not impair food safety.
- The removal of carcasses from the slaughterhouse or a cutting plant connected to slaughter facilities is delayed briefly on occasion.
- The duration of transport exceeds the two-hour limit briefly on occasion, but corrective actions have been appropriate and adequate.
- The receiver of the carcasses is informed of the transport temperature of the carcasses and the need for continued chilling.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- The temperatures of carcasses exceed temperature limits repeatedly.
- There are shortcomings in own-check activities; for example, corrective actions have been deficient or inadequate.

Carcasses dispatched warm:

- There are shortcomings in the compliance of transport with requirements which impair food safety.
- The removal of carcasses from the slaughterhouse or a cutting plant connected to slaughter facilities has been repeatedly delayed.
- The duration of transport has exceeded the two-hour limit.
- The receiver of the carcasses is not informed of the transport temperature of the carcasses and the need for continued chilling.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- The temperature of the dispatched carcasses is not controlled at all.
- There are serious shortcomings in own-check activities; for example, corrective actions are not carried out or they are inadequate to the extent that food safety is jeopardised.

Carcasses dispatched warm:

- There are shortcomings in the compliance of transport with requirements which jeopardise food safety.
- The removal of carcasses from the slaughterhouse or a cutting plant connected to slaughter facilities has been repeatedly and significantly delayed or the duration of transport has exceeded the two-hour limit repeatedly and significantly, which jeopardises food safety.
- Corrective actions are not carried out.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

Updates in version 2:

- The Finnish title of the Guideline has been changed.

6 Food Temperature Management

6.8 Temperature Management of Water used in Disinfection of Working Utensils

To be taken into consideration:

- This Guideline is applied to slaughterhouses, game processing plants and cutting plants, as well as to production establishments of minced meat, meat preparations and mechanically separated meat.
- If some other method than steam or water at a temperature of at least 82°C is used at the establishment for the disinfection of working utensils, the method is evaluated in applicable parts in this point.
- The practices of the personnel of the establishment as regards the use of knife sterilisers is evaluated in point 4.1.

Matters to be controlled:

- The adequacy and suitability of own-check control, and the own-check control plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".
- Temperature management of water used in disinfection of working utensils, if appropriate.

EXCELLENT

Operations comply with requirements.

The temperature of water used for the disinfection of working utensils is at least 82°C.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

There are some minor shortcomings in the monitoring of the temperature of water used for the disinfection of working utensils at the establishment. For example:

- There are some minor shortcomings in the records related to temperature monitoring as concerns deviations and corrective action taken, but corrective actions have been appropriate and adequate.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The monitoring of the temperature of water used for the disinfection of working utensils has been deficient. For example:

- Temperature measurements have not been carried out to an adequate extent to verify detection of deficiencies.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The monitoring of the temperature of water used for the disinfection of working utensils has been neglected. For example:

- Temperatures have not been measured.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

08 Specific Requirements for Food Production

8.1 Processing of TSE Risk Material

To be taken into consideration:

- This Guideline is applied to all establishments where TSE risk material of bovine, ovine or caprine animals is processed, also when no specific approval is required for the processing of TSE risk material.
- Technical matters related to TSE approval, such as application for required approvals, approval documents, own-check plan (up-to-date status and consistency with approval decision) and the facilities related to the approval are evaluated in point 1.3.
- BSE/TSE sampling is evaluated in point 17.1.
- The separation of material of animal origin from wastewater in facilities where TSE risk material is being separated is evaluated in point 1.1 in connection with approval of the facilities, structures and equipment of the establishment.
- The handling and storage of by-products other than TSE risk material are evaluated in point 5.7 insofar as the operations fall under the Food Act, and in point 5.8 insofar as the operations fall under legislation on by-products. The results of the evaluations based on Guideline 5.8 are not presented in the Oiva report, but only in the inspection report.
- The dispatching of and commercial documents related to by-products are evaluated in point 15.5 insofar as the operations fall under the Food Act, and in point 5.8 insofar as the operations fall under legislation on by-products.

Matters to be controlled:

- Compliance of TSE operations and processing of TSE risk material with requirements, and prevention of cross-contamination of foodstuffs.
- Where a specific approval is required for TSE operations, compliance of TSE operations with the TSE approval decision and any specific conditions laid down in the approval decision.
- Correct determination of TSE risk material and verification by the operator of compliance with the age limits laid down in TSE provisions.
- Placing of the carcass, other parts of the slaughtered animal, and by-products in quarantine, keeping in quarantine and releasing from quarantine.
- Marking and separation of TSE risk material.
- Processing, dispatching, reception, and commercial documents of the carcasses or other parts of the slaughtered animal containing TSE risk material.
- Cutting of meat from the head of bovine animals aged over 12 months.
- The adequacy and suitability of own-check activities as concerns the processing of TSE risk material, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- TSE operations are carried out in compliance with the TSE approval decision and any specific conditions laid down in the approval decision. Processing of TSE risk material complies with requirements.
- TSE risk material is marked and kept separate from foodstuffs in a manner that prevents cross-contamination. All parts of animal that legislation defines as TSE risk material are treated as such. The carcass, other parts of the slaughtered animal, and by-products are kept in quarantine until the TSE examination result is confirmed.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in the records related to TSE operations at the establishment as concerns deviations and corrective action taken, but corrective actions have been appropriate and adequate.
- There are some minor shortcomings in the marking of containers used for the collection and storage of TSE risk material, or in the staining of TSE risk material, but there is no risk of confusion with foodstuffs.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- TSE operations are not carried out in compliance with the TSE approval decision or with any specific conditions laid down in the approval decision, and food safety is impaired.
- There are repeatedly shortcomings in the stamping of incorrectly split carcasses or in the sealing of the *foramen magnum* and the plugging of the bolt hole.
- Shortcomings occur on a regular basis or continue for a prolonged period of time.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- TSE operations are not carried out in compliance with the TSE approval decision or with any specific conditions laid down in the approval decision, and food safety is jeopardised.
- TSE risk material is not removed.
- There are shortcomings in the marking of containers used for the collection and storage of TSE risk material, or in the staining of TSE risk material, which cause a risk of confusion between TSE risk material and foodstuffs.

- The result of the TSE examination is not waited for before continuing the processing of carcasses, other parts of the slaughtered animal, and by-products.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 999/2001, rules regarding TSEs
- Regulation (EC) No 1069/2009 on by-products
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on actions related to TSE diseases concerning slaughterhouses and cutting plants 7/EEO/2009
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Evira's Guide 16011: TSE actions at establishments
- Evira's Guide 16010: Handling and control of by-products of animal origin at food establishments

Updates in version 3:

- Example in grade Excellent has been defined.

8 Specific Requirements for Food Production

8.2 Sensory Monitoring of Cleanliness of Carcasses and Organs

To be taken into consideration:

- This Guideline is applied to slaughterhouses and low-capacity slaughterhouses that slaughter ungulates, as well as to reindeer slaughterhouses and game handling establishments for the evaluation of the sensory monitoring of the cleanliness of carcasses and organs.
- This Guideline is also applied to slaughterhouses and low-capacity slaughterhouses that slaughter poultry for the evaluation of the sensory monitoring of the cleanliness of carcasses.
- The adequacy and effectiveness of monitoring and corrective actions can be evaluated on the basis of observations made in the acceptance inspection at the cutting plant.
- Microbiological sampling from the surface of carcasses, carried out to monitor process hygiene, is evaluated in point 17.1 "Sampling and Own-check Tests".
- Management of lactic acid decontamination of bovine carcasses is evaluated in point 8.3.

Matters to be controlled:

- Cleanliness of carcasses and organs
- Organisation of sensory monitoring of cleanliness of carcasses and organs
    - own-check plan
    - implementation of own-check activities
    - records of implementation
    - records of deviations
    - corrective actions carried out due to deviations
    - HACCP system, if appropriate

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- Carcasses in chilling room are clean according to sensory assessment and there is no visible faecal or other contamination on them.
- Sensory monitoring of the cleanliness of carcasses and organs comprises an adequate own-check plan, implementation, records, corrective actions, and a HACCP system, if appropriate.
- Own-check activities are adequate and suitable in relation to the nature and scope of operations at the establishment.
- Corrective actions have been adequate.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- Carcasses in chilling room are clean according to sensory assessment and there is no visible faecal or other contamination on them.

- There are some minor shortcomings in the sensory monitoring of the cleanliness of carcasses and organs, or in own-check or the HACCP system, but they do not impair food safety, however.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- According to sensory assessment, there is some faecal or other contamination on carcasses in chilling room, which impairs food safety.
- There are shortcomings that impair food safety in the sensory monitoring of the cleanliness of carcasses and organs, or in own-check or the HACCP system.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- According to sensory assessment, there is faecal or other contamination on carcasses in chilling room to the extent that food safety is jeopardised.
- There are shortcomings that jeopardise food safety in the sensory monitoring of the cleanliness of carcasses and organs, or in own-check or the HACCP system.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

8 Specific Requirements for Food Production

8.3 Management of Lactic Acid Decontamination of Bovine Carcasses

To be taken into consideration:

- This Guideline is applied to slaughterhouses and low-capacity slaughterhouses that slaughter domestic bovine animals (incl. Bubalus and Bison species) and to reindeer slaughterhouses.
- The purpose of this point is to evaluate the reduction of the surface contamination of bovine carcasses using lactic acid, and the monitoring of the reduction of surface contamination.
- As the use of lactic acid may not affect the obligation of the food business operator to comply with good hygienic slaughter practices and operational procedures, it is recommended that the sensory monitoring of the cleanliness of carcasses and organs (point 8.2) is evaluated at the same time as this point.

Matters to be controlled:

- Compliance of lactic acid solution with requirements.
- Realisation of pre-conditions for lactic acid treatment, and its compliance with requirements.
- HACCP system, incl. sampling before lactic acid treatment as required by the Regulation on microbiological criteria of foodstuffs, lactic acid concentration during treatment, lactic acid temperature during treatment.
- Documentation of lactic acid treatment.
- Notifying operators receiving the carcasses about the lactic acid treatment.
- Documentation of notified information.
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "General Compliance of Own-check with Requirements".

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- Operations meet the specified requirements and the operator has unexpected and occasional shortcomings under control through own-check activities. Implementation of HACCP system complies with requirements.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- Minor shortcomings in compliance with requirements; for example, occasional deficiencies in records.
- However, corrective actions have been adequate and appropriate.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:
- Shortcomings requiring corrective actions in the compliance of the process with requirements, or in records.
- The nature of shortcomings and the standard of corrective actions cause food safety to be impaired.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:
- Serious shortcomings requiring immediate corrective actions in the compliance of the process with requirements.
- Lactic acid treatment is carried out on carcasses on which visible faecal contamination is observed.
- The nature of shortcomings and the standard of corrective actions cause food safety to be jeopardised.

Legislation and guidelines (with any amendments) pertaining to the subject:
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Commission Regulation (EU) No 101/2013 concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcasses

08 Specific Requirements for Food Production

8.4 Management of Trichinella Risk

To be taken into consideration:

- This Guideline is applied to slaughterhouses and game processing establishments that slaughter species susceptible to Trichinella infection.
- Pigs housed under controlled housing conditions are exempt from Trichinella examination.
- The competence of the laboratory used to analyse the samples is evaluated in point 1.6.

Matters to be controlled:

- Sampling for Trichinella examination in compliance with regulatory requirements and Evira's regulations
- Samples and carcasses are linkable and traceable
- Health marking of carcasses before results of Trichinella examination are received
- Cutting of pig carcasses before results of Trichinella examination are received
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-Check Activities".

EXCELLENT

Operations comply with requirements.

Trichinella sampling is carried out in compliance with regulatory requirements. Samples can be traced to carcasses or groups of carcasses.

Carcasses with a health marking are not removed from the slaughterhouse facilities or processed until the Trichinella examination has been completed. Any deviating arrangements applied to pig carcasses have been approved by the controlling inspector of the establishment, and the arrangements meet other regulatory requirements specified for them.

Performance of Trichinella sampling is verified through own-check in compliance with regulatory requirements. The actions to be taken at the establishment in case Trichinella infection is detected are also included in the own-check plan. Any deficiencies in operations are detected through own-check and corrective actions are carried out appropriately.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

There are some minor shortcomings in own-check at the establishment. For example:

- Trichinella sampling is carried out on all the animals for which sampling is required by legislation, but samples cannot always be traced to a specific group of animals in a case where all the samples have tested negative.

TO BE CORRECTED

There are issues with the operations that are not in compliance with legislation or impair food safety or mislead consumers. These issues must be rectified within a set time of period.

For example:

- Carcasses with a health marking have been removed from the slaughterhouse facilities without the approval of the controlling inspector prior to the completion of the Trichinella examination, but the carcasses have not been processed otherwise, however.
- The management of Trichinella risk is deficient at the establishment, corrective actions have not been carried out or they have been inadequate.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- Trichinella sampling is not carried out in compliance with regulatory requirements (for example, no samples are taken, samples are taken from a wrong point, or samples are too small).
- Carcasses that are to be sampled are not identifiable (for example, pigs from ordinary conditions and from controlled housing conditions).
- The results of the Trichinella examination are not waited for before starting the processing of carcasses, or the conditions laid down for any deviating arrangements applied to pig carcasses are not complied with.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Commission Regulation (EC) No 2015/1375
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on meat controls 590/2014
- Regulation of the Finnish Food Safety Authority exempting pigs born and reared under recognized controlled housing conditions from Trichinella examination, 1/2015
- Evira's Guide 16008: Health marking and cutting of pig carcasses prior to completion of result of Trichinella examination

Updates in version 2:

- The title of “To be corrected” has been edited. The number of Trichinella regulation has been updated.

8 Specific Requirements for Food Production

8.5 Production of Minced Meat and Meat Preparations

To be taken into consideration:

- This point is applied to establishments approved for the production of minced meat or meat preparations
- The temperature requirements specified for the production of minced meat and meat preparations are evaluated in point 6.5 "Temperature Management in Food Production Processes"
- Matters related to the connective tissue protein of minced meat are evaluated in Guideline 13.4
- The use of additives in meat preparations is evaluated in point 11.1 "Additives, Flavourings and Enzymes"

Matters to be controlled:

- Muscles or offals permitted by legislation are used as raw material for minced meat.
- Age of the raw material used for minced meat.
- Muscles or offals permitted by legislation are used as raw material for meat preparations.
- Microbiological requirements for mechanically separated meat used for the production of meat preparations intended to be heated.
- Minced meat and meat preparations may not be re-frozen after thawing.
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

- The raw material used for the production of minced meat and / or meat preparations meets regulatory requirements.
- The age of the raw material used for the production of minced meat and / or meat preparations meets regulatory requirements.
- Mechanically separated meat used for the production of meat preparations intended to be heated meets the microbiological requirements laid down for minced meat.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- The raw material used for the production of minced meat and / or meat preparations meets regulatory requirements.
- There are some minor shortcomings in the monitoring of the age of the raw material used for the production of meat and / or meat preparations, but they do not impair food safety.
- The have been some minor shortcomings in the microbiological quality of the mechanically separated meat used for the production of meat preparations intended to be heated.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There are shortcomings in the monitoring of the age of the raw material used for the production of meat and / or meat preparations, or the meat used as raw material is too old, and its use impairs food safety.
- Mechanically separated meat used for the production of meat preparations intended to be heated does not meet the microbiological requirements laid down for minced meat.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- Scrap cuttings and trimmings (other than whole muscle cuttings), mechanically separated meat, meat containing skin, or meat of the head with the exception of the masseters, the non-muscular part of the linea alba, the region of the carpus and the tarsus, or bone scrapings, or the muscles of the diaphragm with the serosa unremoved are used as raw material for minced meat.
- The age of the raw material used for the production of minced meat and / or meat preparations is not known, or it is too old, and its use jeopardises food safety.
- Mechanically separated meat has been used in meat preparations intended to be heated, although the microbiological tests of mechanically separated meat have not been carried out or included in the sampling plan.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin, Annex III, Section V
- Regulation /EC) No 2073/2005 on microbiological criteria for foodstuffs
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments, 795/2014; Annex 2, Chapter 8.2, and Annex 3, Chapter 2.7

8 Specific Requirements for Food Production

8.6 Production of Mechanically Separated Meat

To be taken into consideration:

- This Guideline is applied to establishments that produce mechanically separated meat.
- The temperature requirements specified for the production of mechanically separated meat are evaluated in point 6.5 "Temperature Management in Food Production Processes"
- The time and temperature limits applied to the quick-freezing of mechanically separated meat and to the storage of frozen mechanically separated meat are evaluated in Guideline 6.6 "Temperature Management of Quick-frozen and Frozen Foodstuffs, and Ice Cream"
- The labelling of the prepacked food products containing mechanically separated meat is evaluated in point 13.1 "General Labelling"

Matters to be controlled:

- The raw material for mechanically separated meat is derived from animal parts permitted by legislation.
- The age of the raw material used for mechanically separated meat
- The period of use of meat separated mechanically using high pressure (excluding quick-freezing)
- Mechanically separated meat produced using high pressure or low pressure is marked during production as "mechanically separated meat" instead of as "meat", for example.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check ".

EXCELLENT

Operations comply with requirements.

The raw material used for the production of mechanically separated meat and its age meet regulatory requirements.

Meat separated mechanically using high pressure is quick-frozen, if it is not used within one hour after production.

Mechanically separated meat produced using high pressure or low pressure is marked during production as mechanically separated meat; mechanically separated meat produced using low pressure, for example, is not marked as meat.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- The raw material used for the production of mechanically separated meat meets regulatory requirements.

- The raw material used for the production of mechanically separated meat is slightly too old on occasion, but this does not impair food safety.
- There have been deviations regarding the period of use of meat separated mechanically using high pressure, but they have not impaired food safety, however.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There are shortcomings in the monitoring of the age of the raw material used for the production of mechanically separated meat, or the meat used as raw material is too old, and its use impairs food safety.
- There have been deviations regarding the period of use of meat separated mechanically using high pressure to the extent that they have impaired food safety.
- Mechanically separated meat produced using high pressure or low pressure is marked incorrectly during production; mechanically separated meat produced using low pressure, for example, has been marked as meat.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- Poultry feet, neck skin, or heads, or the head bones, feet, tails, femur, tibia, fibula, humerus, radius and ulna of other animals are used for the production of mechanically separated meat.
- The age of the raw material used for the production of mechanically separated meat is not known, or it is too old, and its use jeopardises food safety.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin, Annex III, Section V
- Finnish Food Act 23/2006

8 Specific Requirements for Food Production

8.7 Production of Dried Reindeer Meat

To be taken into consideration:

- This Guideline is applied to the production of dried reindeer meat based on the traditional outdoor air-drying method in a meat product establishment located in the Finnish reindeer husbandry area.
- Compliance with the requirements specified for approval for production of dried reindeer meat is evaluated in point 1.2.
- The controllability and up-to-date status of the own-check plan is evaluated in point 1.6.
- Production of dried reindeer meat using some other method than the traditional outdoor air-drying method, or in a meat product establishment located outside the reindeer husbandry area, is evaluated in point 5.1 "General Hygiene in Food Production".
- This Guideline is not applied to the production of dried reindeer meat in the place of primary production in the reindeer husbandry area.

Matters to be controlled:

- The requirements of the Decree on food hygiene at establishments are complied with in the production of dried reindeer meat, taking the limitation of the scope of the Decree as defined in Section 2 into account.
- Inspection of the hygiene of the handling of reindeer meat as it is prepared for the drying process in the indoor facilities of the meat product establishment.
- Inspection of the handling of reindeer meat before and after drying as the meat is hung in the drying rack and removed from the rack.
- Inspection of the hygiene of the handling of dried reindeer meat after the drying process in the indoor facilities of the meat product establishment.
- Inspection to verify that vermin and birds cannot contaminate reindeer meat during the drying process.
- Inspection to verify the free circulation of air round the reindeer meat during the drying process.
- Inspection to verify that the drying of reindeer meat is carried out in a suitable period of the year and at a suitable outdoor temperature.
- Only inspected reindeer meat is dried in the drying rack.
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-Check".

EXCELLENT

Operations comply with requirements.

- Reindeer meat is handled in a hygienic manner as it is prepared for drying, hung in the drying rack and removed from the rack, and handled after the drying process.
- Reindeer meat intended to be dried is prepared for drying in appropriate indoor facilities at the meat product establishment.
- Reindeer meat is after drying handled in appropriate indoor facilities at the meat product establishment.

- Vermin and birds cannot contaminate reindeer meat during the drying process.
- Reindeer meat is dried in a suitable period of the year.
- Reindeer meat is hung for drying in a manner that verifies free circulation of air.
- Only inspected reindeer meat is dried in the drying rack.
- The own-check plan is adequate and suitable as regards the controlled matters.
- The operator has sudden and random shortcomings under control through own-check.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- Reindeer meat is dried under highly varying conditions, but the drying process is still adequately under control to ensure that the meat is not spoiled.
- There are some minor shortcomings in the own-check plan as regards the controlled matter.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- Reindeer meat is dried under conditions that are sometimes unsuitable resulting in delayed drying of the meat; for example, unsuitable period of the year or outdoor temperature. The safety of the meat is impaired.
- Air circulation round the drying meat is not effective; for example, the pieces of meat are hung too close to each other. The drying of meat is delayed and the safety of meat is impaired.
- Also other meat and products than inspected reindeer meat are dried in the drying rack.
- There are shortcomings in the own-check plan as regards the controlled matter which impair food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- Reindeer meat is not handled in a hygienic manner as it is prepared for drying, hung in the drying rack and removed from the rack, and handled after the drying process.
- Vermin or birds can contaminate the meat during the drying process.
- Meat is dried under unfavourable climate conditions or air circulation round the drying meat is not adequate, resulting in inadequately controlled drying of the meat and jeopardised safety of the meat.

- There are shortcomings in the own-check plan as regards the controlled matter which jeopardise food safety.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Implementing Regulation (EC) No 2074/2005
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Evira's Guide 16033/2: Approval of an Establishment

8 Specific Requirements for Food Production

8.8 Parasite Checks and Freezing Treatment of Fishery Products

To be taken into consideration:

This point is evaluated at establishments where:

- fish is gutted (parasite checks)
- ready-to- eat fishery products are produced, and the treatment of the fish is not adequate to kill the viable parasites, with the exception of fish species exempt from the freezing treatment

Matters to be controlled:

- Parasite checks of fresh fish
- Freezing treatment required due to parasite risk
- Indication made in the commercial document about the freezing treatment of the product
- The adequacy and suitability of own-check, and the own-check plan, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The controlled matters comply with requirements.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- As a rule, parasite checks are carried out in compliance with requirements, but some individual lots have not been checked.
- As a rule, the freezing treatment is carried out in compliance with requirements, but some individual lots have not undergone the treatment.
- As a rule, an indication is made in the commercial document about the freezing treatment, but in some individual cases the indication has not been made.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:
- Parasite checks are only carried out on a random basis.
- All products or product groups that require the freezing treatment due to a parasite risk do not undergo the treatment.
- No indication is made in the commercial document about the freezing treatment.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:
- The freezing treatment is not carried out on any of the product groups that require the treatment due to a parasite risk.
- Parasite checks are not carried out.

Legislation and guidelines (with any amendments) pertaining to the subject:
- Commission Regulation (EC) No 2074/2005, Annex II, Chapter II
- Commission Regulation (EC) No 853/2004, Annex III, Section VIII, Part D
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Evira's Guide 16023: Control of fishery products

Updates in version 2
- The title of the Guideline has been changed: "mandatory freezing" has been replaced with "freezing treatment"

8 Specific Requirements for Food Production

8.9 Quality Control for Raw Material of Egg Products

To be taken into consideration:

- This Guideline is applied to all establishments that produce egg products.
- For the purposes of this Guideline, raw material refers to the eggs used at egg product establishments for the production of egg products and are procured to the establishment from egg-packing centres and producers.
- The shells of eggs used in the manufacture of egg products must be fully developed and contain no breaks.
- However, cracked eggs may be used for the manufacture of egg products if the establishment of production or a packing centre delivers them directly to the processing establishment, where they must be broken as soon as possible.
- Eggs must not be broken unless they are clean and dry. An egg is considered to be dirty, if the amount of dirt or dirt spots on the surface of the shell exceeds 1/16 of the area of the egg, or if there are lumps of dirt or blood on the shell.
- Dirty eggs can be washed with a detergent suitable for this purpose.
- Only water tested for at least *Escherichia coli* and intestinal enterococci and subjected to an assessment of colour and smell may be used to clean eggs.

Matters to be controlled:

- How is quality control for eggs used for the production of egg products implemented at the egg product establishment.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

- The own-check plan provides a description of how the egg product establishment verifies the quality of the raw material used for egg products.
- The egg product establishment controls the quality of the raw material and removes any eggs that do not meet the criteria laid down for production.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are some minor shortcomings in the description provided in the own-check plan of how the egg product establishment verifies the quality of the raw material used for egg products.
- The egg product establishment controls the quality of the raw material and removes any eggs that do not meet the criteria laid down for production.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There are clear shortcomings in the description provided in the own-check plan of how the egg product establishment verifies the quality of the raw material used for egg products.
- The egg product establishment controls the quality of the raw material, but eggs that do not meet the criteria laid down for production have gone undetected into the production of egg products resulting in impaired food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The own-check plan does not provide a description of how the egg product establishment verifies the quality of the raw material used for egg products.
- Eggs that do not meet the criteria laid down for production have been used in the production of egg products resulting in food safety being jeopardised.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin; Section X, Chapter II, points II and III
- Regulation 1368/2011 on primary production, Annex I, Chapter 2
- Evira's Guide 16006/1 Quality of raw material for liquid egg

9 Reception of Animals and Information on Animals

9.1 Register Queries

To be taken into consideration:

- This Guideline is applied to slaughterhouses, low-capacity slaughterhouses and reindeer slaughterhouses where bovine animals are slaughtered.
- The operations and the own-check activities of the establishment as regards the tagging and identification of bovine animals (checking of ear tags, and shortcomings found in them) are evaluated in point 9.4.

Matters to be controlled:

- A register query is made before a bovine animal is accepted for carriage to slaughter.
- The establishment observes the results of the register query, such as movement restrictions, sampling requests, slaughtering bans and other notifications.
- The establishment reports to the veterinary inspector any errors occurring in the register query process and deviating results of register queries as well as the actions required due to them.
- The adequacy and suitability of own-check activities, and the own-check control plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

A register query is always made for all bovine animals intended to be transported to slaughter before accepting them for carriage. The results of the query are checked and observed in operations.

Any errors or shortcomings in register queries are detected in the own-check activities and corrective actions are taken and recorded appropriately. Any deviations and corrective actions are reported to the official veterinarian.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in the records of deviations and implemented corrective actions in the records related to the register queries made by the establishment.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:
- Errors occur repeatedly in making register queries.
- Errors made in register queries or deviating results of register queries or actions required due to them are not reported to the official veterinarian.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:
- Repeated failure to make a register query or queries are not made at all.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 1760/2000 on identification and registration of bovine animals
- Regulation (EC) No 911/2004 on ear tags
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Decree 1391/2006 of the Ministry of Agriculture and Forestry on the identification and registration of bovine animals
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on meat controls 590/2014
- Evira's Guide: Identification of bovine animals, register queries and regulatory control of these in slaughterhouses and low-capacity slaughterhouses, 16007

9 Reception of Animals and Information on Animals

9.2 Food Chain Information and Other Comparable Information

To be taken into consideration:

- As far as food chain information is concerned, this Guideline is applied to slaughterhouses that slaughter domestic animals, poultry and farmed game, and to corresponding low-capacity slaughterhouses. The Guideline is also applied to reindeer slaughterhouses and wild game processing establishments.
- In addition, as concerns information accompanying hunted wild game, the Guideline is applied to game processing establishments, and as concerns information accompanying live fishery products, to establishments in the fish sector, and as concerns information accompanying eggs, to egg-packing centres.
- The compliance with requirements of the processing of food chain information and other comparable information and documents submitted to the food establishment is evaluated according to this Guideline.
- Other comparable information includes, for example:
  - documents accompanying hunted wild game,
  - declarations of trained persons of a preliminary examination of wild game,
  - information accompanying live fishery products, including e.g. information on the date of catch/harvest and information on medication, as well as
  - any medication information on laying hens submitted to egg-packing centres.
- The compliance of operations with requirements, good practices as well as the adequacy and suitability of own-check activities to verify the management of food safety risks are taken into consideration in the evaluation.
- The checking of the identification documents of horses is evaluated in point 9.5
- The quality testing of raw milk is evaluated in point 17.9.
- Risk management related to residues of medicinal products is evaluated in point 17.11.

Matters to be controlled:

- Requests, reception and assessment of food chain information.
- Submission of assessment results of food chain information to the veterinary inspector.
- Own-check activities regarding time limits for submission of food chain information.
- Reporting of shortcomings related to food chain information to the veterinary inspector.
- Submission of relevant information as feedback to the operator in primary production.
- Own-check activities regarding information accompanying hunted wild game, and declarations of trained persons.
- Own-check activities regarding information accompanying live fishery products.
- Own-check activities regarding information accompanying eggs.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- The slaughterhouse operator has verified that food chain information has been submitted to the slaughterhouse within the time limits and does not contain any manifest errors or shortcomings.
- The slaughterhouse operator has assessed food chain information for every animal or group of animals to verify that the animals can be accepted for reception at the slaughterhouse.
- The slaughterhouse operator has made food chain information and assessment results of food chain information available to the veterinary inspector within the time limit.
- The slaughterhouse operator has provided information on meat inspection decision, the morbidity information referred to in the Decree on monitoring of morbidity in pigs, and other relevant information to the operator in primary production.
- Where the slaughterhouse operator has found errors or shortcomings in food chain information, they have reported this to the veterinary inspector and taken actions in relation to the operator in primary production to rectify the situation.
- The slaughterhouse operator has not accepted animals when their food chain information has revealed factors that prevent the slaughter of the animals for use as food.
- Own-check activities regarding food chain information and also other comparable information is adequate and suitable, and corrective actions have been appropriate and adequate. The own-check plan describes procedures for deviations and instructions regarding reporting to the control authority. Any deviations and corrective actions have been recorded and reporting implemented to the authorities. Records are available of any deviations and corrective actions taken.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in compliance with time limits specified for submission of food chain information.
- There are some minor shortcomings in own-check activities regarding other comparable information.
- There are some minor shortcomings regarding the implementation of own-check activities, deviations, or corrective actions.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- The slaughterhouse operator has found shortcomings in food chain information but has failed to take actions in relation to the operator in primary production to rectify the situation.
- The own-check plan is not up-to-date.
- The own-check records related to the assessment of food chain information have clear shortcomings, or no records are made or records are not stored for the requirement length of time.
- Shortcomings in the assessment of the submitted information as concerns other comparable information.
- Deviations have not been recorded although it becomes known that deviations have occurred.
- Corrective actions taken due to deviations have not been appropriate or adequate, or there is no knowledge of corrective actions.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- The slaughterhouse operator does not check food chain information at all.
- The assessment results of food chain information are not available.
- The own-check plan does not provide a description of the own-check activities of food chain information.
- The operator has failed to fulfil the orders issued with the grade To be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Implementing Regulation (EC) No 2074/2005
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on primary production 1368/2011
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on meat controls 590/2014
- Decree of the Ministry of Agriculture and Forestry on monitoring of morbidity in pigs 6/EEO/2012
- Evira's Guide 16005: Submission and control of food chain information
- Evira's Guide 16027: Evira's Guide on the handling of wild game meat and supply of meat for sale 16027
- Evira's Guide 16031: Indications or marks identifying fishery products, and documents to accompany fishery products

9 Reception of Animals and Information on Animals

9.3 Animal Transport

To be taken into consideration:

- This Guideline is applied to the animal transports of low-capacity slaughterhouses, slaughterhouses and reindeer slaughterhouses.
- The slaughterhouse's own animal transports and transports handled by contractual carriers are evaluated according to the same principles with the slaughterhouse operator responsible in both cases for the cleanliness of the animals.
- The slaughterhouse is responsible for the cleanliness of animals delivered on an occasional basis by private persons to the extent that instructions have been provided, where necessary, at the time of purchase to the person delivering the animals.
- The tagging and identification of animals are evaluated in point 9.4.
- The checking of the identification documents of horses is evaluated in point 9.5.

Matters to be controlled:

- Verification of the cleanliness of animals prior to transport
- Cleanliness of the means of animal transport
- Cleanliness and material of the animal transport containers
- A designated place for washing means of animal transport, provided with appropriate equipment for cleaning, washing and disinfection
- Has approval been granted in connection with the approval of the establishment for washing of means of animal transport somewhere else?
- The facilities and equipment at a poultry slaughterhouse for the washing and disinfection of empty animal transport containers, and a facility for the storage of clean animal transport containers
- The adequacy and suitability of own-check activities, and the own-check plan (sampling and testing plan), if appropriate, are controlled applying the Annex to Guideline 1.6: "General Compliance of Own-check with Requirements".

EXCELLENT

Operations comply with requirements.

Animals accepted for transport at the farm are clean.
The containers used for animal transport are made from a stainless material and they are easy to clean and disinfect.
The means of animal transport are adequately clean to ensure that animals do not become dirty during transport.
The designated place for washing means of animal transport is provided with appropriate equipment.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are minor shortcomings in the cleanliness of animals accepted for transport at the farm. The actions taken by the slaughterhouse operator in relation to the carrier of animals have been appropriate and adequate.
- There are some minor shortcomings in the cleaning and disinfection of the animal transport containers, but they do not affect the cleanliness of the animals.
- There are some minor shortcomings in the cleanliness of the means of animal transport, but the animals do not become dirty during transport to the extent that it would impair food safety/hygiene of slaughtering.
- There are some minor shortcomings in the equipment provided in the designated place for washing means of animal transport, but they do not cause the animals to become dirty during transport.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There are shortcomings in the cleanliness of animals accepted for transport at the farm. The actions taken by the slaughterhouse operator in relation to the carrier of animals in case of a deviation have been inadequate.
- There are shortcomings in the cleaning and disinfection of the animal transport containers which affect the cleanliness of the animals.
- There are shortcomings in the cleanliness of the means of animal transport and food safety is impaired because the animals become dirty during transport.
- There are shortcomings in the equipment provided in the designated place for washing means of animal transport which cause the animals to become dirty during transport.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- Animals accepted for transport at the farm are dirty. The slaughterhouse operator has failed to take corrective actions.
- There are deficiencies in the cleaning and disinfection of the animal transport containers which affect the cleanliness of the animals.
- There are shortcomings in the cleanliness of the means of animal transport and food safety is jeopardised because the animals become dirty during transport.
- The equipment provided in the designated place for washing means of animal transport is deficient and washing cannot be carried out appropriately, or the animal compartments remain dirty after washing.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin; Annex II, Section II; Annex III, Section I, Chapters I and II; Annex III, Section II, Chapters I and II
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments, 795/2014; Annex 2, Chapters 2.1 3.1

9 Reception of Animals and Information on Animals

9.4 Tagging and Identification of Animals

To be taken into consideration:

- This Guideline is applied to slaughterhouses, low-capacity slaughterhouses and reindeer slaughterhouses.
- The compliance of operations with requirements, good practices as well as the adequacy and suitability of own-check activities to verify the management of food safety risks are taken into consideration in the evaluation.
- Guideline 9.5 pertains to matters related to the checking of the identification documents of equine animals. Guideline 9.1 pertains to matters related to register queries regarding bovine animals.

Matters to be controlled:

- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: “General Compliance of Own-check with Requirements".
- Has the slaughterhouse received, delivered, accepted for carriage or slaughter untagged animals or animals with inadequate identification.
- The operator in the slaughterhouse business maintains a list of the bovine animals, pigs, sheep and goats slaughtered at the slaughterhouse.

EXCELLENT

Operations comply with requirements.

Operations comply with requirements, and own-check is adequate and suitable to verify the management of food safety risks. The operator has reacted quickly and effectively to remove any shortcomings. For example:

- The own-check plan of the slaughterhouse describes how information on the animals accepted for slaughter, as well as their origin are checked, and how the animals are identified. The records maintained by the slaughterhouse of these matters are complete.
- The slaughterhouse has not received, delivered, or accepted for carriage or slaughter untagged animals or animals with inadequate identification. In cases where the slaughterhouse has accepted for slaughter animals with inadequate identification, the documentation prepared about the matter complies with Evira's instructions.
- The slaughterhouse maintains the list referred to in provisions of the bovine animals, pigs, sheep and goats slaughtered at the slaughterhouse.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operations comply in the main part with requirements, and own-check is adequate and suitable to verify the management of food safety risks. The grade can be Good e.g. in the following cases where:

- There are some minor shortcomings in the records related to the implementation of own-check, deviations, or corrective actions.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- The own-check plan is not up-to-date.
- The own-check plan does not describe how information on the animals, as well as their origin are checked, and how the animals are identified, but the operator carries out appropriate activities and maintains records of the required matters.
- The slaughterhouse operator accepts animals with inadequate identification for slaughter and does not request the necessary clarifications of the origins, registration or identification of the animals.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The slaughterhouse has frequently received, delivered, or accepted for carriage or slaughter untagged animals or animals with inadequate identification.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on control of food of animal origin
- Finnish Food Act 23/2006
- Act on the Animal Identification System 238/2010
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on meat inspection 590/2014
- Decree of the Ministry of Agriculture and Forestry on the identification and registration of bovine animals 1391/2006
- Decree of the Ministry of Agriculture and Forestry on the identification of pigs 720/2012
- Decree of the Ministry of Agriculture and Forestry on the identification and registration of sheep and goats, 469/2005, 333/2006, 356/2008, 194/2010
- Decree of the Ministry of Agriculture and Forestry on the identification and registration of equine animals 880/2009, 197/2010
- Evira's Guide 16014: Checking of identification document for equine animal delivered for slaughter

9 Reception of Animals and Information on Animals

9.5 Checking of Identification Documents for Equine Animals

To be taken into consideration:

- The Guideline is applied to slaughterhouses and low-capacity slaughterhouses that slaughter equine animals.
- The compliance of operations with requirements, good practices as well as the adequacy and suitability of own-check activities to verify the management of food safety risks are taken into consideration in the evaluation.

Matters to be controlled:

- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "General Compliance of Own-Check with Requirements".
- The slaughterhouse checks the identification documents of horses.
- The slaughterhouse verifies that the identification document is for the horse delivered for slaughter.
- The slaughterhouse checks the items regarding medication in the identification document.
- The slaughterhouse submits the identification document to the official veterinarian before the ante mortem inspection.
- Microchip transponders are recovered from the carcasses after slaughter and destroyed.

EXCELLENT

Operations comply with requirements.

Operations comply with requirements, and own-check is adequate and suitable to verify the management of food safety risks. The operator has reacted quickly and effectively to remove any shortcomings. For example:

- The own-check plan of the slaughterhouse describes the checking of the identification document for horses and the associated activities. The records maintained by the slaughterhouse of these matters are complete.
- The slaughterhouse requires an identification document for all horses delivered for slaughter and checks the identification document for all horses delivered for slaughter.
- The slaughterhouse verifies that the identification document is for the horse delivered for slaughter by checking either the microchip number or the identification details indicated in the identification document against the horse.
- The slaughterhouse checks the medication information on the horse from the identification document: the slaughterhouse checks Section IX of the passport or the "medication sticker" on the register certificate to verify that the slaughtering of the horse for use as food is not banned, and where a six-month withdrawal period has been set for the horse, it has lapsed.
- The slaughterhouse submits the identification document to the official veterinarian before the ante mortem inspection.

- The slaughterhouse recovers the microchip transponder from the carcass and destroys it according to the instructions.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operations comply in the main part with requirements, and own-check is adequate and suitable to verify the management of food safety risks. The grade can be Good e.g. in the following cases where:

- There are some minor shortcomings regarding the implementation of own-check, deviations, or corrective actions.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- The own-check plan is not up-to-date.
- The own-check plan does not provide a description of the checking of the identification document for horses, but the operator does check the identification documents.
- The slaughterhouse operator accepts for slaughter horses with an identification document that has been reissued after 1 July 2009.
- The slaughterhouse operator accepts for slaughter horses without the "medication sticker" on the register certificate.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The slaughterhouse operator does not check the identification document against the identification details of the horse.
- The slaughterhouse operator accepts for slaughter horses which have an indication of being excluded from the food chain in their identification document, or a six-month withdrawal period set for the horse has not yet lapsed.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on control of food of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on meat inspection 590/2014
- Regulation (EC) No 504/2008 on methods for the identification of equidae

- Decree of the Ministry of Agriculture and Forestry on the identification and tagging of equine animals 880/2009
- Evira's Guide 16014: Checking of identification document for horse delivered for slaughter
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Updates in version 2:

- The title of the Guideline has been changed: "Identification document for equine animals" has been replaced with "Checking of identification document for equine animals"

9 Reception of Animals and Information on Animals

9.6 Records of Animals Received for Slaughter

To be taken into consideration:

- This point is applied to slaughterhouses and low-capacity slaughterhouses that slaughter red meat and poultry, and to slaughterhouses that slaughter farmed game.
- The making of register queries is evaluated in point 9.1.
- Information on the food chain is evaluated in point 9.2.
- The tagging and identification of animals are evaluated in point 9.4.
- The checking of the identification documents of horses is evaluated in point 9.5.

Matters to be controlled:

- The records maintained by the slaughterhouse operator of animals accepted for slaughter.
- The records maintained by the slaughterhouse operator of animals excluded from the production process.
- The consistency of the number of animals excluded from the production process and slaughtered animals with the number of animals accepted for slaughter.
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "General Compliance of Own-check with Requirements".

EXCELLENT

Operations comply with requirements.

The slaughterhouse operator maintains records of animals accepted for slaughter and animals excluded from the production process.

The records are adequately reliable to verify that animals accepted for slaughter and animals excluded from the production process have been recorded.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There have been some minor shortcomings in the records of animals accepted for slaughter or animals excluded from the production process with respect to e.g. indication of dates.
- The records of animals accepted for slaughter and animals excluded from the production process have been consistent with the number of slaughtered animals and animals removed from production, however.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- The records of animals accepted for slaughter and animals excluded from the production process are not consistent with the number of slaughtered animals and animals removed from production.
- The records have been written by hand and are illegible.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The records are not adequately reliable to verify that animals accepted for slaughter have been recorded or that all animals excluded from the production process have been recorded.
- No records have been maintained of animals accepted for slaughter or animals excluded from the production process.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments, 795/2014; Annex 2, Chapter 1.5, Annex 3, Chapters 2.1, 2.2, 2.3, and 2.4

Updates in version 3:

- The change concerns only the Finnish version.

9 Reception of Animals and Information on Animals

9.7 Separation of Animals Delivered to a Slaughterhouse

To be taken into consideration:

- This point is evaluated in slaughterhouses that slaughter domestic animals, poultry and farmed game, and in corresponding low-capacity slaughterhouses, as well as reindeer slaughterhouses and game processing establishments.
- The purpose of this point is to evaluate the separation of live animals, and the arrangements for slaughtering in the reception facilities of the slaughterhouse, low-capacity slaughterhouse or reindeer slaughterhouse, such as animal sheds or pens.
- The reception, and separation, if appropriate, of wild game, bears and seals (can be delivered as skinned, i.e., carcasses) as well as farmed game and bison (can be delivered killed and unskinned) are also evaluated in this point.
- The factors considered in the evaluation include compliance of operations with requirements, consideration of food chain information in the separation of animals, adequacy and suitability of own-check activities, and good operational practices.
- The prevention of cross-contamination during the slaughtering process, after the stunning stage, is evaluated in point 5.2 "Separation of Activities of Different Hygiene Levels".
- The separation of pigs from controlled housing conditions and other pigs to verify *Trichinella* sampling of other pigs is evaluated in point 5.2.

Matters to be controlled:

- Consideration of factors related to food chain information and identification of animals in the separation of animals and in the slaughtering arrangements.
- Consideration of the epidemiological situation on the location where the animals come from in the slaughtering arrangements.
- Placing the animal in quarantine e.g. when food chain information is not provided before slaughter.
- Separation of animals from other animals and slaughtering arrangements e.g. when:
  - animals are suspected or found to be sick,
  - animals are injured,
  - animals are dirty to the extent that slaughtering hygiene could be affected,
  - animals need to be slaughtered separately after other slaughtering operations due to determined or suspected salmonella or lack of salmonella results,
  - animals received from the same location have in successive slaughterings been found to carry campylobacter and the animals need to be slaughtered as the last animals of the day,
  - animals come from EHEC positive farms, or
  - separation of animals and slaughtering arrangements are necessary due to the results of the *ante mortem* examination.
- Animals are slaughtered as the last animals of the day or separately from other animals
- Own-check activities of carcass hygiene and freezing of carcasses as concerns wild game, and if appropriate, separation of carcasses.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- Food chain information has been taken into consideration and requirements have been complied with as concerns the separation of animals delivered to the slaughterhouse, and the slaughtering arrangements.
- Where necessary, animals are slaughtered as the last animals of the day or separately from other animals so as to enable a thorough cleaning to be carried out after them before the next animals are slaughtered.
- The own-check plan related to the separation of animals delivered to the slaughterhouse is adequate and suitable to ensure that food safety risks are under control.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings as concerns the consideration of food chain information at the separation stage of the animals.
- There are some minor shortcomings as concerns the separation of the animals, and the slaughtering arrangements, but the animals are slaughtered separately, which ensures that food safety is not jeopardised.
- There are some minor shortcomings as concerns the own-check plan related to the separation of animals delivered to the slaughterhouse, but in practice activities have been appropriate.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- There are shortcomings as concerns the consideration of food chain information which impair food safety.
- The actions necessary due to sickness or suspected sickness, injury, faecal contamination, own-check activities of salmonella, EHEC and campylobacter are not adequately taken into consideration in the separation of animals and in the slaughtering arrangements, and this impairs food safety.
- There are shortcomings in the adequacy and suitability, and/or execution of the own-check plan which impair food safety.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- Food chain information is not taken into consideration in the separation of the animals, and in the slaughtering arrangements and food safety is jeopardised.
- The actions necessary due to sickness or suspected sickness, injury, faecal contamination, own-check activities of salmonella, EHEC and campylobacter are not adequately taken into consideration in the separation of animals and in the slaughtering arrangements, and this jeopardises food safety.
- There are shortcomings in the adequacy and suitability, and/or execution of the own-check plan which jeopardise food safety.
- The operator has failed to fulfil the orders issued with the grade To be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Implementing Regulation (EC) No 2074/2005
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on meat controls 590/2014
- Decree of the Ministry of Agriculture and Forestry on salmonella control at establishments in meat sector, 134/2012
- Decree of the Ministry of Agriculture and Forestry on campylobacter control of chickens, 10/EEO/2007
- Decree of the Ministry of Agriculture and Forestry on EHEC tests of bovine animals at slaughterhouse and location where animals are housed, 24/EEO/2006
- Evira's Guide 5001: Prevention of EHEC bacteria at bovine holdings and slaughterhouses
- Evira's Guide 16005: Submission and control of food chain information
- Evira's Guide 16027: Evira's Guide on the handling of wild game meat and supply of meat for sale 16027

10 Substances Causing Allergies or Intolerances

10.1 Separation and Cross-contamination

To be taken into consideration:

The separation and cross-contamination of the following substances causing allergies or intolerances are controlled in this point:

- cereals containing gluten, namely wheat, rye, barley, oats, and products thereof
- crustaceans and products thereof
- eggs and products thereof
- fish and products thereof
- peanuts and products thereof
- soybeans and products thereof
- milk and products thereof (excl. lactose)
- nuts and products thereof
- celery and products thereof
- mustard and products thereof
- sesame seeds and products thereof
- sulphur dioxide and sulphites
- lupin and products thereof
- molluscs and products thereof

This point is controlled, when

1. **The store or catering establishment**
   - prepares and/or sells unpackaged foodstuffs from a service counter
   - prepares and/or sells meals

   and the meals or unpackaged foodstuffs are indicated in writing or verbally to be suitable for a gluten-free or allergy diet in terms of the aforementioned allergens.

   Any shortcomings found concerning the presentation of unpackaged foods or meals available in self-service sale or self-service lines are recorded in the control report, but not in the Oiva report (not evaluated).

2. **Some other food establishment**
   - manufactures, has manufactured for it and/or packages foodstuffs

The product-specific controls of recipes and labelling on substances causing allergies or intolerances are carried out in point 13.1 General Labelling.

Matters to be controlled:

The implementation of own-check activities is evaluated by controlling the following matters:

- Practical arrangements and practical activities in use to verify gluten and allergen safety: the operator has identified the risks related to their own operations and has them under control; the foods do not contain any substances causing allergies or intolerances that are not included in the recipe, and no cross-contamination occurs. The objective of control is to obtain a total picture of the management of separation and cross-contamination.

- Attention is primarily focused on the work phase or activity of the highest risk-based importance, and on the substances causing allergies or intolerances that in the food establishment or premises concerned are in the key role in terms of the management of cross-contamination.

  Key work phases to be controlled include, for example:
  - procurement and reception of raw materials
  - marking, storage and handling or raw materials and intermediate products, as well as their routes and passage (e.g. storage containers and locations, marking of raw materials and intermediate products in a way that eliminates the risk of confusion)
  - manufacture and preparation of foodstuffs and meals, production processes, transport (e.g. work utensils, work facilities, equipment, work sequence, cleanliness)
  - packaging
  - presentation and sale (e.g. unpackaged foods are presented in a way that eliminates the risk of cross-contamination)

- Compliance with requirements can be verified:
  - through observing practical activities, interviewing the personnel
  - where necessary, through a review of the own-check plan
  - where necessary, on the basis of analysis certificates and/or own-check testing

 EXCELLENT	**Operations comply with requirements.** The separation of substances causing allergies or intolerances and the management of cross-contamination meet requirements.
 GOOD	**There are small issues with the operations which do not impair food safety or mislead consumers.** The separation of substances causing allergies or intolerances has been taken into consideration in the operations and the management of cross-contamination meets requirements in most parts. There are some minor shortcomings in the separation of substances causing allergies or intolerances, such as • minor shortcomings in instructions, practices and/or marking or storage of raw materials and/or intermediate products which make it impossible to verify the management of allergen safety in all respects, for example in abnormal conditions.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The separation of substances causing allergies or intolerances has been taken into consideration in the operations, but there are some essential shortcomings regarding separation which may result in the risk of cross-contamination, such as

- raw materials or foodstuffs containing substances causing allergies or intolerances are stored inadequately packaged, enclosed and/or marked
- inadequate separation in time or place between gluten-free and regular baking
- use of the same deep-frying fat for gluten-free and wheat-containing foods
- the adequacy of the cleaning activities of the production lines cannot be verified as concerns the allergens used and their state (e.g. powder/liquid)
- the presentation and arrangement of unpackaged foodstuffs may cause a risk of cross-contamination

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

There are issues in the separation of substances causing allergies or intolerances and management of cross-contamination which require immediate rectification or recall, such as

- the risk of cross-contamination by allergens or gluten has not been taken into consideration at all
- the food has probably been cross-contaminated by an allergen not included in the recipe
- the presentation and arrangement of unpackaged foodstuffs cause a significant risk of cross-contamination

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, 178/2002/EC
- Regulation of the European Parliament and of the Council on the hygiene of foodstuffs, 852/2004/EC
- Finnish Food Act 23/2006
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers
- Evira's Guide 17050/1. Nordic control project on allergen labelling.

Updates in version 3:
Sulphur dioxide and sulphites added in the point To be taken into consideration.

11 Composition of Foodstuffs

11.1 Additives, Flavourings and Enzymes

To be taken into consideration:

This point is evaluated when the operator manufactures, has manufactured for it or imports (from the internal market or third countries)

- additives, flavourings (incl. smoke flavourings), enzymes, mixtures thereof or premixtures containing these substances and ingredients,
- foodstuffs in which additives, flavourings (incl. smoke flavourings), enzymes, mixtures thereof or premixtures containing these substances and ingredients are/have been used.

Where control concerns foodstuffs which the operator manufactures, has manufactured for it or imports for marketing to consumers, it is recommended that point 13.1 General labelling is controlled at the same time, verifying that additives, flavourings and enzymes are appropriately included in the list of ingredients and the packaging bears any warning labelling that is needed.

The use of additives, flavourings and enzymes is not controlled in retail stores or catering establishments where only compound ingredients are used in the manufacture and preparation of foods. This point is to be evaluated if the retail store or catering establishment itself imports (from the internal market and/or third countries) foodstuffs manufactured using additives, flavourings or enzymes.

Since there is as of yet no list of enzymes approved for food use in the EU, as far as enzymes are concerned, control covers the compliance of enzyme mixtures with labelling requirements.

Matters to be controlled:

The implementation of own-check activities is evaluated by random checks (on e.g. 1-3 products, taking the scope and nature of operations into consideration) of compliance with requirements with respect to additives, flavourings and enzymes.

The following matters are to be controlled separately for each activity:

1. Use of additives, flavourings and enzymes, mixtures thereof or premixtures containing these substances and ingredients in the manufacture of foodstuffs:

- Additives and flavourings are authorised for use in the foodstuffs in which they are used and their maximum amounts specified for each food group are not exceeded
    - the operator is able to present recipe calculations, and where necessary, own-check tests that supplement them
- The labelling and purity criteria specified for additives, flavourings and enzymes are fulfilled
    - information (labelling and product specification or some other documentation) has been obtained from suppliers of improvement agents, or if this information is missing, information has been requested, which makes it possible to verify compliance and which can be used e.g. as a basis for recipe calculations. Risk management related to purity requirements can also be demonstrated on the basis of procurement contracts and/or audits of suppliers of improvement agents.

- where necessary, the operator who uses mixtures has supplemented the information received from the supplier by means of own-check tests.

2. Import of foodstuffs containing additives or flavourings (from the internal market or third countries):

- Additives and flavourings are permitted in the foodstuffs imported by the operator and their maximum amounts specified for each food group are not exceeded
  - the operator is able to demonstrate by means of records or documents (e.g. procurement contract, product specification, analysis certificate and/or supplier audit) that the foodstuffs comply with requirements in terms of additives and flavourings,
  - where necessary, the operator has supplemented information received from the supplier with own-check tests.

3. Operator manufactures additives, flavourings and enzymes, mixtures thereof or premixtures containing these substances and ingredients, or has them manufactured:

- The purity criteria specified for additives and flavourings as well as other specific criteria for raw materials, manufacture and composition are fulfilled
  - the operator is able to present information received from raw material suppliers (e.g. product specifications, analysis certificates, etc.), recipe calculations, and where necessary, own-check tests for the verification of compliance with requirements.
- Additive, flavouring and enzyme preparations only contain additives and carriers authorised for use in them and the specified maximum amounts are not exceeded.
  - the operator has performed the required recipe calculations, and where necessary, has supplemented them with own-check tests, or the operator is able to present some other documentation that proves compliance with requirements.
- The labelling requirements specified for additives, flavourings and enzymes as well as premixtures containing these substances and ingredients are met and labelling is consistent with recipe information.
  - all mandatory information can be found in labelling and associated documents,
  - the operator is able to present information received from raw material suppliers (e.g. product specifications, analysis certificates, etc.), recipe calculations, and where necessary, own-check tests for the verification of the consistency of the recipe and labelling.
- Additives and flavourings are authorised for use in the foodstuffs for the manufacture of which they are marketed.
- The additives, flavourings and enzymes as well as premixtures containing these substances and ingredients that are supplied to customers are accompanied with appropriate information (labelling and product specification or some other documentation) enabling the customer to verify compliance with composition and purity criteria and to perform recipe calculations and prepare labelling for the final product. Documentation related to purity criteria is not required to be provided separately with each batch.

4. Import of additives, flavourings, enzymes, mixtures thereof or premixtures containing these substances and ingredients (from the internal market or third countries):

- The labelling requirements and purity criteria specified for additives, flavourings and enzymes as well as other specific criteria for raw materials, manufacture and composition are fulfilled
  - the operator is able to present information (product specifications, labelling and associated documents, analysis certificates, etc.) obtained from the

manufacturer, or if this information is missing, the required information, which makes it possible to verify compliance with requirements,
    - where necessary, the importer has supplemented information received from the manufacturer with own-check tests.
- Additives and flavourings are authorised for use in the foodstuffs for the manufacture of which they are marketed.
- The additives, flavourings and enzymes as well as premixtures containing these substances and ingredients that are supplied to customers are accompanied with appropriate information (labelling and product specification or some other documentation) enabling the customer to verify compliance with composition and purity criteria and to perform recipe calculations and prepare labelling for the final product. Documentation related to purity criteria is not required to be provided separately with each batch.

EXCELLENT

Operations comply with requirements.

Operations that involve additives, flavourings and enzymes comply with the aforementioned requirements.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operation is mainly implemented in compliance with the aforementioned requirements. There are some minor shortcomings, **for example:**

1. In the use of additives, flavourings and enzymes, mixtures thereof or premixtures containing them and ingredients in the manufacture of foodstuffs
    - the operator is unable to present documented recipe calculations, but the inspector carrying out control can verify from the recipe by calculating that the content of the additive or flavouring does not exceed the permitted maximum amount in the foodstuff,
    - there are some minor shortcomings in the labelling of the additive, flavouring or enzyme, and in associated documents, but notwithstanding these, it is possible to perform the required recipe calculations or verify that the product is intended for food use.

2. In the import of foodstuffs containing additives or flavourings (from the internal market or third countries)
    - there are some minor shortcomings, inaccuracies or errors in the operator's documents, but notwithstanding these, it is possible to verify the compliance of the product with requirements.

3. In manufacturing additives, flavourings and enzymes, mixtures thereof or premixtures containing them or in having them manufactured
    - there are some minor shortcomings, inaccuracies or errors in recipes, own-check tests, purity criteria documents or labelling, and in associated documents, but notwithstanding these, it is possible to verify the compliance of the product with requirements.

4. In the import of additives, flavourings, enzymes, mixtures thereof or premixtures containing these substances and ingredients (from the internal market or third countries)
- there are some minor shortcomings, inaccuracies or errors in purity criteria documents or labelling, and in associated documents, but notwithstanding these, it is possible to verify the compliance of the product with requirements.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

Operations related to additives, flavourings and enzymes do not comply with the aforementioned requirements but show some essential shortcomings, **for example:**

1. In the use of additives, flavourings and enzymes, mixtures thereof or premixtures containing these substances and ingredients in the manufacture of foodstuffs
- an additive or flavouring is used in the manufacture of the foodstuff which is authorised for food use in the EU, but which is not authorised to be used in the foodstuff concerned,
- additives, flavourings or enzymes are not shown in the recipe
- the amount of the additive or flavouring in the foodstuff exceeds the maximum permitted amount in the foodstuff concerned. Where the limit is exceeded considerably (to be evaluated specifically in each case), a recall procedure shall be initiated and the grade will be POOR
- the composition of the additives or flavourings used in the manufacture of the foodstuffs cannot be verified, because of deficiencies in or complete lack of documentation, for example
  - there is no indication "for food use" or comparable information that would make it possible to verify that the additive, flavouring or enzyme is intended for food use,
  - there is no information on the amount of an additive or flavouring for which a content limit in food has been specified,
- the certificate of a smoke flavouring preparation is missing completely or is so deficient that the compliance of the preparation with requirements cannot be verified.

2. In the import of foodstuffs containing additives or flavourings (from the internal market or third countries)
- the information provided on an additive or flavouring for which a maximum content has been specified in legislation is deficient to the extent that it is completely impossible to verify compliance with requirements,
- an additive or flavouring is used in the foodstuff which is authorised for food use in the EU, but which is not authorised to be used in the foodstuff concerned,
- the amount of the additive or flavouring in the foodstuff exceeds the maximum permitted amount in the foodstuff concerned. Where the limit is exceeded considerably (to be evaluated specifically in each case), a recall procedure shall be initiated and the grade will be POOR.

3. & 4. In the manufacture or import of additives, flavourings, enzymes, mixtures

thereof or premixtures containing these substances and ingredients (from the internal market or third countries) or in having them manufactured

- an additive or flavouring which is authorised for use in the EU is marketed for use in a foodstuff in which its use is not authorised,
- the recipes of mixtures of additives, flavourings or enzymes and ingredients are deficient or missing completely (pertains to manufacturing and having manufactured),
- additives, flavourings or enzymes contain additives or carriers which are authorised in the EU, but not authorised for use in the additives, flavourings or enzymes concerned, however,
- the content of the additive or carrier in the additive, flavouring or carrier exceeds the permitted maximum amount. Where the limit is exceeded considerably (to be evaluated specifically in each case), a recall procedure shall be initiated and the grade will be POOR,
- there are no documents regarding compliance with the purity criteria specified for additives and flavourings as well as other specific criteria for raw materials, manufacture and composition, or the documents are deficient to the extent that compliance with requirements cannot be verified, for example
  - it cannot be verified that the amount of heavy metals does not exceed the permitted maximum amount,
- the labelling of additives, flavourings and enzymes or premixtures of these substances and ingredients, or the associated documents, are deficient to the extent that the operator who carries out further processing cannot verify that the foodstuffs manufactured by them comply with requirements, for example
  - there is no information on the amount of an additive or flavouring for which a content limit in food has been specified (e.g. the P_2O_5 content of phosphate or the coumarin content of cinnamon is not indicated),
  - there is no indication "for food use" or comparable information that would make it possible to verify that the additive, flavouring or enzyme is intended for food use.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

There are issues in the operations that require immediate rectification and/or recall, **for example**

1. In the use of additives, flavourings and enzymes, mixtures thereof or premixtures containing these substances and ingredients in the manufacture of foodstuffs

- an additive or flavouring is used that has not been authorised for food use in the EU,
- the maximum amount specified for an additive or flavouring authorised for food use is exceeded considerably (to be evaluated specifically in each case).

2. In the import of foodstuffs containing additives, flavourings or enzymes (from the internal market or third countries)

- an additive or flavouring is used in the foodstuff that has not been authorised

for food use in the EU,
- the maximum amount specified for an additive or flavouring authorised for food use is exceeded considerably (to be evaluated specifically in each case).

3. & 4. In the manufacture or import of additives, flavourings, enzymes, mixtures thereof or premixtures containing these substances and ingredients (from the internal market or third countries) or in having them manufactured
- an additive or flavouring not authorised in the EU is marketed for use in the manufacture of foodstuffs,
- additives, flavourings or enzymes contain additives or carriers not authorised in the EU,
- additives, flavourings or enzymes contain authorised additives or carriers, but the maximum content is exceeded considerably (to be evaluated specifically in each case).

Legislation and guidelines (with any amendments) pertaining to the subject:
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives,
- Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council,
- Commission Regulation (EC) No 889/2009 on organic production (additives in organic products),
- Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods,
- Commission Implementing Regulation (EU) No 1321/2013 establishing the Union list of authorised some flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings,
- Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes,
- Evira's Guide 17054: Guide on control of food improvement agents.

11 Composition of Foodstuffs

11.2 Nutritional Fortification

To be taken into consideration:

This point is controlled, when the operator

- manufactures or has manufactured for it
- imports (from the internal market and/or third countries, including agency business) fortified food products within the meaning of Fortification Regulation EC No 1925/2006.

It is recommended that the following points be controlled at the same time

- 13.1 General Labelling and
- 13.2 Nutrition Labelling
  to verify the compliance of also other labelling with requirements.

This point is only controlled in retail stores and catering establishments if the retail store or catering establishment itself manufactures, has manufactured for it and/or imports (from the internal market and/or third countries) fortified foodstuffs.

Matters to be controlled:

The implementation of own-check activities is evaluated by random checks (on e.g. 1-3 products, taking the scope and nature of operations into consideration) of the following matters:

- the vitamins, minerals and their compounds used for the fortification of a food product are authorised;
- the compounds of vitamins and minerals used for the fortification of food products meet the purity criteria set out for them (applies to manufacturing and having manufactured)
- the content of the added vitamin or mineral is significant in the final product (15% of the daily reference intake for solids and 7.5 % of the daily reference intake for liquids);
- the amount of the added substances does not cause a health hazard;
- added vitamins and minerals are appropriately indicated in nutrition labelling;
- a notification has been submitted to Evira about the placing on the market of a food product fortified with a vitamin or a mineral.

Compliance with requirements can be verified by means of, for example:

- inspections of labelling, recipes and documents
- where necessary, analysis certificates and/or own-check tests.

EXCELLENT

Operations comply with requirements.

Nutritional fortification and the labelling of fortified foods comply with the aforementioned requirements.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Nutritional fortification and the labelling of fortified foods comply in main parts with the aforementioned requirements. There are some minor shortcomings, such as:

- there are some minor shortcomings in labelling or documents, but notwithstanding these, it is possible to verify the compliance of the product with requirements.
- notifications to Evira have only been submitted on part of the food products fortified with a vitamin or mineral that are to be placed on the market.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are some essential shortcomings in fortification and the labelling of fortified foods, such as:

- it is not possible to verify that the vitamin or mineral compound used is authorised, because documentation is deficient or completely missing.
- the amount of the added vitamin or mineral is not indicated in labelling
- the added vitamin or mineral is not present in the food product in a significant amount
- the amount of vitamin, mineral or some other substance indicated in the recipe is not consistent with the amount used in production
- notifications have not been submitted to Evira about the food products fortified with a vitamin or mineral that are to be placed on the market.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

There are defects requiring immediate rectification and/or recall as concerns nutritional fortification, for example:

- use of unauthorised vitamins, minerals or their compounds for fortification of food
- the content of the added vitamin, mineral or some other substance is so high in the food product that it endangers the safety of the consumer (to be evaluated specifically in each case).

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods
- Commission Regulation (EC) No 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) N0 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements
- Decree (726/2007) of the Ministry of Trade and Industry on the national measures required by the entry into force of Regulation (EC) No. 19025/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers
- Finnish Food Act 23/2006 Section 8
- Commission Guidance (December 2012): Guidance document for competent authorities with regard to setting of tolerances for nutrient values declared on a label, and on the control of compliance with them http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/guidance_tolerances_december_2012_fi.pdf
- Evira's Guide 17059/1. Guide for control of nutritional fortification

11 Composition of Foodstuffs

11.3 Genetically Modified Ingredients

To be taken into consideration:

This Guideline is not applied to retail stores or catering establishments, unless they also act as importers (from the internal market or third countries). Also, the Guideline is not applied if the operator does not use any foodstuffs that might be genetically modified (e.g. soy, maize, rapeseed, rice, or papaya).

This point is controlled, when

- the operator manufactures, has manufactured for it or imports (from the internal market or third countries) food products which are or contain genetically modifies organisms or ingredients made of genetically modified organisms.
- the operator manufactures, has manufactured for it or imports (from the internal market or third countries) food products which with high probability may be or contain genetically modified organisms or ingredients made of genetically modified organisms. Such high-risk foodstuffs include plants that are widely farmed in the world as genetically modified varieties, i.e., for example, soy or maize from the USA, rapeseed from Canada, rice from China, or papaya from the USA.
- the operator uses on its products the voluntary "gmo free" or comparable marketing claim.

Matters to be controlled:

The implementation of own-check activities is evaluated by controlling the following matters:

- The operator has ensured (based on e.g. a batch-specific agreement or an analysis certificate) that any high-risk foodstuffs that might contain a genetically modified substance (e.g. soy, maize, rapeseed, rice or papaya) comply with the order, i.e., they either are or are not genetically modified.
- The operator is able to demonstrate by means of documents and/or analyses (in the operator's own-check activities or on behalf of the supplier of the foodstuff/ingredient) that the food products only contain genetically modified organisms authorised in the EU for food use.
    - The use of genetically modified organisms not authorised in the EU is prohibited.
- Labelling regarding genetic modification complies with legislation.
    - It shall be indicated in the list of ingredients or elsewhere in labelling if the foodstuff is genetically modified or an ingredient of the foodstuff contains more than 0.9 % of a GM substance.
- The traceability requirements laid down in legislation on genetically modified organisms and food are met (e.g. indication of genetic modification and a unique identifier, 5-year filing obligation for documents).
- The voluntary "gmo free" or comparable marketing claim used on the products are not misleading to the consumer.

EXCELLENT

Operations comply with requirements.

The operator has in their own-check activities identified and assessed requirements related to any GM foods and is able to demonstrate by means of documents (e.g. appropriate procurement contracts, product specifications, analysis certificates and/or audits) that the management of critical points is under control.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The management of any GM foods complies in main parts with the aforementioned requirements. There are some minor shortcomings, such as:

- documents related to high-risk foodstuffs possibly containing a genetically modified substance show some minor shortcomings, inaccuracies or errors, but notwithstanding these, it is possible to verify that the management of critical points is under control.
- GM foods or ingredients authorised in the EU are indicated, but labelling does not fulfil exactly the conditions laid down in legislation
- there are some minor shortcomings or errors in traceability documents on genetically modified organisms or food, but notwithstanding these, they can be traced
- documents or analysis certificates related to "gmo free" products show some minor shortcomings, inaccuracies or errors, but notwithstanding these, it is possible to verify that the "gmo free" or comparable marketing claims used by the operator are not misleading to the consumer.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are some clear shortcomings in the management of documents related to any GM foods or ingredients, or in the labelling of such foodstuffs or ingredients. Such issues include, for example:

- no documentation can be presented regarding the genetic modification, or non-modification, of high-risk foods possibly containing a GM substance
- GM foods or ingredients authorised in the EU that have been used are not indicated in labelling
- there are no traceability documents on genetically modified organisms or foods, or the documents contain essential shortcomings or errors, and the traceability of the products cannot be verified
- documents or analysis certificates related to "gmo free" products are missing or they contain some essential shortcomings or errors, which makes it impossible to verify that marketing claims are not misleading to the consumer.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Risks related to any GM foods are not under control. Such shortcomings requiring immediate rectification or recall include:

- an analysis has shown the foodstuff to contain a GM substance unauthorised in the EU; but the operator has failed to take corrective actions
- no documentation can be presented regarding the genetic modification, or non-modification, of high-risk foodstuffs possibly containing a GM substance, and the operator has failed to take corrective action despite being requested or ordered to do so
- GM foods or ingredients authorised in the EU that have been used are not indicated in labelling despite a request or order to do so
- the operator is unable to present traceability documents on genetically modified organisms or foods, despite a request or order to do so
- the "gmo free" or comparable marketing claim used by the operator is misleading to the consumer, and the operator has failed to take corrective actions despite being requested or ordered to do so.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed
- Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms (GMOs) and the traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC
- Evira's Guideline 17071/3: Control guideline for genetically modified food
- Evira's Guideline 10017/3: Use of voluntary "gmo free" marketing claim on food and feed
- Evira's Guideline 10019/2: Guideline on withdrawal of unauthorised genetically modified food and feed

Updates in version 2:

- Numbers of Guidelines updated
- More specific instructions provided for when the Guideline is not to be applied
- Examples of high-risk foodstuffs added
- First point added in "Matters to be controlled"

11 Composition of Foodstuffs

11.4 Novel Foods and New Processes

To be taken into consideration:

This point is only controlled, when

- The operator manufactures, has manufactured for it, imports (from the internal market of third countries) or markets foods or ingredients of foods not widely known for their use as food. Such foods or ingredients of foods include:
  - wild plants with no generally known use as food
  - exotic plants from non-EU countries (particularly in food supplements)
  - insects
  - new extracts made from a food of animal origin or a plant
  - new synthetic ingredients of foods.
- The operator uses some other than a generally used production method/process and this method gives rise to significant changes in the composition or structure of the foods or ingredients of foods in terms of the nutritional value, metabolism or levels of undesired substances. Such production methods/processes can include:
  - nanotechnology
  - pasteurisation methods not based on heating (e.g. high-pressure pasteurisation).

Matters to be controlled:

The implementation of own-check activities is evaluated by checking the following matters:

- The operator knows the novel food status of the foods, ingredients of foods and processes they use, i.e. whether the food has an established history of food use to a significant degree in the area of the EU prior to 1997, or whether the new process gives rise to any significant changes in the structure or composition of the final product.

- No foods or ingredients of foods and/or processes considered to be unauthorised foods are used, i.e. the novel foods and/or new process used have been authorised in the EU or a notification has been submitted to the Commission regarding them, where necessary.

EXCELLENT

Operations comply with requirements.

The operator has in own-check activities identified and assessed requirements related to any novel foods and/or new processes and is able to demonstrate by means of records or documents that the management of critical points is under control.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The management of novel foods and/or new processes complies in main parts with the aforementioned requirements. However, there are some minor shortcomings, inaccuracies or errors in documents, but withstanding these, it is possible to verify the novel food status or authorisation status of the foodstuff, ingredient of food or process.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are some clear shortcomings in the management of requirements related to novel foods and/or new processes. Such shortcomings include:

- a comparable novel food or new process of another operator has been authorised in the EU, but the required notification of the product in concern has not been submitted to the Commission
- it is to be suspected that the foodstuff, ingredient of food or process used by the operator is considered an unauthorised novel food, but the operator has failed to verify its novel food status.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Risks related to novel foods and/or new processes are not under control. Such shortcomings requiring immediate rectification or recall include:

- foodstuffs, ingredients of foods and/or processes considered to be novel foods are used, but the safety assessment required by the Novel Food Regulation has not been carried out on them
- the required notification about the product has not been submitted to the Commission despite a request or order to do so
- it is to be suspected that the foodstuff, ingredient of food or process used by the operator is considered an unauthorised novel food, but the operator has failed to verify its novel food status despite a request or order to do so.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients
- Evira's Guide 17020/5 for the recall of unauthorised novel foods
- Novel food catalogue of the Commission http://ec.europa.eu/food/food/biotechnology/novelfood/novel_food_catalogue_en.htm

12 Special Requirements for Specific Food Products

12.1 Food Supplements

To be taken into consideration:

This point is controlled, when the operator

- manufactures or has manufactured for it
- imports or brokers (from the internal market or third countries) food supplements within the meaning of Food Supplement Regulation 78/2010.

It is recommended that the following points be controlled at the same time

- 13.1. General Labelling and
- 13.3. Marketing,
  to verify the compliance of also other labelling with requirements.

This point is only controlled in retail stores (incl. distance selling) and catering establishments if the retail store or catering establishment itself manufactures, has manufactured for it or imports (from the internal market and/or third countries) food supplements.

Matters to be controlled:

The implementation of own-check activities is evaluated (by random checks on e.g. 1-3 products, taking the scope and nature of operations into consideration) by checking the compliance with the requirements as regards food supplements:

- the food supplement meets the criteria set out in the definition of a food supplement,
- the food supplement is not a medicinal product and does not contain hormones or doping substances,
- the composition of the food supplement with respect to characteristic substances and their amounts is consistent with the labelling information,
- the food supplement only contains authorised vitamins and minerals and their compounds,
- the compounds of vitamins and/or minerals used in the product meet the purity criteria set out for them (applies to operators who manufacture food supplements or have them manufactured),
- the amount of vitamin and/or mineral that is the characteristic substance of the food supplement is significant (at least 15% of the daily reference intake in the recommended daily dose) in the final product,
- the characteristic substance or the amount of the substance does not present a hazard to health,
- the amounts of characteristic substances are appropriately indicated,
- the labelling of the food supplements provides the mandatory information referred to in the Decree on Food Supplements,
- a notification has been submitted to Evira on the food supplement.

Compliance with requirements can be verified by means of, for example:

- inspections of labelling, recipes and documents,
- where necessary, analysis certificates and/or own-check tests.

EXCELLENT

Operations comply with requirements.

The operator has verified that food supplements meet the aforementioned criteria.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The operator has verified in main parts that food supplements meet the aforementioned criteria. There are some minor shortcomings, such as:

- there are some minor shortcomings in labelling or documents, but notwithstanding these, the compliance of the product with requirements can be verified (e.g. the names of the categories of nutrients or substances that characterise the product are not provided or there is no mention of the nature of those nutrients or substances),
- notifications have only been submitted to Evira on part of food supplements to be placed on the market.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are shortcomings in the operator's own-check activities resulting in the non-compliance of food supplements with the aforementioned requirements. Essential shortcomings include:

- the food supplement does not meet the criteria set out in the definition of a food supplement (for example, a conventional foodstuff or medicine is placed on the market as a food supplement),
- it is not possible to verify the category of the product (food supplement/medicine) because of deficient or completely missing documentation,
- the vitamin or mineral which is the characteristic substance in the food supplement is not present in a significant amount in the final product,
- some of the mandatory labelling referred to in the Decree on Food Supplements is missing completely (for example, the amount of characteristic substances is not indicated in labelling),
- notifications have not been submitted to Evira on food supplements to be placed on the market.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The operator has failed to verify that food supplements meet the aforementioned requirements. Shortcomings requiring immediate rectification or recall include:

- the characteristic substances (vitamins, minerals or their compounds, or other substances) contained in the food supplement are not permitted (for example, the food supplement contains hormones, doping substances or harmful substances),
- the amount of the added vitamin, mineral or some other characteristic substance is so large in the daily dose of the food supplement that it causes a health hazard to the consumer (for example, UL values are exceeded with respect to some vitamins and minerals, to be evaluated specifically in each case).

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, Annex XIII (daily reference intakes)
- Criminal Code of Finland 1889/39, Chapter 44, Sections 6 and 16 (doping offence and definition of a doping substance)
- Finnish Food Act 23/2006, Section 8 (notification obligation)
- Finnish Narcotics Act 373/2008
- Government Decree on psychoactive substances prohibited on the consumer market 1130/2014
- Government Decree 705/2002 on doping substances as referred to in Chapter 44, Section 16 (1) of the Criminal Code
- Decree 78/2010 of the Ministry of Agriculture and Forestry on food supplements
- Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements (latest consolidated version) (permitted sources of nutrients)
- Decision 201/2016 of the Finnish Medicines Agency on medicinal products list
- Evira's Guide 17012/5: Food Supplement Guide
- Commission Guidance (December 2012): Guidance document for competent authorities with regard to setting of tolerances for nutrient values declared on a label, and on the control of compliance with them http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/guidance_tolerances_december_2012_fi.pdf

Updates in version 3

- The list of legislation has been updated, and *Commission Regulation (EC) No 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) N0 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements* has been removed and *Regulation 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements* (consolidated version) has been added.

12 Special Requirements for Specific Food Products

12.2 Foods for Specific Groups

To be taken into consideration:

This point is evaluated when the operator manufactures, has manufactured for it or imports (from the internal market or third countries) foods for specific groups within the meaning of Regulation (EU) No 609/2013:

1. Infant formulae and follow-on formulae
2. Baby foods
3. Foods for special medical purposes
4. Total diet replacements for weight control

Compliance with requirements can be verified by means of

- inspections of labelling, recipes and documents, for example
- where necessary, analysis certificates and/or own-check tests.

It is recommended that the following points be controlled at the same time

- 13.1. General Labelling and
- 13.3. Marketing (excl. infant formulae which are controlled in this Guideline also with respect to marketing), to verify the compliance of also other labelling with requirements.

This point is only controlled in retail stores and catering establishments if the retail store or catering establishment itself manufactures, has manufactured for it and/or imports (from the internal market and/or third countries) foods for specific groups.

Matters to be controlled:

The implementation of own-check activities is evaluated by random checks (on e.g. 1-3 products, taking the scope and nature of operations into consideration) of the following matters separately in each group:

1. Infant formulae and follow on formulae:

- The criteria specified for the composition and purity of infant formulae and follow-on formulae are met:
  - the formula is ready for use as such or nothing more is required than the addition of water
  - the formula does not contain any substance in such a quantity as to endanger the health of infants and young children
  - the criteria specified for the composition of the formulae are met (energy, protein, fatty acids, carbohydrates, vitamins, minerals and other substances)
  - approved sources of protein are used in the manufacture of the formula
  - the vitamins, minerals and certain other nutrients and their chemical compounds used in the manufacture of the formula are approved
  - the chemical compounds of the vitamins, minerals and certain other nutrients used in the manufacture of the formula meet the purity criteria specified for them (concerns manufacturing and having manufactured)

    - Guidelines 17.12-17.16 are to be controlled at the same time to verify that the infant formula or follow-on formula does not contain any contaminants or residues of plant protection products in amounts exceeding the maximum approved amounts
- Labelling requirements are met, not only with respect to general labelling but also as concerns labelling requirements specified for infant formulae and follow-on formulae (the requirements apply in part also to presentation and advertising):
    - the formula is sold as a prepacked product under the name infant formula or follow-on formula (preceded by "milk-based", as necessary)
    - labelling contains the age recommendation for infant formula and follow-on formula as well as any other mandatory statements
    - nutrition labelling meets requirements and is consistent with the composition of the formula
    - labelling does not include text or information prohibited on infant formula and follow-on formula
    - only specifically authorised nutrition and health claims are used in the labelling of infant formula
- Infant formula may not be marketed to consumers and no promotional devices targeted at consumers may be used; instead, any advertising is to be restricted to publications specialising in baby care intended for health care professionals, as well as scientific publications. Advertising material may only contain information of a scientific and factual nature.
- A notification has been submitted to Finnish Food Safety Authority Evira about placing on the market of an infant formula.

2. Baby foods
- The criteria specified for the composition and purity of cereal-based and other baby foods are met:
    - the baby food does not contain any substance in such a quantity as to endanger the health of children
    - the criteria specified for the composition of cereal-based baby foods in each group are met
    - the criteria specified for the composition of other baby foods are met
    - the vitamins, minerals and certain other nutrients and their chemical compounds used in the manufacture of the baby food are approved
    - the chemical compounds of the vitamins, minerals and certain other nutrients used in the manufacture of the baby food meet the purity criteria specified for them (concerns manufacturing and having manufactured)
    - Guidelines 17.12-17.16 are to be controlled at the same time to verify that the baby food does not contain any contaminants or residues of plant protection products in amounts exceeding the maximum approved amounts
- Labelling requirements are met, not only with respect to general labelling but also as concerns labelling requirements specified for baby food:
    - labelling contains the age recommendation for baby food as well as any other mandatory statements and any specific additional labelling, where appropriate
    - nutrition labelling meets requirements and is consistent with the composition of the formula

3. Foods for special medical purposes
- The product meets the definition of a food for special medical purposes
- The criteria specified for the composition and purity of foods for special medical purposes are met

  - the composition and quality of the product ensure that it satisfies the special medical needs of the patient
  - nutritionally complete food for special medical purposes meets the specific composition criteria specified for it
  - the vitamins, minerals and certain other nutrients and their chemical compounds used in the manufacture of the product are approved
  - the chemical compounds of the vitamins, minerals and certain other nutrients used in the manufacture of the product meet the purity criteria specified for them (concerns manufacturing and having manufactured)
- Labelling requirements are met, not only with respect to general labelling but also as concerns labelling requirements specified for foods for special medical purposes
  - the product is sold as prepacked food under the name " food for special medical purposes"
  - nutrition labelling meets requirements and is consistent with the composition of the formula
  - labelling contains the mandatory additional labelling specified for food for special medical purposes, and any specific additional labelling, where appropriate
  - labelling contains an indication of the illness, disorder or medical condition for the treatment of which the product is intended, expressed in the form "For the dietary management of . . ." Marketing is in all other respects to be controlled in accordance with Guideline 13.3 Marketing (nutrition and health claims)
- A notification has been submitted to Finnish Food Safety Authority Evira on a food for special medical purposes placed on the market in Finland for the first time, if the product
  - is manufactured in Finland, or
  - is imported from outside the European Economic Area and has not previously been marketed in any other EU state

4. Total diet replacements for weight control
   - The product meets the definition of a total diet replacement for weight control
   - The criteria specified for the composition and purity of total diet replacements for weight control are met
     - the composition and quality of the product make it suitable for use as the sole source of nourishment for purposes of weight control
     - a low-calorie diet product (LCD) meets the specific criteria for composition specified for these products
     - the vitamins, minerals and certain other nutrients and their chemical compounds used in the manufacture of the product are approved
     - the chemical compounds of the vitamins, minerals and certain other nutrients used in the manufacture of the product meet the purity criteria specified for them (concerns manufacturing and having manufactured)
   - Labelling requirements are met, not only with respect to general labelling but also as concerns labelling requirements specified for total diet replacements for weight control
     - nutrition labelling meets requirements and is consistent with the composition of the product
     - a low-calorie diet product (LCD) is marketed as a prepacked product under the name total diet replacement for weight control
     - the labelling of a low-calorie diet product contains the mandatory additional labelling specified for total diet replacements

EXCELLENT

Operations comply with requirements.

The composition and labelling of foods for specific groups meet the aforementioned requirements.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The composition and labelling of foods for specific groups meet the aforementioned requirement in main parts. There are some minor shortcomings, such as:

- there are some minor shortcomings in labelling or documents, but notwithstanding these, it is possible to verify the compliance of the product with requirements.
- notifications have only been submitted to Evira on part of products to be placed on the market.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The composition and labelling of foods for specific groups uses do not meet the aforementioned requirements but there are essential shortcomings in them, such as:

- nutrition labelling is deficient, unclear or difficult to read
- the amount indicated in the recipe or labelling is not consistent with the amount used in production
- it cannot be verified that the chemical compounds of the vitamins, minerals and certain other nutrients used in the manufacture of the product are approved and meet the purity criteria specified for them, because of shortcomings in documentation
- notifications have not been submitted to Evira on products to be placed on the market.
- the labelling of an infant formula does not bear a statement concerning the superiority of breast feeding, or some other mandatory statement
- pictures, statements or nutrition and health claims that have not specifically been authorised are used in the labelling of an infant formula
- a baby food, food for special medical purposes or total diet replacement for weight control does not meet the composition criteria specified for it
- the labelling of a food for special medical purposes does not state that the product must be used under supervision of a health care professional

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

There are issues requiring immediate rectification, and where necessary, recall in the composition and labelling of foods for specific groups, such as

- the product contains some substance in an amount that causes a health hazard to the consumer (not enough/too much)
- an infant formula, follow-on formula or food for special medical purposes intended for infants does not meet the composition criteria specified for it
- a baby food, food for special medical purposes or total diet replacement for weight control deviates significantly from the composition criteria specified for it
- the vitamins, minerals, certain other nutrients and their chemical compounds used in the manufacture of the product are not approved in the product group concerned or do not meet the purity criteria specified for them
- nutrition labelling is missing completely
- as regards infant formulae and follow-on formulae
  - the name is not right, or is missing completely
  - labelling does not provide instructions for preparation, use, storage and disposal, and a warning against the health hazards of inappropriate preparation and storage
- the labelling of a food for special medical purposes does not contain
  - an indication of the disease, disorder or medical condition for the treatment of which the product is intended
  - where appropriate, an indication of whether the product is suitable for use as the sole source of nourishment
  - where appropriate, an indication that the product is intended for a specific age group
  - where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.
  - where appropriate, a statement concerning adequate precautions and contra-indications
  - where appropriate, a warning that the product is not for parenteral use
  - where appropriate, instructions for the appropriate preparation, use and storage of the product after the opening of the container.
- the labelling of a total diet replacement for weight control does not provide the required instructions for preparation and use

Legislation and guidelines (with any amendments) pertaining to the subject:

- Commission Regulation (EC) No 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses
- Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control
- Decree KTM 1216/2007 of the Ministry of Trade and Industry on infant formulae and follow-on formulae

- Decree of the Ministry of Social Affairs and Health on information material regarding the feeding of infants and young children 267/2010
- Decree 406/2000 of the Ministry of Trade and Industry on dietary foods for special medical purposes
- Decision 1997/789 of the Ministry of Trade and Industry on baby foods
- Decision 904/1997 of the Ministry of Trade and Industry on weight loss products

Updates in version 2

- More specific examples given under To be corrected, and Poor

Updates in version 3

- Decree 121/2010 of the Ministry of Agriculture and Forestry on foods for particular nutritional uses has been repealed on 20 July 20916. References to Decree 121/2010 and to dietetic products have been removed from the Guideline.
- The Finnish term for foods for special medical purposes has been updated in compliance with Regulation (EU) No 609/2013.
- The notification obligation related to VLCD products has been removed.

12 Special Requirements for Specific Food Products

12.3 Foodstuffs with Protected Status

To be taken into consideration:

This point is controlled, when the operator

- manufactures, has manufactured for it and/or packages
- imports and/or brokers (from the internal market and/or third countries) or exports
- sells by distance selling as packaged
- sells in a store as unpackaged
- sells/serves in a facility of a mass caterer as unpackaged

Food products with a protected status according to EU's scheme for protection of names, or food products with an ingredient with a protected status indicated in the labelling.

The scheme for protection of names comprises three groups: protected designation of origin, protected geographical indication and traditional speciality guaranteed. The requirements that apply to them are slightly different, which shall be taken into consideration in control.

The use of the logo indicating the protected status is mandatory in the labelling and marketing of food products placed on the market after 4 January 2016, and this shall be taken into consideration in control.

The operator shall submit a notification indicating the name and the manufacturing location of the protected product to the competent food control authority before the introduction of the product on the market. For products with a protected name that were already on the market at the beginning of the year 2015 this notification had to be submitted by the end of 2015.

Food products that do not have a protected status may not be marketed using expressions referring to a food product with a protected status using expressions such as "style", "produced like", "manufactured like", etc. This needs to be taken into consideration if point 13.1 General Labelling is controlled at the same time.

Matters to be controlled:

The conditions on which the name of the food product is registered are met as concerns manufacture and packaging. Control is based on a comparison of the ingredients and processes used with the approved product specification of the food product concerned.

The EU symbol (logo) indicating the protected status is presented in the labelling, and the symbol is correct in shape, size and colours.

The labelling requirements related to protected names are met in a case where a protected product is used as an ingredient in another product.

EXCELLENT

Operations comply with requirements.

The product with a protected status is manufactured and packaged in compliance with the product specification registered for the product. Labelling indicates clearly both the registered name of the food product and the correct symbol of the protection scheme.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The product with a protected status is manufactured and packaged in compliance with the product specification registered for the product. Labelling indicates both the registered name of the food product and the correct symbol of the protection scheme. There are some minor shortcomings in labelling, such as

- the symbol is too small (under 15 mm, or under 10 mm on small packages)
- a clearly incorrect tone of colour on the symbol
- an error in the voluntary text statement. (In addition to the symbol, labelling may contain the indication "protected designation of origin", "protected geographical indication" or "traditional speciality guaranteed", or the corresponding abbreviations "PDO", "PGI", or "TSG". Corresponding indications in the language of the country of production are also permitted.)

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The food product is not manufactured or packaged in compliance with the product specification. For example

- butter which is a required ingredient is replaced with vegetable oil
- flakes not indicated in the specification are used in addition to flour
- the manufacturing method differs slightly from the one described in the product specification (baking time, temperature, manufacturing conditions, etc.).
- the colouring of the symbol indicating the protected status is incorrect, or the symbol is missing completely
- when a food product with a protected status is used as an *ingredient* in another product and this is indicated in marketing or labelling, the protected status is used slightly wrong, for example
  - another ingredient of a similar type as the ingredient with a protected status is used (Kitkan viisas vendace caught in the lakes of the Koillismaa highlands/vendace caught somewhere else, or Lapin Puikula potato from Lapland/some other potato)
  - the amount of the ingredient with a protected status is so small that the characteristics of the product are not essentially due to it

- the marketing of the food product creates the impression that the product has a protected status

The operator has not submitted the notification referred to in Section 54 e of the Finnish Food Act prior to placing a product with a protected status on the market, or notified about the suspension or discontinuation of the manufacture of the product.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The food product deviates considerably from the product specification in terms of manufacture or packaging. For example

- the raw material used in a food product benefiting from the PDO designation comes from outside the area indicated in the specification, or production or packaging takes place outside the area indicated in the specification
- the significant production stage recorded in the specification of a food product benefiting from the PGI designation does not take place in the area indicated in the specification
- the recipe or the manufacturing method differs essentially from the one described in the specification
- the marketing or labelling of a food product indicates a food product with a protected status as an ingredient, although it is not.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation of the European Parliament and of the Council (EC) No 1151/2012
- Commission Communication – Guidelines on the labelling of foodstuffs using protected designations of origin (PDOs) or protected geographical indications (PGIs) as ingredients (2010/C 341/03)
- Finnish Food Act 23/2006, Sections 9, 54 d and 54 e:
- Decree 1153/2014 of the Ministry of Agriculture and Forestry on the registration of products with a protected name and on the notification of the manufacture of a registered name-protected product:
- Commission Implementing Regulation (EU) No 668/2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs:
- Evira's Guide 17049/2: Guide for control of protection of names for foodstuffs
- DOOR database of the European Commission: http://ec.europa.eu/agriculture/quality/door/list.html;jsessionid=pL0hLqqLXhNmFQyFl1b24mY3t9dJQPflg3xbL2YphGT4k6zdWn34!-370879141 (link provided also on Evira's website: www.evira.fi/Elintarvikkeet/Valmistus ja myynti/Elintarvikkeista annettavat tiedot/Pakkausmerkinnät/EU:n nimisuojajärjestelmä (List of registered products).

Updates in version 2:

- A mention of prior notification added in the point To be taken into consideration
- The operator's notifications regarding prior notification of placing a product on the market, suspension and discontinuation of manufacture added as grounds for evaluation under To be corrected.

Updates in version 3:

- The demand of logo in marketing material has been removed

12 Special Requirements for Specific Food Products

12.4. Other Product-specific Requirements (Composition and Labelling of Berry and Fruit Preparations)

To be taken into consideration:

This point is to be controlled when general labelling is provided for mass caterers and end consumers in compliance with the Food Information Regulation (No. 1169/2011), as well as in cases where the operator

- manufactures, has manufactured for it or packages
- imports or brokers (from the internal market or third countries) the following food products packaged:
    - jams, jellies and marmalades
    - juices and similar preparations.

It is recommended that points 13.1 General Labelling and 13.2 Nutrition Labelling are controlled at the same time.

Matters to be controlled:

The implementation of own-check activities is evaluated by random checks, on e.g. 1-3 different packages, taking the scope and nature of operations into consideration:

Control of the compliance of product-specific labelling with requirements, i.e. is the correct information provided in labelling/label:

- product name
- composition
- other labelling referred to in specific labelling.

Compliance with requirements can be verified by means of, for example:

- inspections of labelling, recipes and documents
- where necessary, analysis certificates and/or own-check tests.

EXCELLENT

Operations comply with requirements.

The composition and labelling of berry and fruit preparations comply with the requirements laid down in legislation.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The composition of berry and fruit preparations and the labelling referred to in specific legislation comply in main parts with the requirements laid down in legislation. There are some minor shortcomings in labelling, such as:

- there are some minor shortcomings in labelling, but notwithstanding these, it is possible to verify the compliance of the product with requirements
- the name of the food product is not exactly compliant with legislation

- no instructions are provided for the dilution of a fruit or vegetable juice (for juices designed to be diluted for consumption)

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are some essential defects or deficiencies in labelling, such as:
- recipes are outdated or not in use
- a misleading name
- the berry content of a jam is missing or is incorrect
- the total sugar content indication for a jam is missing or is incorrect
- the indication "made with concentrate" or "partially made with concentrate" (if appropriate) is missing for a juice
- sugar has been added in a fruit juice in violation of legislation
- there is no indication of the juice content of a juice

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Labelling is missing completely or there are defects that require immediate rectification or withdrawal, such as:
- counterfeit products

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; Articles 17 - 19
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers
- Council Directive relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption (2001/113/EC)
- Council Directive relating to fruit juices and certain similar products intended for human consumption (2001/112/EC)
- Finnish Food Act 23/2006, Sections 1, 2 and 9
- Decree (474/2003) of the Ministry of Trade and Industry on fruit jams, jellies, marmalades and certain similar products, Sections 3, 5 and 6, and Annexes 1-3,
- Decree (662/2013) of the Ministry of Agriculture and Forestry on fruit juices and certain similar products, Sections 3, 6 and 7, and Annexes 1-3
- Decree (264/2012) of the Ministry of Agriculture and Forestry on requirements laid down for certain food products, Sections 8 and 9
- Evira's Guide 17021/3. Composition and labelling of fruit jams, jellies and marmalades – guide for control authorities and operators
- Evira's Guide 17072/2. Composition and labelling of fruit and vegetable juices and certain similar products – guide for control authorities and operators
- Evira's Guide 17068/1. Food Information Guide for food control authorities and food sector operators
- Evira's Guide 17055/1. Guide for control of labelling

Updates in version 2:

- Evira's previous Guide (17021/2 part 1 and part 2) relating to the composition and labelling of berry and fruit preparations has been replaced with updated Guides 17021/3 (jams, jellies and marmalades) and 17072/2 (juices and other similar products).

13 Information Provided on Foods

13.1 General labelling

To be taken into consideration:

This point is to be controlled when general labelling is provided for mass caterers and end consumers in compliance with the Food Information Regulation (No. 1169/2011, Degree 834/2014 of the ministry of Agriculture and Forestry), as well as in cases where the operator

- manufactures, has manufactured for it and/or packages food products
- brokers (e.g. an agency business), imports and/or markets prepacked food products it imports (from the internal market and/or third countries)
- sells prepacked food products in distance selling
- sells unpackaged food products in a retail store
- sells/serves unpackaged meals in a facility of a mass caterer

It is recommended that the following points are controlled at the same time 10.1 Separation and Cross-contamination, 13.2 Nutrition Labelling, and 13.4 Labelling of Meat Required by Specific Legislation and 13.5 Labelling of Fishing and Aquaculture Products Required by Specific Legislation. The indication of the country of origin for beef, minced beef and fishery and aquaculture products are addressed as a separate point in points 13.4 and 13.5.

Matters to be controlled:

The implementation of own check activities is evaluated by random checks (on e.g. 1-3 packages of different products and/or batches of loose foods, taking the scope and nature of operations into consideration) of the following matters:

Compliance with requirements which can be verified by means of, for example:

- inspections of labelling, recipes and documents
- where necessary, analysis certificates and/or own check astivities tests.

1. Control of compliance of labelling with regulations, i.e. is the information provided in the labelling/label formally correct:
   - information can be read without difficulty (x-height of the font size equal to or greater than 1.2 mm; exception x-height of the font size equal or greater than 0.9 mm in case of packaging the largest surface of which has an area of less than 80 cm^2)
   - mandatory labelling information is provided in Finnish and in Swedish (only unilingual labelling is required on products marketed in unilingual municipalities)
   - the mandatory information required by Article 9 of the Food Information Regulation includes:
     a) the name of the food
     b) the list of ingredients
     c) any ingredients causing allergies or intolerances emphasised in the list of ingredients (Food Information Regulation, Annex II)
     d) the quantity of certain ingredients or categories of ingredients (if applicable)
     e) the net quantity of the food
     f) the date of minimum durability (best before) or the use-by date, and the date of freezing, if applicable

g) any special storage conditions and/or conditions of use (if applicable)
h) the name or business name and address of the food business operator
i) the country of origin or place of provenance, if applicable (Food Information Regulation, acc. to Article 26)
j) instructions for use (where required)
k) the actual alcoholic strength by volume for beverages containing more than 1.2% by volume of alcohol

In addition, the labelling shall contain the following:

- salt indication and high-in-salt indication, and indication of iodine in the list of ingredients if iodised salt is used
- an identification mark in food products of animal origin.

The indications are formally correct; additives, for example, are designated both by the name of the category and the specific name or E number of the additive, and allergens are emphasised in the list of ingredients.

Sale of loose foods **in a retail store:**

a) the name of the food
b) substances and products causing allergies or intolerances
c) ingredients
d) the country of origin or place of provenance (similarly as for packaged products)
e) instructions for use and storage (if applicable)

In addition, the amount of fat and salt in *cheeses, sausages* and *other meat products used as deli meats* and the amount of salt *in bread.*

Sale/serving of loose foods **in a catering establishment:**

a) the name of the product
b) substances and products causing allergies or intolerances
c) the country of origin or place of provenance (similarly as for packaged products)

This information can in retail stores and catering establishments be provided on unpackaged food products also verbally, provided there is a poster or similar in the vicinity of the food product stating that information can be obtained from the staff on request. The information must then be in written or electronic form.

The mandatory information on loose foods must be provided at least in Finnish or in Swedish.

Prepacked foods marketed in **distance selling** (Food Information Regulation, Article 14)
All mandatory general labelling, except the date of minimum durability or the use-by date (or the date of freezing and batch number),shall be available before the purchase is concluded and shall appear on the material supporting the distance selling or be provided through other appropriate means clearly identified by the food business operator. All mandatory information shall be available at the moment of delivery.

2. Verification of the accuracy of labelling by means of an inspection of the recipe taking into consideration the ingredients used, and/or product specifications:

- recipes are up-to-date and complied with in production
- recipes/manufacture/finished product are mutually consistent
- the name of the food is correctly formed
- the ingredients used are indicated in the list of ingredients
- the break-down of compound ingredients is correctly presented in the list of ingredients
- ingredients causing allergies or intolerances are indicated
- the ingredients are in the correct order
- the indicated quantity of the ingredient is correct
- the origin of the food is correctly indicated
- the claims (e.g. lactose-free, gluten-free, dairy-free or additive-free) used are justified.

EXCELLENT

Operations comply with requirements.

The labelling presented above complies with the aforementioned requirements laid down in legislation. The information is marked in such a way as to be easily visible.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operation is mainly implemented in compliance with the aforementioned requirements laid down in legislation. There are some minor shortcomings in labelling, such as:

- the list of ingredients does not follow the correct order of quantity
- the water used is not indicated in the list of ingredients (water need not be indicated if the amount of water does not exceed 5% by weight of the finished products, with the exception of meat, meat preparations, unprocessed fishery products and unprocessed bivalve molluscs)
- the name of the category for an additive is not indicated or is incorrect.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are several essential defects and/or deficiencies in labelling, such as:

- a misleading name of the food
- the country/region of origin is not indicated or is incorrect
- the best-before indication is not provided or is incorrect
- the quantity of the emphasised ingredient is not indicated
- the additives contained in the product are not indicated in labelling, although they serve a technological function in the finished product
- an additive-free or lactose-free claim is used, but is incorrect
- the recipe used is not consistent with the labelling.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Labelling is missing completely or there are defects that require immediate rectification or recall, such as:

- very unclear, illegible labelling
- failure to indicate allergens
- a required warning or instructions for use are not provided, which causes a severe health hazard
- the use-by date is not indicated or is incorrect (wrong month or year, for example)
- instructions for storage are not provided or are incorrect (microbiologically perishable)
- the required Finnish or Swedish labelling is not provided
- a misleading gluten-free claim is used

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; Articles 17 - 19
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers
- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin, Article 5 and Annex II (Section I)
- Finnish Food Act 23/2006, Sections 1, 2 and 9
- Decree (795/2014) of the Ministry of Agriculture and Forestry on food hygiene at approved establishments, Annex 2, Chapter 9 (point 9.3)
- Decree (834/2014) of the Ministry of Agriculture and Forestry on the provision of food information to consumers
- Decree (1010/2014) of the Ministry of Agriculture and Forestry on the labelling of certain foods
- Evira's Guide 17068/1. Food Information Guide for food control authorities and food sector operators
- Evira's Guide 17055/1. Guide for control of labelling
- Evira's Guide 17050/1. Nordic control project on allergen labelling. National food control programme (EVO 2011).

Updates in version 3:

- legislation revoked as of 13 December 2016 removed.

13 Information Provided on Foods

13.2 Nutrition Labelling

To be taken into consideration:

This point is to be controlled when general labelling is provided for mass caterers and end consumers in compliance with the Food Information Regulation (No. 1169/2011, Degree 834/2014 of the ministry of Agriculture and Forestry), as well as in cases where the operator

- manufactures, has manufactured and/or packages food products
- brokers (e.g. an agency business), imports and/or markets prepacked foods it imports (from the internal market and/or third countries)
- sells prepacked foods in distance selling

As of 13 December 2016, the nutrition labelling referred to in the Food Information Regulation is mandatory on almost all prepacked foods. If the products have been packaged as from 13 December 2014 and bear the nutritional declaration on a voluntary basis, or if the labelling contains nutrition or health claims, or if the food has been fortified with vitamins and/or minerals, the nutritional labelling shall comply with the Food Information Regulation (derogation dietetic products until July 2016, foods for particular nutritional uses after that). (The nutrition labelling referred to in the Food Information Regulation is not applied to food supplements, natural mineral water, spring water, and not required on the foods listed in Annex V to the Food Information Regulation.

It is recommended that point 13.1 General Labelling is controlled at the same time.

Matters to be controlled:

The implementation of own-check activities is evaluated by random checks (on e.g. 1-3 packages of different products and/or batches of loose foods, taking the scope and nature of operations into consideration) of the following matters:

Compliance with requirements which can be verified by means of, for example:

- inspections of labelling, recipes and documents
- where necessary, analysis certificates and/or own-check activities tests.

1. Control of compliance of labelling with regulations, i.e. is the nutrition declaration provided in the labelling/label formally correct:
   - information can be read without difficulty (x-height of the font size usually at least 1.2 mm)
   - labelling information is provided in Finnish and in Swedish (only unilingual labelling is required on products marketed in unilingual municipalities)
   - nutrition information is expressed per 100 g or 100 ml of the food
   - the mandatory nutrition labelling contains the following information: energy kJ/kcal, fat (g), saturated fats (g), carbohydrates (g), sugar (g), protein (g) and salt (g)
   - labelling information is presented formally correctly, for example, those nutrients are indicated that may be indicated in the actual nutrition declaration (Food Information Regulation, Annex XV)
   - for vitamins and minerals, both their amount and percentage of the daily reference intake are declared (Food Information Regulation, Annex XIII)
   - the order of the declaration of nutrients is followed (Food Information Regulation, Annex XV).

If the information declared in mandatory nutrition labelling is repeated on a voluntary basis, the requirements laid down in Articles 30.3 and 33.2 of the Food Information Regulation shall be complied with.

Prepacked foods marketed in distance selling (Food Information Regulation, Article 14)
The nutrition labelling, like all mandatory general labelling, except the date of minimum durability / the use-by date (or the freezing date and batch number),shall be available before the purchase is concluded and shall appear on the material supporting the distance selling or be provided through other appropriate means clearly identified by the food business operator. All mandatory information shall be available at the moment of delivery.

2. Verification of the accuracy of labelling by means of an inspection of the recipe taking the ingredients used into consideration, and or product specifications:
   - recipes are up-to-date and complied with
   - the amounts of nutrients declared are based on calculations or laboratory analyses or on some other generally established and accepted data
   - the amount of salt is calculated and determined based on sodium (salt = sodium x 2.5). Both sodium occurring naturally in the ingredients and sodium from added salt are taken into account in the amount of salt.
   - the vitamins and minerals contained in the food are correctly indicated.


EXCELLENT

Operations comply with requirements.

The nutrition labelling presented above complies with the aforementioned requirements laid down in legislation. The information is marked in such a way as to be easily visible.


GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operation is mainly implemented in compliance with the aforementioned requirements laid down in legislation. There are some minor shortcomings in nutrition labelling, such as
- There are some minor errors in nutrition labelling, but notwithstanding these, it is possible to verify the compliance of the product with requirements; nutrition information, for example, is declared in an order that completely differs from the order specified in the Regulation.
- the amount of energy is expressed only in kilocalories or kilojoules.


TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are some essential defects and/or deficiencies in nutrition labelling, such as:
- the recipe used is not consistent with the labelling.

- nutrition labelling in Finnish or Swedish is not provided
- nutrition labelling is unclear and illegible
- nutrients that are not allowed to be declared are declared

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The issues related to nutrition labelling do not result in an immediate risk to food safety or seriously mislead the consumer. For this reason, the grade Poor is only awarded in case the grade To be corrected has been awarded repeatedly and the shortcomings have not been rectified within the set deadline.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; Articles 17 - 19
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, Articles 8, 29 - 35, and Annex V
- Finnish Food Act 23/2006, Sections 1, 2 and 9
- Decree of the Ministry of Agriculture and Forestry on the provision of food information to consumers (834/2014), Section 4
- Evira's Guide 17068/1. Food Information Guide for food control authorities and food sector operators
- Evira's Guide 17055/1. Guide for control of labelling
- Commission Guidance (December 2012): Guidance document for competent authorities for the control of compliance with the following EU legislation
  http://ec.europa.eu/food/safety/docs/labelling_legislation_guidance_methods_2012_en.pdf

Updates in version 3:

- The point To be taken into consideration supplemented with the words: foods for particular nutritional uses.

13 Information Provided on Foods

13.3 Marketing (Nutrition and Health Claims)

To be taken into consideration:

This point is to be controlled, when the operator uses nutrition or health claims in the labelling, presentation or advertising of foodstuffs which the operator manufactures, has manufactured for it, imports (from the internal market or third countries), packages and/or brokers (e.g. agency business).

In retails stores, distance selling and catering establishments this point is controlled as concerns marketing material and labelling for which the operator itself is responsible

- the retail store, distance selling or catering establishment is responsible for the nutrition and health claims used in the marketing material produced by the operator,
- the retail store, distance selling or catering establishment is responsible for the nutrition and health claims used in the labelling of the foodstuffs that the operator itself manufactures, has manufactured for it, imports (from the internal market or third countries), packages or brokers (e.g. agency business).

The control only concerns nutrition and health claims made on a voluntary basis, not mandatory labelling, for example, which is controlled in point 13.1 General Labelling. It is recommended that this point and point 13.2 Nutrition Labelling are controlled at the same time to verify their compliance with regulations.

Matters to be controlled:

The implementation of in-house control is evaluated by random checks of nutrition claims made on 1-3 products and the related labelling, taking the scope and nature of operations into consideration.

The labelling and marketing material used by the operator at the time of the control are taken into consideration, such as advertising in magazines, radio and TV, brochures, newspapers, books, product catalogues, mail order catalogues, websites, social media (e.g. Facebook, Twitter, Pinterest, YouTube), public announcements in shopping centres, shelf labels, presentation material, etc.

It is to be controlled that the nutrition and health claims used in the labelling, presentation or marketing material of foodstuff:

- are not false or misleading (Food Information Regulation, Article 7.1, Food Regulation, Article 16),

- are not prohibited
  - medicinal claims prohibited by Section 9 of the Finnish Food Act
    - related to the prevention, treatment or curing of human diseases
  - prohibited by Article 3 of the Claims Regulation

    Claims shall not:
    - be false, ambiguous or misleading,
    - give rise to doubt about the safety and/or nutritional adequacy of other foods,
    - encourage or condone excess consumption of a food, or

- state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general
- refer to changes in bodily functions which could give rise to or exploit fear in the consumer

- prohibited by Article 12 of the Claims Regulation

  Claims which:
  - suggest that health could be affected by not consuming the food,
  - make reference to the rate or amount of weight loss, or
  - make reference to recommendations of specific doctors or health professionals and associations other than the national associations of medical and health and nutrition professionals, and health-related charities referred to in Article 11

- are authorised in compliance with the Claims Regulation, and included in either
  - the Annex of authorised nutrition claims or the list of authorised claims referred to in Article 10 of the Claims Regulation
  - the so-called waiting list, waiting for the completion of EFSA's scientific assessment and/or decision of the Commission (only applies to health claims submitted for assessment prior to 2008), or
  - the claims to which a transition period applies, i.e. a transition period granted for stopping the use of the claim has not ended yet.

- generic expressions, pictures, symbols, graphic representations, product names, brand names, etc. that are considered to be claims have been taken into consideration and a specific authorised nutrition or health claim is placed next to or following them.

- the conditions defined for the use of a nutrition or health claim are fulfilled
  - the food contains an adequate amount of the substance referred to in the claim, and this can be verified through, for example
    - inspections of labelling, recipes and documents, or
    - where necessary, on the basis of analysis certificates and/or in-house control tests
  - the amount of the substance referred to in the claim is indicated in the nutrition declaration or in the same field of vision with it, or for food supplements in the list of characteristic substances.

- the substance referred to in the claim is used in the correct product group, and

- the compulsory additional labelling referred to in the Claims Regulation is used in connection with the use of health claims
  - Article 10(2) a) - A statement indicating the importance of a varied and balanced diet and a healthy lifestyle
  - Article 10(2) b) - The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect
  - Article 10(2) c), where appropriate – A statement addressed to persons who should avoid using the food.
  - Article 10(2) d), where appropriate – An appropriate warning for products that are likely to present a health risk if consumed to excess.
  - as concerns health claims that refer to reduction of disease risk, the additional statement referred to in Article 14(2): "*The disease has multiple risk factors and altering one of these may or may not have a beneficial effect".*

EXCELLENT

Operations comply with requirements.

Nutrition and health claims are used in compliance with the aforementioned requirements.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Nutrition and health claims are in main parts used in compliance with the aforementioned requirements. There are some minor shortcomings, such as:

- the nutrition and health claims used are authorised, but their wording does not have the exact same meaning as the original authorised claims,
- a specific authorised claim is not placed next to or following a generic expression, picture, symbol, graphic representation, product name or brand name,
- the amount of the substance referred to in the claim is indicated somewhere else and not in the nutrition declaration or in the same field of vision with it, or for food supplements in the list of characteristic substances,
- the additional labelling required by Articles 10(2) a-b to be used with a health claim is provided, but is deficient, or
- the additional statement required by Article 14(2) to be used with health claims that refer to reduction of disease risk is provided, but is deficient.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

Nutrition and health claims are not used in compliance with the aforementioned requirements but there are some essential shortcomings related to their use, such as:

- unauthorised nutrition and health claims are used,
- claims prohibited by Article 3 or Article 12 are used,
- generic expressions, pictures, symbols, graphic representations, product names or brand names that are considered to be claims are used without a specific authorised claim (taking into consideration, however, the transition period referred to in article 27(2) for trademarks and brand names existing before 1 January 2005),
- the conditions defined for the use of claims are not fulfilled; for example, the product does not contain an adequate amount of the substance referred to in the claim,
- the amount of the substance referred to in the claim is not indicated in the nutrition declaration or in the same field of vision with it, or for food supplements in the list of characteristic substances,
- the additional labelling required by Articles 10(2) a-b to be used with a health claim is not provided at all, or the additional labelling referred to in Articles 10(2) c-d) is provided, but is deficient, or
- the additional statement required by Article 14(2) to be used with health claims that refer to reduction of disease risk is not provided.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

There are issues with the use of nutrition and health claims that require immediate rectification, and defects that in some cases require a recall.

Such shortcomings requiring immediate rectification include:

- medicinal claims that are in violation of The Finnish Food Act 23/2006, Section 9, are made on the food
- the additional labelling regarding instructions for use and warnings, required by Articles 10(2) c-d to be used with a health claim, is not provided at all.

Defects requiring a recall are found in the marketing of foods, such as:

- medicinal claims that may cause a health hazard to the consumer are made in the marketing of the food, for example because the foodstuff is marketed for the treatment of a specific disease giving rise to the suspicion that as a result of such marketing, appropriate medicinal treatment will be replaced with consumption of the foodstuff.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods (= Claims Regulation)
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (= Food Information Regulation), Article 7.1
- Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (= Food Regulation); Article 16
- Finnish Food Act 23/2006, Section 9

- Commission Register of authorised health claims http://ec.europa.eu/nuhclaims/
- Register of the European Food Safety Authority EFSA of questions related to health claims under assessment http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=NDA&foodsectorarea=26
- Commission Guidance (December 2012): Guidance document for competent authorities with regard to setting of tolerances for nutrient values declared on a label, and on the control of compliance with them http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/guidance_tolerances_december_2012_fi.pdf
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- Evira's Guide 17052/3. Nutrition and Health Claim Guide
- Evira's Guide 17060/1. Guide for control of nutrition and health claims
- Evira's Guide 17065/1. Form for review of health claims
- Evira's Guide 17068/1. Food Information Guide for food control authorities and food sector operators
- Evira's Guide 17055/1. Guide for control of labelling

13 Information Provided on Foods

13.4 Labelling of Meat Required by Specific Legislation

(Beef, and the meat of swine, sheep, goats and poultry and minced or ground meat of these animals)

To be taken into consideration:

This point is to be controlled, **where the following foods are concerned**:

- beef or beef product or minced beef (fresh/chilled/frozen)
- meat of swine, sheep, goats and poultry, or minced meat of these animals (fresh/chilled/frozen)

and when general labelling is provided for mass caterers and end consumers in compliance with the Food Information Regulation (No. 1169/2011, Degree 834/2014 of the Ministry of Agriculture and Forestry) in cases where the operator

- manufactures, has manufactured and/or packages food products
- brokers (e.g. an agency business), imports and/or markets prepacked foods it imports (from the internal market and/or third countries)
- sells packaged food products in distance selling
- sells unpackaged food products in a retail store

Control particularly concerns information on the country of origin for beef and the meat of swine, sheep, goats and poultry, and minced meat containing the meat of these animals, as well as information on the composition of industrially packaged minced meat of these animals.

The labelling of beef refers to the labelling of carcases and quarters, wrapping or packaging of cut and minced beef, and the sale of loose beef in retail stores. The diaphragm and the masseters are part of the skeletal muscles. The fat removed from the carcass before weighing, the muscles of the head (other than the masseters), the viscera, the tongue, and the muscles of the carpus, the tarsus and the tail are excluded from the scope of the beef labelling provisions.

The labelling provisions for beef as well as for the meat of swine, sheep, goats and poultry do not apply to meat preparations and meat products.

The labelling requirements of general labelling legislation shall otherwise be applied to the information provided in labelling and in the sale of loose meat or minced meat.

It is recommended that the following points be controlled at the same time 8.5 Production of minced and ground meat, 13.1 General Labelling, 16.2 Labelling and Traceability of Beef, and 16.8 Traceability of Meat of Swine, Poultry, Sheep and Goats.

Matters to be controlled:

The implementation of own check activities is evaluated by random checks (on e.g. 1-3 packages of different products and/or batches of loose foods, taking the scope and nature of operations into consideration):

Compliance with requirements which can be verified by means of, for example:

- inspections of labelling, recipes and documents
- where necessary, analysis certificates and/or own check activities tests.

1. **Compliance of indication of origin on packaged and cut beef or a beef product or minced beef with requirements; mandatory labelling includes:**
   - consignment identification
   - indication of origin
   - indication "slaughtered in" (minced beef: the approval number of the slaughterhouse is not indicated)
   - indication "cut in" (only for cut beef)
   - indication "produced in" (minced beef only: the approval number of the production establishment is not indicated).

2. **Indication of country of origin (or place of provenance) for packaged meat of swine, sheep, goats and poultry (fresh, chilled, frozen) and minced meat containing the meat of these animals**
   - For animals born, reared and slaughtered in one country, information on the country of origin (or place of provenance) can be provided with a single indication: "Origin: name of member state or third country and the batch code (consignment identification)
   - In other cases information on the origin of meat is to be indicated in compliance with Article 5 of Commission Implementing Regulation (EU) No 1337/2013 with regards to "Reared in: (name of member state or third country", "Slaughtered in: (name of member state or third country)" and "batch code".
   - For minced meat, the indications defined in Article 7 of Commission Implementing Regulation (EU) No 1337/2013 are to be used.

3. **Specific indications regarding the composition of minced meat**
   Packaged minced meat shall be labelled with the following specific indications (Food Information Regulation No 1169/2011, Annex VI, Part B):
   - "fat content less than…",
   - "collagen/meat protein ratio less than...".

   The composition of minced meat is monitored at the establishment (fat content and collagen/meat protein ratio) to verify the validity of the designation of minced meat:
   - lean minced meat (fat content ≤ 7 %, collagen/meat protein ratio ≤ 12 %),
   - minced pure beef meat (fat content ≤ 20 %, collagen/meat protein ratio ≤ 15 %)
   - minced meat containing pigmeat (fat content ≤ 30 %, collagen/meat protein ratio ≤ 18 %)
   - minced meat of other species (fat content ≤ 25 %, collagen/meat protein ratio ≤ 15 %).

   Evidence provided by the operator is sufficient when they present recipe calculations based on, for example, the generally established fat and collagen contents of cut beef and pigmeat used in minced meat of beef and pigmeat.

4. **The following information is provided on beef and meat of swine, sheep, goats and poultry imported from third countries, if all information on country of origin is not available or only part of the information is available:**
    - Reared in: non-EU state
    - Slaughtered in: (Name of third country where the animal was slaughtered).

5. **Unpackaged beef and meat of swine, sheep, goats and poultry (fresh- chilled, frozen) or minced meat containing the meat of these animals, sold from a service counter:**
    - Information corresponding to the information on origin provided in the labelling of meat packages shall be provided in the immediate vicinity of beef or minced beef sold loose, e.g. on a separate board, indicated in a visible manner, excluding the approval numbers of the slaughterhouses and cutting plants.
    - Information corresponding to the information on origin required to be provided on packaged products shall be indicated in a visible manner in the immediate vicinity of meat of swine, sheep, goats and poultry and minced meat of these animals sold loose, e.g. on a separate board. This information can also be provided verbally, provided the consumer is informed in a clear and easily visible manner at the point of service that the information can be obtained from the staff on request. The information must be available at the point of service to the staff and the control authority in written or electronic form.

EXCELLENT

Operations comply with requirements.

The labelling presented above complies with the aforementioned requirements laid down in legislation. The information is marked in such a way as to be easily visible.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operation is mainly implemented in compliance with the aforementioned requirements laid down in legislation. There are some minor shortcomings in labelling, such as:

- there are some minor shortcomings in indications of origin, but notwithstanding these, it is possible to verify the compliance of labelling with requirements.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are several essential defects and/or deficiencies in labelling, such as:

- indications of origin are unclear or too small
- the indication of origin is not provided
- mandatory specific labelling has several essential shortcomings
- industrially packaged minced meat does not show the "fat content less than…" and/or "collagen/meat protein ratio less than..." -indication
- the fat content or collagen/meat protein ratio of minced meat exceeds the permitted maximum amount

- there are shortcomings in the composition data related to the designation of minced meat

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Labelling is missing completely or there are defects that require immediate rectification or recall, such as:

- the name of the product is indicated misleadingly wrong
- the origin of the product is indicated misleadingly wrong.

Legislation and guidelines pertaining to the topic:

- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, Articles 17 and 26, and Annex VI, Part B
- Commission Regulation (EC) No 1825/2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products
- Regulation (EC) No 1760/2000 of the European Parliament and of the Council establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
- Commission Implementing Regulation (EU) No 1337/2013 laying down rules for the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry
- Finnish Food Act 23/2006, Sections 1, 2 and 9
- Decree No 434/2008 of the Ministry of Agriculture and Forestry on the labelling of beef
- Decree 435/2008 of the Ministry of Agriculture and Forestry on the marketing of veal
- Decree 834/2014 of the Ministry of Agriculture and Forestry on the provision of food information to consumers
- Evira's Guide 16024/1. Labelling and traceability of beef
- Evira's Guide 17068/1. Food Information Guide for food control authorities and food sector operators
- Evira's Guide 17055/1. Guide for control of labelling

13 Information Provided on Foods

13.5 Labelling of Fishing and Aquaculture Products Required by Specific Legislation

To be taken into consideration:

This point is to be controlled **where fishery or aquaculture products** (fresh / frozen / dried / salted / smoked / charred) are concerned

and when general labelling is provided for mass caterers and end consumers in compliance with the Food Information Regulation (No. 1169/2011, Degree 834/2014 of the ministry of Agriculture and Forestry) in cases where the operator

- manufactures, has manufactured and/or packages food products
- brokers (e.g. an agency business), imports and/or markets prepacked foods it imports (from the internal market and/or third countries)
- sells packaged food products in distance selling
- sells unpackaged food products in a retail store

Control particularly covers information on the country of origin of fishery and aquaculture products, but also other specific indications, such as the indication of the type of gear used.

The labelling requirement does not pertain to fish products, such as fish fingers and pickled herring, and spicy smoked products.

It is recommended that points 13.1 General labelling and 16.1 Traceability of foodstuffs are controlled at the same time.

Matters to be controlled:

The implementation of own-check activities is evaluated by random checks (on e.g. 1-3 packages of different products and/or batches of loose foods, taking the scope and nature of operations into consideration) of the following matters:

Compliance with requirements can be verified by means of, for example:

- inspections of labelling, recipes and documents
- where necessary, analysis certificates and/or own-check activities tests.

1. **Compliance of indication of origin for prepacked fishery and aquaculture products with requirements: mandatory information includes:**
   - commercial designation and scientific name of the species
   - production method (designation *"caught"* (caught at sea) or *"caught in freshwater"* or *"farmed"*
   - catch area
     - *fish caught at sea* must display the catch area,

- *name of major fishing area*, e.g. Northeast Atlantic, Baltic Sea, Western Mid-Atlantic, Eastern Mid-Atlantic, Southwest Atlantic, Southeast Atlantic
- *derogation: fish caught in the Northeast Atlantic (FAO 27), Mediterranean or Black Sea (FAO 37)* must display, instead of the major fishing area, the name of the sub-area (e.g. Western Mediterranean (area 37.1) or division (e.g. Sardinia (area 37.1.3). The area must also be indicated using a name that is easy for the consumer to understand, or a map or a pictogram indicating the area.
- The FAO area number need not be indicated.
- The FAO list of the major fishing areas, sub-areas and divisions (ICES) can be found on the FAO website at: http://www.fao.org/fishery/cwp/handbook/h/en. http://ec.europa.eu/fisheries/documentation/publications/cfp_factsheets/fishing_areas_en.pdf

- *fish caught in freshwater* must display both the country (state) of origin and the name of the body of water (river, lake)
- *farmed fish* must display the country of production, where maturing of the product has taken place. The farming area refers to the state where the product grew by more than half of its weight.
- *mixed products of the same species caught in different catch areas / fish-farming countries* must, at least, display the area / country of the batch that is more representative in terms of quantity, and indicate that products come from different areas / countries.

In addition, other specific labelling:

- the date of minimum durability or the use-by date (*only applied to prepacked*) (Does not apply to fishery and aquaculture products eaten alive.)
- type of fishing gear
  - wild fish must display one of the following fishing gear categories used to catch the fish: "seines", "trawls", "gillnets", "surrounding nets", "lift nets", "hooks and lines", "dredges", "pots and traps".
  - mixed products of the same species caught with different categories of fishing gear must display the fishing gear category for each batch (e.g. nets, seines). For example, when whitefish caught with different categories of fishing gear is marketed, an accepted indication is "caught with seine, trawl or hooks".
- in addition, the label should indicate whether the product has been "defrosted". The indication "defrosted" is not required in the following cases:
  - ingredients present in the final product
  - foods for which freezing is a technologically necessary step of the production process
  - fishery and aquaculture products referred to in Regulation (EC) No 853/2004, Annex III, Section VIII, which have been previously frozen for health safety purposes
  - fishery and aquaculture products which have been defrosted before smoking, salting, cooking, pickling, drying or a combination of these processes.
- date of packaging (at least dd.mm): only applies to packaged bivalve molluscs.

2. Non-prepacked fishery and aquaculture products sold from service counter

- Information corresponding to the specific information provided in the labelling of prepacked fishery and aquaculture products shall be provided in the immediate vicinity of fishery and aquaculture products sold loose, e.g. on an advertising board or poster, indicated in a visible manner, *excluding the date of minimum durability period or the use-by date.* Displaying the list of the Ministry of Agriculture and Forestry of commercial names for the consumer to browse is an adequate method for the indication of the scientific name of the fish species.

- *The scientific name of the fish and the type of gear* can also be provided verbally, provided a poster or similar in the vicinity of the food product indicates that the information can be obtained from the staff on request. This information must be available to the staff in written or electronic form. Information on the type of gear is provided in the information that accompanies the batch of fish, or otherwise available to the retailer.

EXCELLENT

Operations comply with requirements.

The labelling presented above complies with the aforementioned requirements laid down in legislation. The information is marked in such a way as to be easily visible.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operation is mainly implemented in compliance with the aforementioned requirements laid down in legislation. There are some minor shortcomings in labelling, such as:

- there are some minor shortcomings in indications of origin, but notwithstanding these, it is possible to verify the compliance of the labelling with requirements.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are several essential defects and/or deficiencies in labelling, such as:

- indications of origin are unclear or too small
- the indication of origin is not provided
- mandatory specific labelling has several essential shortcomings.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Labelling is missing completely or there are defects that require immediate rectification or recall, such as:

- the name of the product is indicated misleadingly wrong
- the origin of the product is indicated misleadingly wrong.

Legislation and guidelines pertaining to the topic:

- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, Articles 17 and 26, and Annex VI, Part B
- Decree 834/2014 of the Ministry of Agriculture and Forestry on the provision of food information to consumers
- Regulation (EU) No 1379/2013 of the European Parliament and of the Council on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000, Chapter IV, Article 35
- Decree (597/2008) of the Ministry of Agriculture and Forestry on permitted trade names of fishery and aquaculture products
- Commission Implementing Regulation (EU) No 1420/2013
- Guide of the European Commission. A pocket guide to the EU's new fish and aquaculture consumer labels http://ec.europa.eu/fisheries/documentation/publications/eu-new-fish-and-aquaculture-consumer-labels-pocket-guide_fi.pdf
- Evira's Guide 16023/3. Control of fishery products
- Evira's Guide 17068/1. Food Information Guide for food control authorities and food sector operators
- Evira's Guide 17055/1. Guide for control of labelling

Updates in version 2:

- The indication of the date of harvest and catch of fresh fish removed from Matters to be controlled.

14. Packaging Materials and Food Contact Materials

14.1 Packaging Materials and Other Food Contact Materials

To be taken into consideration:

This point is to be controlled in retail stores and catering facilities as well as other registered food premises and approved food establishments in cases where the operator handles, manufactures, has manufactured for it, stores, packages, imports (from the internal market or third countries), transports or brokers (e.g. agency business) foodstuffs.

- The control concerns packaging materials and other materials, machines, equipment, utensils and articles (e.g. containers, receptacles, working utensils, disposable gloves) that come into contact with food.
- When the control concerns machinery, equipment or articles that come into contact with food, it is recommended that their condition and intactness be controlled at the same time in point 2.3 and cleanliness in point 3.2.
- Production hygiene with respect to packaging is controlled in point 5.5.
- Control is to be prioritised in the premises/establishments being controlled using a risk-based approach primarily on materials that come into contact with fatty foodstuffs and/or foodstuffs stored at high temperatures and/or for long periods of time.
- High production volumes/position of market leader of a foodstuff are also grounds for subjecting materials to risk-based control.

Matters to be controlled:

The implementation of own-check activities is evaluated by random checks (on e.g. 1-3 products, taking the scope and nature of operations into consideration) of compliance with requirements with respect to packaging and other food contact materials.

The following matters are to be controlled separately for each activity:

- The operator has matters related to the food grade quality and traceability of packaging materials as well as new equipment, utensils and articles under control.
- Packaging and food contact materials are correctly used and any restrictions to use (e.g. using only packaging films, bags, containers and disposable gloves suitable for the purpose for fatty foodstuffs and foodstuffs sold or stored hot) are taken into consideration. Aluminium materials (e.g. pans, foils) are not used for acidic foodstuffs and steel utensils are not used with vessels made from aluminium.
- If the operator has detected that regulatory requirements are not met, they have initiated adequate corrective actions.

1. Retail stores and catering facilities

- The control of packaging materials also covers packaging materials used by the store or facility itself.
- Packaging materials and other food contact materials are accompanied by either words that refer to food grade quality ("for food contact") or the glass and fork symbol. However, these are not obligatory for articles which are clearly intended to come into contact with foodstuff. As a

rule, the glass and fork symbol can be considered adequate proof of the food grade quality of articles, provided their correct use has been verified,

or

- The operator can present traceable declarations of compliance which state that the packaging materials and other food contact materials are suitable. If the packaging materials and other food contact materials have been procured through a wholesaler/central organisation and the commercial designation of the product indicates its intended purpose of use (e.g. barbecue bag, bread bag, cheese film), a certificate indicating the food contact use of the article or material need not be displayed in the store or catering facility. In this case it is enough that the certificate can be obtained from the wholesaler/central organisation, if necessary

and

- the operator is familiar with the correct use of packaging materials and other food contact materials and this is implemented in practical activities.
- Operators who import (from the internal market and/or third countries) pre-packed foodstuffs: the fulfilment of the requirements laid down for food contact materials is also verified (e.g. included in the procurement contract or product specification).

2. Other food establishments

- The operator is able to present traceable declarations of compliance for packaging materials and other food contact materials, and the declarations are not too old (e.g. more than three years old).
- Declarations of compliance are not required of old equipment used in industrial manufacture, but some other information must be produced of their suitability. As a rule, the glass and fork symbol can be considered adequate proof of the food grade quality of articles, provided their correct use has been verified,

  Declarations of compliance provide adequate and appropriate information, e.g. at least:
  - *Name and contact information for the manufacturer, importer or trader of the food contact material*
  - *Identification data on the contact material (name, construction)*
  - *Date of issue of the declaration*
  - *The legislation whose requirements the contact material meets (always at least Regulation (EC) 1935/2004) and also material-specific provisions, if any exist*
  - *[for example, for plastics data showing that the limit value of total migration is not exceeded; data on substances for which restrictions of use have been specified (always at least one of the following: FCM substance number, reference number, CAS number, chemical name, limit value) and a declaration that their limit values are not exceeded].*
  - *Restrictions of use for contact materials, such as the food types which the contact material is suitable to be used with, restrictions related to temperature of use and time of contact*
  - *Information about any dual use additives contained in the contact material.*

- Small-scale operation:
- (when packaging materials and other food contact materials are procured from a cash and carry wholesaler or a retail store), comparable food grade quality requirements apply as above in points 1. Retail store and catering facility, sub-items 2, 3 and 4. Materials, articles, equipment and machinery are used in compliance with the instructions for use/suitability indicated in their declarations of compliance; taking into consideration, for example, suitable food groups, indicated temperature limits (filling and after-use) and times of

contact, and that the possible migration of dual use additives meets the requirements laid down in provisions pertaining to additives.

- Operators who import (from the internal market and/or third countries) or broker pre-packed foodstuffs: the fulfilment of the requirements laid down for food contact materials is also under control (e.g. included in the procurement contract or product specification).


EXCELLENT

Operations comply with requirements.

Operation meets the aforementioned requirements. The operator has clear knowledge, and where necessary, adequate documents as regards the food grade quality of materials, and they are used correctly.


GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

1. Retail stores and catering facilities

Operation meets in the main parts the aforementioned requirements. The operator has knowledge about the suitability of most packaging materials, and uses articles accordingly. There are some minor shortcomings in operation, but notwithstanding these, the compliance of the use of the packaging and other food contact materials with requirements can be verified. For example:

- The majority of packaging materials and other food contact materials bear an indication referring to food contact use, or the operator has declarations of compliance for them. As concerns food contact materials that do not have this indication or a declaration of compliance, the operator has in some other way verified their suitability for the intended use in the order or procurement process.
- The suitability of the disposable gloves used to handle fatty foodstuffs has not been verified; for example, PVC (vinyl) gloves the labelling of which displays the glass and fork symbol, but there is no indication of suitability for use in contact with fatty foodstuffs.

2. Other food establishments

Operation meets in the main parts the aforementioned requirements. The operator has knowledge about the suitability of most packaging materials and food contact materials. There are some minor shortcomings in operation, but notwithstanding these, the compliance of the use of packaging and food contact materials with requirements can be verified. For example:

- The operator has valid declarations of compliance for most of the packaging materials and food contact materials. A small part of the declarations of compliance have inadvertently not been renewed, not been received yet or present deficient information. Small scale operation (articles procured from a cash and carry wholesaler or a retail store): the operator has comparable knowledge about the suitability of the materials they use.
- The suitability of the disposable gloves used to handle fatty foodstuffs has not been verified; for example, PVC (vinyl) gloves the labelling of which displays the glass and fork symbol, but there is no indication of suitability for use in contact with fatty foodstuffs.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

1. Retail stores and catering facilities:

The operator does not have adequate knowledge about the quality and suitability of the packaging materials and other materials they use, and has not made any attempt to verify these matters. There is cause to suspect that the materials used in the operations are not suitable for their purpose of use. For example:

- Packaging materials and other food contact materials do not bear an indication referring to food contact use, or the operator does not have declarations of compliance for them. The operator has failed to verify the suitability of the food contact material in any way in the order or procurement process and in fact has no knowledge about the suitability of the packaging and food contact materials.
- Fatty foodstuffs are handled wearing disposable gloves not suitable for the handling of fatty foodstuffs.
- Aluminium materials (e.g. pans, foils) are used for acidic foodstuffs and/or steel utensils are used with vessels made from aluminium.
- The operator is unable to demonstrate that the prepacked foodstuffs imported (from the internal market or third countries) or brokered by the operator meet the requirements laid down in food legislation also as regards their packaging materials (e.g. a statement in the procurement contract or product specifications).

2. Other food establishments

The operator does not have adequate knowledge about the quality and suitability of the packaging materials and other materials they use. For example:

- Declarations of compliance are missing for several of the materials used by the operator, or are clearly out-of-date (e.g. more than three years old) or contain completely deficient information, and the operator has not taken any action to get/renew them. Small scale operation (articles procured from a cash and carry wholesaler or a retail store): the operator does not have knowledge about the suitability of the majority of the articles they use.
- The packaging and food contact materials used in the operation are not suitable for their purpose of use or they are used in conditions for which they are not suitable (e.g. temperatures of use are too high compared with the temperatures indicated in the declaration of compliance, or food contact materials are used for food types for which they are not suitable, or the foodstuff does not meet the requirements laid down in provisions concerning additives, because of the migration of a dual use additive).
- The operator is unable to demonstrate that the prepacked foodstuffs imported (from the internal market or third countries) or brokered by the operator meet the requirements laid down in food legislation also as regards their packaging materials (e.g. a statement in the procurement contract or product specifications).


POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

1. Retail stores and catering facilities

It is obvious that food contact materials are used in a way that endangers food safety. The operator has no knowledge about the quality or suitability of the packaging materials and food contact materials they use, and has failed to take corrective actions despite being requested to do so, or the operator is aware of the defects in smell and taste caused to the product by the food contact material, but has failed to initiate a product recall process.

2. Other food establishments

It is obvious that food contact materials are used in a way that endangers food safety. The operator has no knowledge about the quality or suitability of the packaging materials and food contact materials they use, and has failed to take corrective actions despite being requested to do so.
For example:

- The operator does not have any declarations of compliance for packaging and food contact materials. Small scale operation (articles procured from a cash and carry wholesaler or a retail store): the operator has not verified in any way the suitability of food contact materials (no certificates, no glass and fork symbol, not indicated in the name or by the nature of the article.)
- The operator is aware of the defects in smell and taste caused to the product by the packaging material or other food contact material, but has failed to initiate a product recall process

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation of the European Parliament and of the Council on materials and articles intended to come into contact with food (EC) No 1935/2004
- Commission Regulation on plastic materials and articles intended to come into contact with food (EU) No 10/2011
- Finnish Food Act 23/2006
- Evira's Guide for control of food contact materials, No 17018/3

Updates in version 5

- Number of revision corrected

15 Food and By-product Deliveries

15.1 Reception of Foodstuffs and Commercial Documents

To be taken into consideration:

- This Guideline is applied to all establishments.
- The commercial documents of fishery products requiring a freezing treatment due to the parasite risk are evaluated in point 8.8.
- Information accompanying live fishery products is evaluated in point 9.2.
- The own-check of egg-packing centres as concerns the salmonella results of egg production is evaluated in point 15.2.
- Indications related to the traceability of commercial documents are evaluated in point 16.1.
- The commercial documents of beef are evaluated in point 16.2.
- The commercial documents of fishery products exempt from the dioxin requirements are evaluated in point 16.4.
- The tests carried out on raw milk batches received at the establishments (test for residues of antimicrobial agents, temperature measurement and organoleptic assessment) are evaluated in point 17.9.
- Temperature management during the transport of carcasses dispatched from the establishment is evaluated in point 6.7.

Matters to be controlled:

- The practices followed at the establishment in the reception of foodstuffs and the acceptance inspections carried out by the establishment (e.g. temperature measurements), including documentary checks
- Temperature control of received carcasses
- Records maintained of acceptance inspections (measurement results, deviations, corrective actions, complaints, returned foodstuffs, sampling results, etc.)
- Storage and controllability of commercial documents related to received foodstuffs (documents can be in electronic form)
- The adequacy and suitability of own-check activities, and the own-check control plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check.

EXCELLENT

Operations comply with requirements.

The reception of foodstuffs is implemented in a manner that ensures their safety is not impaired. For example, the cold chain is not broken and food packages remain clean and undamaged.

Commercial documents related to received foodstuffs are stored according to requirements and they are readily available for control by the authority.

The establishment detects through own-check activities any deviations, such as batches of foodstuffs with an incorrect temperature or with shortcomings in

commercial documents and carries out, and if appropriate records corrective actions appropriately.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:
- There are some minor shortcomings in the storage or controllability of commercial documents.
- There are some minor shortcomings in the records related to acceptance inspections as concerns deviations and corrective action taken, but corrective actions have been appropriate and adequate.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:
- The establishment fails on occasion to carry out acceptance inspections on received foodstuffs.
- Deviations found in acceptance inspections do not give rise to adequate corrective actions.
- Specific handling requirements laid down in commercial documents are not observed and food safety is impaired.
- Practices followed as concerns the reception of foodstuffs result in impaired safety of foodstuffs.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to rectify the issues within the set deadline.

For example:
- The establishment fails repeatedly to carry out acceptance inspections on received foodstuffs or does not carry out inspections at all.
- Deviations found in acceptance inspections are not taken into consideration.
- Practices followed as concerns the reception of foodstuffs jeopardise food safety.
- Specific handling requirements laid down in commercial documents are not observed and food safety is jeopardised.
- Commercial documents related to received foodstuffs are not stored.

Legislation and guidelines (with any amendments) pertaining to the subject:
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

15 Transport of Food and By-products

15.2 Management of Salmonella Certificates in Egg Production

To be taken into consideration:

- This Guideline is applied to all egg-packing centres.
- Egg producers shall maintain records of the dates and results of tests carried out within the salmonella control programme as well as of the dates and examination results of examination visits made by the municipal veterinarian. When the results of the tests or examinations are available, the operator in primary production shall submit the information to the egg-packing centre to which eggs are delivered from the place of primary production.

Matters to be controlled:

- The own-check plan provides a description of how the egg-packing centre verifies that eggs are delivered to the packing centre from production farms that meet the requirements laid down in the salmonella control programme.
- The egg-packing centre monitors the compliance of the egg producers with the salmonella control programme also in practice and verifies that results of tests and examinations are submitted timely to the packing centre.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

- The own-check plan provides a description of how the egg-packing centre verifies that eggs are delivered to the packing centre from production farms that meet the requirements laid down in the salmonella control programme.
- The egg-packing centre has a system/practice in place for monitoring the submission of test certificates by the egg producers within the salmonella control programme to the packing centre.
- All the egg producers delivering eggs to the egg-packing centre submit salmonella test certificates timely.
- The egg producers take salmonella samples in compliance with the national salmonella control programme.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- The own-check plan provides a description of how the egg-packing centre verifies that eggs are delivered to the packing centre from housing farms that meet the requirements laid down in the salmonella control programme.
- The egg-packing centre has a system/practice in place for monitoring submission of test certificates by the egg producers within the salmonella control programme to the packing centre.
- All the egg producers delivering eggs to the egg-packing centre do not submit salmonella test certificates timely although the producers have been informed

about the matter. The egg-packing centre needs to request salmonella sampling certificates separately from the producers.
- However, the egg producers have taken the salmonella samples in compliance with the national salmonella control programme, although test certificates have not been submitted timely to the egg-packing centre.
- Salmonella samples have not been taken exactly in compliance with the schedule, but the required number of samples have been taken, however.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:
- The own-check plan does not provide a description of how the egg-packing centre verifies that eggs are delivered to the packing centre from housing farms that meet the requirements laid down in the salmonella control programme, or the description is inadequate. However, implementation of the salmonella control programme has been monitored and the test results are available at the egg-packing centre for control.
- Some of the egg producers delivering eggs to the egg-packing centre have not taken all the requirement salmonella samples, i.e., they have not fully complied with the national salmonella control programme with respect to salmonella sampling.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:
- The egg-packing centre does not have a system/practice in place for monitoring submission of test results by the egg producers within the salmonella control programme to the packing centre.
- The egg-packing centre has not reacted to the lack of test results on salmonella samples.
- Some of the egg producers delivering eggs to the egg-packing centre do not comply with the sampling requirements of the national salmonella control programme at all, and the egg-packing centre accepts eggs from these producers despite of this.

Legislation and guidelines (with any amendments) pertaining to the subject:
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments, 795/2014; Annex 3, Chapter 2. point 2.11
- Decree of the Ministry of Agriculture and Forestry on primary production, 1368/2011, Annex 2, Chapter 5
- Decree of the Ministry of Agriculture and Forestry on salmonella, 1037/2013
- Evira's Guide 15312/2 Salmonella control in poultry

Updates in version 2

- The title of the Guideline has been changed: "Documents Related to Salmonella Results" has been changed into "Management of Salmonella Certificates".

15 Transport of Food and By-products

15.3 Dispatch of Foodstuffs, Commercial documents and Transport Conditions

To be taken into consideration:

- This Guideline is applied to all establishments.
- If another operator (e.g. a registered food premises) is responsible for transport operations, the authority controlling the carrier is responsible for the control of the transport operations. However, the establishment purchasing transport services shall verify in this case that the carrier has been registered as a food premises and is thus covered by control. In addition, the in-house control of the establishment purchasing transport services shall provide a description of the organising of transport operations.
- Drivers who handle unpackaged perishable foodstuffs (e.g. carcasses) shall have a proficiency certificate that corresponds to Evira's model certificate. This is evaluated in point 4.6.
- Temperatures during transport are evaluated in point 15.4.
- The labelling of dispatched foodstuffs is evaluated in point 13.1.
- The commercial documents of fishery products requiring a freezing treatment due to the parasite risk are evaluated in point 8.8.
- Indications related to the traceability of commercial documents are evaluated in point 16.1.
- The commercial documents of beef are evaluated in point 16.2.
- The commercial documents of fishery products exempt from the dioxin requirements are evaluated in point 16.4.

Matters to be controlled:

- Commercial documents (can be in electronic form). Commercial documents are also checked for indications of any specific handling requirements laid down by the authority (e.g. requirement for heating of carcasses or meat), information on any conditions and restrictions laid down for foodstuffs to which specific conditions related to placing on the market are applied, indications of the heat treatment of milk and cream used as raw material, as well as the ability to link documents to the foodstuffs that they concern. Information on the country of origin is not needed in the commercial documents for meat, minced meat and meat preparations, if the information is provided in the labelling of the product.
- Practices followed at the establishment in the dispatch of foodstuffs
- Cleanliness and intactness of load compartment or receptacle as well as transport containers
- Adequate protection and separation of foods from other products being carried
- Means of transport classified according to the ATP Agreement are used as the means of transport for international carriage of perishable foodstuffs.
- The adequacy and suitability of own-check activities, and the own-check control plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The dispatch and transport of foodstuffs is implemented in a manner that ensures their safety is not impaired. For example, foodstuffs are protected and/or adequately separated from other carried products during transport to ensure that there is no risk of contamination of the foodstuffs; structures and surfaces that come into contact with foodstuffs are suitable for the purpose; and load compartments, receptacles or transport containers are adequately clean and undamaged.

Commercial documents provide the information required by legislation, documents are stored in compliance with requirements, and they are readily available for control by the authority.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in the storage or controllability of commercial documents.
- There are some minor shortcomings in the protection or separation of foodstuffs but they do not impair food safety.
- Load compartments show some minor uncleanliness that does not impair food safety.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- Foodstuffs are not adequately protected or separated from other products carried, which causes the risk of some smell or flavour being transferred from the other products to the foods.
- Products or goods that impair food safety are transported together with food products.
- Load compartments or receptacles show uncleanliness that impairs food safety.
- Commercial documents do not comply with regulatory requirements.
- Means of transport used for international transport of perishable foodstuffs do not have valid ATP classification.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- Foodstuffs are transported clearly inadequately protected or completely unprotected in cases where protection is necessary, or foods are placed among other products carried in a way that jeopardises food safety.
- Products or goods that jeopardise food safety are transported together with unpackaged food products.
- Load compartments or receptacles are extremely dirty or have other defects which jeopardise food safety.
- Commercial documents related to foodstuffs dispatched by the establishment are not stored.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Agreement on the international carriage of perishable foodstuffs and on the special equipment to be used for such carriage 48/1981 (ATP Agreement)
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014

Updates in version 2:

- Text concerning the indication of information on country of origin in commercial documents made more specific in the Guideline.

15 Transport of Food and By-products

15.4 Temperature Management in Food Transport

To be taken into consideration:

- To be applied to the transport conditions when control concerns food transport operations organised by the establishment, with the own-check plan related to transports included in the own-check plan prepared and implemented by the supplier or the receiver of the foodstuffs, and in the approval of the establishment.
- When another operator (a registered food premises) is responsible for transport operations and to the extent that transport operations are not covered by the own-check plan of the establishment, transport conditions are evaluated according to the Evaluation Guidelines that pertain to registered food premises. The evaluation does not in that case concern the operation of the establishment, but the operation of the carrier, and responsibility for control rests with the authority that controls the carrier. However, the establishment shall have a transport agreement and a description of the organising of transport operations in the in-house control plan, as well as commercial documents.
- The Guideline is only applied when the products being transported require cold or hot storage.
- A recording temperature-monitoring system is required in the transport of quick-frozen products and in the transport of perishable products with a duration of more than two hours.
- A recording temperature monitoring system is not required in distribution of foods of less than 2 hours in duration or distribution of foods directly from the food establishment to the consumer. In this case, the own-check plan shall indicate how it is verified that food temperatures remain within the permissible limits.
- Monitoring and recording equipment that meets the requirements laid down in the Commission's quick-freezing regulation and in the ATP Agreement must be used in the transport of quick-frozen products and transport operations covered by the ATP Agreement.
- Temperature control of dispatched carcasses is evaluated in point 6.7.

Matters to be controlled:

- Temperature management in food transport
- Records of temperature deviations and corrective actions
- Temperature monitoring system
- The adequacy and suitability of in-house control, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

- Product-specific temperatures are under control in food transport.
- Temperature deviations during transport remain within the regulatory limits.
- A recording temperature monitoring system is used in food transports or means are presented in own-check for the management of the required temperatures.

- The measurement accuracy of the measurement equipment is controlled on a regular basis.
- Deviations and corrective actions have been recorded. Corrective actions have been adequate and appropriate.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in the following cases where:

- There are some minor shortcomings related to the temperature measurements referred to in own-check.
- There are some minor shortcomings in the records of deviations and corrective actions. However, corrective actions have been adequate and appropriate.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- Transport temperatures frequently deviate by slightly more than the permissible limits.
- Monitoring and recording equipment that meets the requirements laid down in the Commission's quick-freezing regulation and in the ATP Agreement is not used in the transport of quick-frozen products and transport operations covered by the ATP Agreement.
- Temperature monitoring equipment is not calibrated on a regular basis in accordance with standards or the instructions of the equipment manufacturer.
- Deviations have not been recorded although it becomes known that deviations have occurred or corrective actions taken because of deviations have been inappropriate or inadequate or no information is available about them.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The management of transport temperatures is not under control and nothing is being done to rectify matters.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 37/2005 on the monitoring of temperatures of quick-frozen foodstuffs

- Agreement on the international carriage of perishable foodstuffs and on the special equipment to be used for such carriage 48/1981 (ATP Agreement)
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on quick-frozen products, 818/2012
- Decree of the Ministry of Agriculture and Forestry on food hygiene in registered food premises, 1367/2011
- Evira's Guide 16015: Guide on Food Hygiene in Registered Food Premises

Updates in version 2:

- The title of the Guideline has been changed: "Management of Transport Temperatures" has been changed into "Temperature Management in Food Transport".

15 Food and By-product Deliveries

15.5 Dispatch of By-products, Commercial Documents and Transport Conditions

To be taken into consideration:

- This Guideline is applied to all approved establishments.
- Control of by-product transport operations is included within the scope of the control of the establishment and to be evaluated in compliance with this Guideline when the establishment carries out transport operations as their own operation and transport operations are covered by the approval of the establishment. The establishment is then responsible for transport operations and the own-check plan related to transport is included in the own-check plan of the establishment.
- If the transport of by-products has been outsourced to another operator (that can be another food establishment, a registered food premises or other operator in the transport branch), the authority that controls the carrier is responsible for the control of transport conditions. The dispatching establishment shall have a description of the organising of transport operations in their own-check plan.
- Regardless of whether the establishment arranges the transport itself or outsources it, the dispatching establishment shall always have records of the dispatched by-products as well as copies of the commercial documents (transport documents) related to the dispatched by-products.
- The purpose of this point is to evaluate the transport of by-products insofar that it may cause a risk to food safety. This means that e.g. the separation of by-products of different categories during transport is not evaluated.
- Other by-product operations of the establishment that are covered by the Food Act are evaluated in point 5.7 "Hygiene in Handling and Storage of By-products".
- Operations covered by legislation related to by-products are evaluated in point 5.8 "Production and Traceability of By-products". The results of the evaluations based on Guideline 5.8 are not presented in the Oiva report, but only in the inspection report.

Matters to be controlled:

- Identification marks of dispatched by-products to the extent that they distinguish the transported material from foodstuffs
- Commercial documents (transport documents) to the extent that they distinguish the transported material from foodstuffs
- Intactness of transport containers and means of transport
- Separation of by-products from foodstuffs during transport

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- The dispatched by-products (packaging, container or vehicle) have identification marks which indicate that the dispatched material consists of animal by-products, and there is no risk of confusion with foodstuffs.
- Packages, containers and load compartments are undamaged.

- In combination transport, by-products are carried packaged and adequately separated from foodstuffs to eliminate any risk of contamination of foodstuffs.
- The transport document of by-products indicates clearly that the transported material comprises by-products.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- The transport documents of by-products do not always indicate that the transported material comprises by-products, or the means of transport or transport containers on occasion do not bear an indication of by-product transport. However, even in these cases the transported by-products are identifiable as by-products on the basis of the indications provided on the transport containers and there is no risk of confusion with foodstuffs.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- An identification intended for foodstuffs is used in commercial documents of by-products.
- Transport containers or packages are damaged, which impairs the hygiene level at the establishment and during transport.
- By-products are transported together with foodstuffs, but adequate separation has not been implemented and food safety is impaired.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- All information describing the dispatched product as a by-product excluded from the food chain is missing from commercial documents or transport containers/packages, and a risk of confusion with foodstuffs exists in combination transport of by-products and foodstuffs.
- The operator has failed to fulfil the orders issued with the grade to be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 1069/2009 on by-products, Articles 4, 21-23
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Annex II, Chapter IV
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Annex 3
- Evira's Guide 16010: Handling and control of by-products at food establishments

Updates in version 4:

- Point three in to be taken into consideration has been defined.

15. Transport of Foodstuffs

15.6 Compliance of International Transport

This evaluation is at present not presented in the Oiva report, but only in the control report.

To be taken into consideration:

- This Guideline is used when controlling ATP-classified transport equipment, i.e., transport equipment within the scope of the ATP Agreement. The International ATP Agreement pertains to the international carriage of perishable foodstuffs and to the special equipment used for such carriage.
- In practice, almost all international land carriages of quick-frozen foodstuffs are ATP carriages. The majority of the carriages of chilled foodstuffs are also included within the scope of the agreement.
- The ATP Agreement primarily applies to land transport, but also sea crossings of less than 150 km without transloading are covered by the agreement. In addition, transport equipment classified according to the ATP Agreement can also be used for national carriage of foodstuffs. The ATP Agreement is to be complied with, if ATP-classified transport equipment is used for national carriage, but national temperature requirements are to be applied to such carriage.
- Temperatures during carriage according to the ATP Agreement: During carriage, a brief rise of the temperature of the surface of the foodstuffs of not more than + 3°C can occur during the defrosting of the evaporator of the refrigeration equipment.
- Temperatures during carriage according to the ATP Agreement: Perishable foods: The temperature requirement varies according to the foodstuff; the temperature of melting ice for fish, +2°C for minced meat, +4°C for game, +6°C or the temperature indicated on the documents for perishable foodstuffs, +7°C for red meat. The temperature requirements applied to national carriage of perishable foodstuffs are laid down in Chapter 3 of Decree 1367/2011.
- Quick-frozen foodstuffs: Ice cream -20°C, quick-frozen fish, fish products, molluscs and crustaceans and all other quick-frozen foodstuffs -18°C.
- Frozen foodstuffs: Frozen fish, fish products, molluscs and crustaceans -18°C, frozen foodstuffs -12°C and butter -10°C.
- The temperature requirements applied to national carriage of quick-frozen foodstuffs are presented in Section 9 of Decree 818/2012, and for frozen colostrum in Decree 1368/2011.
- The temperature recording equipment shall meet the requirements of EN 12830 and 13485. The temperature recording equipment shall be calibrated in compliance with the manufacturer's instructions.

EXCELLENT

Operations comply with requirements.

The transport equipment has an ATP certificate which has been issued by its country of registration.

The ATP certificate is consistent with the data of the transport equipment.

The ATP classification and the markings are valid and up-to-date.

The type plate of the transport equipment is easy to read (usually on the front wall outside the body).

The wall structures are intact and clean.

The seals are intact and clean.

The in-house control plan is adequate (need not be carried in the vehicle).

The equipment is provided with a temperature recording device which meets the requirements of EN 12830 and/or 13485.

Temperatures comply in international carriage with the temperatures specified in the ATP Agreement, and in national transport with Decrees 818/2012 and 1367/2011.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The wall structures are not completely clean and they show some signs of wear, but this does not endanger food safety.

The seals are not completely clean and/or they show some damage, but this does not affect the temperature in the load area.

The in-house control plan is otherwise adequate, but it needs to be updated.

The equipment is provided with a temperature recording device which meets the requirements of EN 12830 and/or 13485 in the carriage of quick-frozen foodstuffs.

Temperatures comply with the ATP Agreement, a brief rise in the temperature of the surface of the foodstuffs of not more than + 3°C has occurred in international carriage of foodstuffs (during the defrosting of the evaporator of the refrigeration equipment). Temperatures comply in national carriage with Decrees 818/2012 and 1367/2011 and temperature deviations are within the limits specified in Section 9 of Decree 818/2012
and Section 11 of Decree 1367/2011.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The transport equipment has an ATP certificate issued by its country of registration, but the ATP certificate is not consistent with the data of the transport equipment.

The ATP classification and markings are out-of-date.

The wall structures are damaged (e.g. a hole or a fracture).

The seals are damaged.

There is no in-house control plan.

The temperature recording device does not meet the requirements of EN 12830 and/or 13485.

Temperature deviations:

1) International carriage: the temperature of quick-frozen foodstuffs is more than -15 degrees, but their quality has not been affected and they are acceptable for further processing. However, they may not be re-frozen or sold as quick-frozen products to consumers.
2) National carriage: the surface temperature of frozen foodstuffs is at least +18°C. A Brief increase to more than -15°C or an increase that cannot be considered brief to at most -15°C. They may not be re-frozen, stored or used as such/
unprocessed, but the quality of the quick-frozen product has not been affected.
3) International carriage: A brief temperature deviation on the surface of the perishable foodstuffs compared with the temperature requirements defined in Annex 3 of the ATP Agreement is either more than 3°C, or no more than 3°C,

but cannot be considered to be brief. The foodstuffs may no longer be stored or used as such/unprocessed. Their quality has not been affected.

4) National carriage: A brief temperature deviation of perishable foodstuffs compared with the temperature requirements defined in Section 3 of Decree 1376/2011 is either more than 3°C, or no more than 3°C, but cannot be considered to be brief. The foodstuffs may no longer be stored or used as such/unprocessed. Their quality has not been affected.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Transport equipment with ATP classification does not have an ATP certificate issued by its country of registration.

There is no type plate on the transport equipment (usually on the front wall outside of the body).

The wall structures are so badly damaged (e.g. a hole or a fracture) that the specified temperature is not achieved.

A type plate is affixed to the transport equipment although the equipment is not ATP classified.

The seals are so badly damaged that the specified temperature is not achieved.

There is no temperature recording device.

Temperature deviations:

1) In international carriage by more than 3 degrees from the temperatures specified in the ATP Agreement. The foodstuffs are not fit for use as food.
2) In national carriage: by more than +3 degrees from the temperature requirements laid down in Decree 818/2012 (quick-frozen products) or Section 3 of Decree 1376/2011. The foodstuffs are not fit for use as food.

Legislation and guidelines pertaining to the topic:

- Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for Such Carriage (48/1981)
- Decree (971/2006) of the Ministry of Social Affairs and Health on the National Implementation of the Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage, amended by Decree 120/2010 of the Ministry of Agriculture and Forestry
- Finnish Food Act 23/2006, Section 11
- Decree of the Ministry of Agriculture and Forestry on Food Hygiene in Registered Food Premises, 1367/2011, Sections 5, 10 and 11
- Decree 818/2012 of the Ministry of Agriculture and Forestry on Frozen Foodstuffs, Section 9
- Evira's Guide on food hygiene in registered food premises 16025, Chapter 3, Section 6

16 Traceability and Recalls

16.1 Traceability of Foodstuffs

To be taken into consideration:

The control of this point covers all operators in the food sector.
Consumers are not included in traceable customers.

The traceability of foodstuffs must be demonstrated according to the "one-step back" and "one step forward" approach. This implies that the operator must be able to identify their supplier of raw materials and the customers to whom they have delivered the products. The date of procurement and the date of dispatch must also be known. Operators in the food business shall have in place a system that enables them to link information on received and dispatched consignments of foodstuffs with adequate accuracy. The decision of the level of detail of the system should be left for the food business operator to make, based on the nature and scope of the food business.

The term lot stands for a unit of foodstuff that belongs to a practically identical production, manufacture (= "production batch", "batch") or packaging characteristics. The lot is determined and the indication is affixed by the producer, manufacturer or packager of the foodstuff or the first seller established within the European Union. The size of a batch cannot exceed the production of one day. A consignment (delivery, shipment) can contain several lots.

It is recommended that point 13.1 General Labelling is controlled at the same time.

Matters to be controlled:
The implementation of own-check is evaluated by controlling the following matters, on a total of 1 – 3 foodstuffs from different food groups, but taking the nature and scope of operation into consideration, however:

- The operator is able to demonstrate where the foodstuffs have come from and when, and where they have been delivered and when, and is able to link, with adequate accuracy (= the controlling inspector is convinced that they are adequate linkable), information on received lots and information on dispatched lots.
- Commercial documents (primarily delivery notes and corresponding commercial documents) as well as the information systems of the company. Where necessary, (also) waybills, received and sent invoices and/or stock records or some other link between a foodstuff and a commercial document. A hard copy of an electronic document need not accompany the foodstuff.
- Documents can be linked to procured and delivered foodstuffs.
- Documents can be linked to the labelling of foodstuffs.

EXCELLENT

Operations comply with requirements

The operator is able to demonstrate where the foodstuffs have come from and when, and where they have been delivered and when.

The operator is able to identify a natural or legal person who has delivered the foodstuff or a substance which is intended to or can be assumed to be added in the foodstuff.

Traceability can be verified by a comparison of documents and other information with e.g. indications or identifying information attached to the foodstuff.

The information required to be provided on consignments of foodstuffs of animal origin is appropriate.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers

There are some individual deficiencies in operations or documents that affect traceability, or some minor shortcomings, but notwithstanding these, the fulfilment of the traceability requirements for foodstuffs can be verified. Individual deficiencies or minor shortcomings include, for example:

- The delivery notes accompanying foodstuffs dispatched by the operator do not present the operator's contact information, but the operator can still be reliably identified in some other way (e.g. logo and other information).
- The consignment documents do not indicate the reference code that identifies a lot or consignment of foodstuffs of animal origin. The validity of the information can be verified by connecting and comparing other information.
- The documents printed from the information system do not show e.g. dates and the operator has not recorded them separately. The validity of the information can be verified by connecting and comparing other information (dates and other required information is linkable).
- There are some minor shortcomings as concerns the linking of documents and labelling.
- In general; minor shortcomings regarding a systematic approach, or an occasional inaccuracy in documents or stock records, despite of which, however, it is possible to verify where the foodstuff has come from and when and/or where it has been delivered and when.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time

The operator has some clear defects/shortcomings in the management and verification of traceability which need to be rectified within a set deadline. Such defects/shortcomings include, for example:

- The operator (or e.g. the accountant) do not possess commercial documents from several deliveries of a foodstuff and the operator must request them from the supplier and/or recipient of the foodstuff.
- Key documents are missing for three or more deliveries implying that it is no longer a question of an occasional defect. The management of traceability cannot be satisfactorily demonstrated.
- The reference code that identifies the lot or consignment is missing at several incidents from the information provided on foodstuffs of animal origin

dispatched by the operator or some other required information of animal origin (description of foodstuffs, amount, etc.) is missing to an essential extent.
- The documents on received foodstuffs systematically contain indications that are open to interpretation or are otherwise unclear (names, supplier or quality of foodstuff, delivery date) so that traceability is not satisfactorily demonstrated. The operator is unable to demonstrate that they have ordered the supplier or suppliers to rectify the matter.
- There are shortcomings requiring rectification without delay as concerns the linking of documents and labelling.
- In general; information is missing to the extent that it is no longer a question of an individual defect, and thereby the management of traceability is not satisfactorily demonstrated. Where information is missing from documents related to received foodstuffs, the operator must be able to demonstrate that they have observed the shortcoming and reacted to it (e.g. a written complaint to the supplier).

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The operator is not able to identify lots or show where the foodstuff has come from or which foodstuff is concerned. Such issues include, for example:

- commercial documents, documentation or labelling are not provided on foodstuffs, making it impossible to identify or trace the foodstuffs
- the suppliers of received lots and/or the recipients of delivered lots cannot be identified.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; Articles 3 and 18
- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin, Articles 5, 6 and 7, ANNEX II, SECTION I
- Commission Implementing Regulation (EU) No 931/2011, on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin, Article 3
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, Article 9
- Finnish Food Act 23/2006, Sections 9, 17 and 18
- Decree 795/2014 of the Ministry of Agriculture and Forestry on food hygiene at approved establishments, Sections 3, 4 and 5, ANNEX 1, Chapter 4, ANNEX 3, Chapter 1.3
- Decree of the Ministry of Agriculture and Forestry on the provision of food information to consumers 834/2014, Section 3, sub-section 4, and Section 5

Updates in version 2:

- Added in the point To be taken into consideration: A description of a lot and a consignment, and more specific text on the operators that the control covers.

- Added in the point To be controlled: the controlling inspector is convinced that they are adequate linkable, and the linking of documents with the labelling of foodstuffs.
- Added under the grade "Good": There are some minor shortcomings as concerns the linking of documents and labelling.
- Added under the grade "To be corrected": There are some shortcomings requiring rectification without delay as concerns the linking of documents and labelling.
- Added under the Legislation: Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, Article 9, and Finnish Food Act 23/2006, Section 9

16 Traceability and Recalls

16.2 Labelling and Traceability of Beef

To be taken into consideration:

This point is controlled, when the operator

- slaughters bovine animals or cuts beef
- manufactures, has manufactured for it and/or packages food products
- imports or brokers (from the internal market or third countries) food products:
- stores, markets or exports food products.

Beef must be traceable between establishments and operators, as well as at all stages of the preparation and production of meat in approved food establishments and registered food premises.

The labelling system laid down for beef anf beef products apply to chilled and frozen beef which is considered to include:

- carcass and quarters
- cut beef
- minced beef
- thick skirts
- neck, where it is used to make minced meat.

Fat removed from the carcass before weighing, muscles of the head, viscera and ongue, for example, are excluded from the scope of the beef labelling system.

The labelling provisions for beef and beef products do not apply to raw meat preparations and meat products. However, cut or minced beef intended for use as raw material for them must be traceable.

It is recommended that point 13.4 Labelling of Meat Required by Specific Legislation is controlled at the same time.

Matters to be controlled:

The implementation of own-check is evaluated by random checks, on e.g. 1-3 different lots/raw materials/products, taking the scope and nature of operations into consideration:

- The system regarding labelling beef and beef products and the associated documents and records. The evaluation of the following matters – implementation in practice and description in the own-check plan:
  - a description of the process of beef and how different lots of beef are kept separate, and of the associated work stages;
  - a description of the tracing and labelling of beef;
  - a description of the determination of the lot identification mark and the markings used in the labelling of beef;
  - records of received and dispatched and/or sold beef, including the amount and the markings;
  - in slaughterhouses, recordings of bovine animals brought in for slaughter;
  - a plan for the recall of incorrectly marked products from the market, and the associated informing plan;
  - a plan for the familiarizing of the personnel in the system regarding labelling beef and beef products; and
  - the name of the person responsible for the system regarding labelling beef and beef products.

- Documents related to traceability (i.e. commercial documents, such as delivery notes and similar, and the information systems of the company).

EXCELLENT

Operations comply with requirements.

Beef is at all stages of handling, production or manufacturing traceable by individual lot to the operators who have delivered it and to the operators to whom it has been delivered. Beef is appropriately labelled and traceable by individual lot to the individual lots it originates from. The operator has records of received and dispatched and/or sold beef, including the amounts and the indications or marks. The labelling and marking of lot is used appropriately. The own-check plan includes a written description, complete with all the required points, of the system regarding labelling beef and beef products.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Beef is traceable to the operators who have delivered it and to the operators to whom it has been delivered. Beef is traceable to the individual lots it originates from. There are some minor shortcomings affecting traceability in labelling, documents, records, lot identification marks or internal traceability. The own-check plan includes a written description of the system regarding labelling beef and beef products, but it is not up-to-date or some essential required point is not included in it (but is implemented in practical operations, however). These include, for example:

- Required markings on several carcases or quarters or thick skirts are not clear, but can be interpreted as a whole (approved food establishments).
- Documents related to traceability are unclear or deficient in part, but the validity of the information can be verified by connecting and comparing other information.
- The separation (internal traceability) of individual lots of beef does not meet the requirements of the system regarding labelling beef and beef products completely.
- The ability to link beef lot information stored in the electronic information system to products is open to interpretation. The validity of the records and information (amounts, dates and other required data are linkable) can be verified by connecting and comparing other data.
- The lot identification mark and/or labelling is not used in a way that is systematic or linkable, or is too open to interpretation in some parts.
- The description provided in the own-check plan of the tracing and labelling of beef is not completely up-to-date, or some required point is missing.
- In general; minor shortcomings regarding a systematic approach in operation, or an individual inaccuracy in commercial documents or records, despite of which, however, it is possible to verify the effectiveness of the system regarding labelling beef and beef products and the verifiability of traceability.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are several shortcomings related to the traceability of beef to the operators who have delivered it and to the operators to whom it has been delivered. Beef cannot in all respects be traced with adequate certainty to the individual lots it originates from. The traceability of beef by lot is not under control due to significant shortcomings in labelling, lot marking, records or commercial documents. The own-check plan provides a written description of the system regarding labelling beef and beef products, but it is not up-to-date in its essential parts, or several required points are missing from it, or a written description is not provided at all. Such defects/shortcomings include, for example:

- Information of lots of beef of several operators is deficient.
- Invoices and lot identification markings related to deliveries can be presented and linked to the lots, but commercial documents (what, when, where) are missing.
- Required health marks are missing from a significant part of carcasses or quarters or thick skirts, or the health marks are so unclear as a whole that they cannot be interpreted (approved food establishments).
- The ability to link lot information stored in the electronic information system to products is highly uncertain. The validity of the data (dates and other required data are linkable) cannot be verified with adequate certainty by connecting and comparing other data.
- There is no system in place as concerns the use of a lot identifying mark and linking it to products, or the system is not used.
- The description provided in the in-house control plan of the tracing and labelling of beef is not up-to-date in almost any respects, or several required points are missing or a written description is not provided at all.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Beef cannot be traced and/or no indications or lot markings or health marks are provided on beef. Such shortcomings include, for example:

- Beef cannot be identified (is it beef at all) or traced in any way.
- The operator is not able to identify or indicate where beef has been received from or where it has been delivered to.
- There is no link at all between the lot identificatio of the meat and the animal or animals in question. There are no documents, labelling or records.
- The records of the operator concerning beef that has been received and dispatched and/or sold, including the amount and labelling of the beef, is completely uncertain or false and gives rise to justified suspicions of even knowingly committed fraud.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 1760/2000 of the European Parliament and of the Council establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97, Article 3 and Articles 12-14
- Commission Regulation (EC) No 1825/2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products, Articles 1-5
- Commission Regulation (EC) No 275/2007 amending Regulation (EC) No 1825/2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products
- Commission Implementing Regulation (EU) No 931/2011, on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin, Article 3
- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin, Articles 5, 6 and 7, ANNEX II, SECTION I
- Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; Article 18
- Finnish Food Act 23/2006, Sections 17 and 18
- Decree No 1391/2006 of the Ministry of Agriculture and Forestry on the identification and registration of bovine animals
- Decree No 434/2008 of the Ministry of Agriculture and Forestry on the system regarding labelling beef, Sections 1 - 3
- Decree 795/2014 of the Ministry of Agriculture and Forestry on food hygiene at approved establishments, Sections 3, 4 and 5, ANNEX 1, Chapter 4, ANNEX 3, Chapter 1.3
- Evira's Guide 16024/1 on the labelling and traceability of beef

Updates in version 2:

- Added: the beef that the compulsory beef labelling system pertains to.
- Updated: the title of Guideline 13.4.
- Added in the point Matters to be controlled: a description of the system regarding labelling beef and beef products in the own-check plan.

16 Traceability and Recalls

16.3 Traceability of Sea-caught Fish and Fishery Products

At present, the evaluation result is not presented in the published document, i.e. the Oiva report. The control referred to in this point is not part of food safety control. The municipal food control reports any suspected violations and detected violations to the Agency for rural Affairs (cf. Act 1188/2014, Section 35, and Government Decree 1442/2014).

To be taken into consideration:

The control referred to in this point is control required under legislation on the common fisheries policy of EU. It is therefore to be taken into consideration that the terminology differs from the terminology used in food legislation, the term "lot", for example. In legislation related to the fishery policy, "lot" does not refer to a production lot.

"Lot" refers to a quantity of fishery and aquaculture products of a certain species and of the same presentation and originating in the same relevant geographical area and the same fishing vessel or group of fishing vessels, or the same aquaculture production unit. A "lot" is registered, when it is weighed (= weighing of the catch of fish after landing of catch). In this Guideline the term "maiden lot" is used of that weigh-registered lot for the sake of clarity.

The aforementioned sea-caught lots (maiden lots) of fishing/aquaculture products must be traceable by every operator in the chain directly to the catching/harvesting of the lot from all stages of production, processing and distribution, up to and including retail sale.

Information of the maiden lot must be available for the authority to examine at any time.
"Any time" = during the control visit.

This point is to be controlled when the operator handles sea-caught fish caught in sea areas of the EU states or sea-farmed fishery and aquaculture products farmed in sea areas of the EU states.

The traceability requirements referred to in this point only apply to fishery and aquaculture products intended for human consumption.

The traceability requirements referred to in this point do not apply to the following product groups:

- live, fresh, chilled or frozen molluscs
- live, fresh, chilled or frozen crustaceans
- prepared or preserved fish
- caviar and caviar substitutes
- fishery and aquaculture products imported to the European Union from third countries
- fishery and aquaculture products caught in freshwater or farmed in freshwater.

The traceability requirements referred to in this point apply to the following product groups:

- live fish, fresh fish, chilled fish, frozen fish
- chilled or frozen fish fillets and other fish meat
- chilled or frozen minced fish or fish flour
- dried fish, salted fish or fish in brine, smoked and charred fish
- roe
- pellets.

It is recommended that point 13.5. Labelling of Fishery and Aquaculture Products Required by Specific Legislation, and point 16.4. Traceability of Fish and Fishery Products under Dioxin Derogation be controlled at the same time.

Matters to be controlled:
The fulfilment of the requirements is evaluated by controlling the following matters, on e.g. 1-3 different production lots and/or delivery lots / raw materials / products, taking the scope and nature of operations into consideration:

- Traceability of operators: The operator is able to identify the direct suppliers and buyers of fishery and aquaculture products (excluding individual consumers).

- Information of the maiden lot:
- The maiden lot created at the first sale shall be affixed with a lot-specific code and information of the maiden lot.
  - Information shall be affixed with lots in the form of a code, barcode or an identification device, such as an electronic chip, or using a labelling system.
  - "Affixed" means that information can be provided in e.g. a commercial document. It must be possible to link the commercial document and the maiden lot together by means of an identification code.
- Every production lot and delivery lot shall be affixed with the information of the maiden lot(s) they include throughout the chain of operators.
- If lots are merged, the information of the maiden lot(s) shall still be affexed the new combined production lot(s) or delivery lot(s).
- If the maiden lot is split into parts, the information of the maiden lot shall still be affexed to the new created production lots or delivery lots.

Thus it shall be possible to present throughout the whole chain for each production lot or delivery lot the following information on the maiden lot(s) included in it:

  - identification number
  - the external identification number and name of the fishing vessel or the name of the aquaculture production unit
  - the FAO alpha-3 code of each species
  - the date of catches or the date of production
  - the quantities of each species in kilograms expressed in net weight or, where appropriate, the number of individuals
  - the name and address of the operator.

- Information of the maiden lot(s) must be available for the authority to examine at any time.
- Commercial documents may be hard copies or in electronic format.

- Internal traceability. If the operator merges maiden lots or splits a maiden lot, the new formed lots must be documented and the documents stored systematically.
  - Operator-specific merging or splitting stages and information on them are not required as information that has to accompany deliveries in the chain.

EXCELLENT

Operations comply with requirements.

- The operator is able to identify the direct suppliers and buyers of fishery and aquaculture products (excluding individual consumers).
- Information of maiden lots is available for the competent authority to examine at any time.
- Lots are provided with a code or a corresponding identification.

- The required information of the maiden lot(s) are affixed to the lot.
- Internal traceability is effective (any merging or splitting is documented).

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The operator is able to identify the direct suppliers and buyers of fishery and aquaculture products (excluding individual consumers). There are minor shortcomings in the management of information on maiden lots or in internal traceability, but notwithstanding these, the accuracy of the information can be verified. Individual deficiencies or minor shortcomings include, for example:

- The operator has the information of the maiden lots, but the information is not available during the control visit, because the operator stores it in such a manner or in such a location that it is not available for the authority to examine at any time.
- The operator is able to rectify the manner of storage in practice during the same day. The use of a code or a information system is not quite systematic.
- There are some individual shortcomings in the documentation of internal traceability.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The operator has some clear defects/shortcomings in information on suppliers and/or buyers, clear defects/shortcomings in information of maiden lots or internal traceability which need to be rectified within a set period of time. Such defects/shortcomings include, for example:

- Clear shortcomings in the identification of direct suppliers or buyers.
- The operator itself do not have information on maiden lots. However, the operator is able to obtain the information afterwards from the suppliers of the products.
- Information of maiden lots is deficient at the time of control and the operator is not able to provide the information at all.
- The use of a lot-specific identification number or code or a information system is confusing or deficient to the extent that the linking of information of maiden lots to the production lot and/or delivery lot is uncertain.
- Information of maiden lots can be linked to the formed lots, but the operator does not use an identification number or code or a information system at all.
- There are significant shortcomings in the documentation of internal traceability.

->The municipal food control reports any suspected violations and detected violations to the Agency for rural Affairs (cf. Act 1188/2014, Section 35, and Government Decree 1442/2014).

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Such issues include, for example:

- The operator is not able to identify the direct suppliers or buyers of fishery and aquaculture products.
- Information of maiden lots is lacking in significant parts and the operator is unable to provide it.
- The operator does not affix a code or similar to the lot and has no information system in place.
- The operator splits or merges maiden lots systematically, but has no internal traceability system in place.

->The municipal food control reports any suspected violations and detected violations to the Agency for rural Affairs (cf. Act 1188/2014, Section 35, and Government Decree 1442/2014).

Legislation and guidelines (with any amendments) pertaining to the subject:

- Council Regulation (EC) No 1224/2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008 and (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006, Article 4 (2), (19), (29) and (22), Articles 57 and 58
- Commission Implementing Regulation (EU) No 404/2011 laying down detailed rules for the implementation of Council Regulation (EC) No 1224/2009 establishing a Community control system for ensuring compliance with the rules of the Common Fisheries Policy, Articles 66 and 67
- Regulation (EU) No 1379/2013 of the European Parliament and of the Council on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000, Chapter IV, Article 5
- Finnish Food Act 23/2006, Section 3 sub-section 20, Section 6 sub-section 4, Sections 17 and 34
- 1188/2014 Act on a system of sanctions for and monitoring of the Common Fisheries Policy, sub-sections 1, 2, 4, 7, 11, 12, 17, 35, 49 20 and 22, Section 50 and 53
- 1442/2014 Government Decree on suspected violations and suspected serious violations to be reported to the Agency for Rural Affairs
- News release of the Ministry of Agriculture and Forestry on the traceability requirements laid down for fisheries and aquaculture products
  https://mmm.fi/kalat/elinkeinokalatalous/kalastuksen-valvonta-ja-kiintioseuranta/jaljitettavyys
- News release of the Ministry of Agriculture and Forestry on improving the traceability of lots of fish by means of an identification number
  https://mmm.fi/artikkeli/-/asset_publisher/tunnistenumeron-avulla-parannetaan-kalaerien-jaljitettavyytta

Updates in version 2:

- Added: The control referred to in this point is not part of food safety control. The municipal food control reports any suspected violations and detected violations to the Agency for rural Affairs (cf. Act 1188/2014, Section 35, and Government Decree 1442/2014).
- Added: The control referred to in this point is control required under legislation on the common fisheries policy of EU. It is therefore to be taken into consideration that the terminology differs from the terminology used in food legislation, the term "lot", for example. In legislation on fisheries policy, "lot" does not refer to a production lot.
- The description of the "lot" terminology as used in fisheries policy updated, and when to document a "lot".
- Updated: The aforementioned sea-caught lots of fishery/aquaculture products must be traceable by every operator in the chain directly to the catching/harvesting of the lot from all stages of production, processing and distribution, up to and including retail sale.
- Added: This point is to be controlled when the operator handles sea-caught fish caught in sea areas of the EU states or sea-farmed fishery and aquaculture products farmed in sea areas of the EU states.
- Updated with the recommendation that point 13.5 Labelling of fishing and aquaculture products required by specific legislation be controlled at the same time.
- Content of the point "Matters to be controlled / Information of maiden lot updated.
- Added in the point "Operations comply with the requirements". The required information of the maiden lot accompanies the lot.
- Updated Finnish Food Act 23/2006, Section 3 sub-section 20, Section 6 sub-section 4, Sections 17 and 34
- Added: 1188/2014 Act on a system of sanctions for and monitoring of the Common Fishery Policy, sub-sections 1, 2, 4, 7, 11, 12, 17, 35, 49 20 and 22, Section 50 and 53
- Added: 1442/2014 Government Decree on suspected violations and suspected serious violations to be reported to the Agency for Rural Affairs
- Added: News release of the Ministry of Agriculture and Forestry on the traceability requirements laid down for fisheries and aquaculture products https://mmm.fi/kalat/elinkeinokalatalous/kalastuksen-valvonta-ja-kiintioseuranta/jaljitettavyys
- Added: News release of the Ministry of Agriculture and Forestry on improving the traceability of lots of fish by means of an identification number https://mmm.fi/artikkeli/-/asset_publisher/tunnistenumeron-avulla-parannetaan-kalaerien-jaljitettavyytta;
- Added at the end of Grades "To be corrected" and "Poor": ->The municipal food control reports any suspected violations and detected violations to the Agency for rural Affairs (cf. Act 1188/2014, Section 35, and Government Decree 1442/2014).

16 Traceability and Recalls

16.4 Traceability of Fish and Fishery Products under Dioxin Derogation

To be taken into consideration:
This point is to be controlled, when the operator

- imports, stores, brokers, packages, sells or exports from Finland fish or fishery products under temporary dioxin derogation
- manufactures or has manufactured for it fishery products from fish under dioxin derogation.

The derogation applies to wild caught salmon (*Salmo salar*) originating in the Baltic Region, herring (*Clupea harengus*) larger than 17 cm or unsorted, char (*Salvelinus spp*.), river lamprey (*Lampetra fluviatilis*) and trout (*Salmo trutta*), and products thereof.

Fish under dioxin derogation and products made from such fish may not be delivered without a lot-specific analysis certificate (showing that the limit values of dioxin and dioxin-like PCBs are not exceeded) to other member states apart from Finland and Sweden. Salmon and products thereof may also be delivered to Latvia. These delivery restrictions apply to all operators.

If the operator delivers fish under dioxin derogation or products thereof to countries other than Finland or Sweden (salmon Latvia), the operator must be able to produce for each delivery lot a lot-specific analysis certificate showing that the limit values of dioxin and dioxin-like PCBs are not exceeded (cf. the definition of "lot" in this case, Commission Regulation (EU) No 589/2014). Where the operator only delivers fish under dioxin derogation and products thereof to Finland or Sweden (salmon Latvia), no analysis certificate is needed.

An indication of the delivery restriction must be attached on the primary production site and approved food establishment to the document accompanying fishery products under dioxin derogation.

It is recommended that point 16.1 Traceability of Foodstuffs is controlled at the same time.

Matters to be controlled:
The implementation of own-check is evaluated by controlling the following matters:

- The operator identifies the requirements of dioxin derogation provisions and has them under control.
- Operation is evaluated by checks of e.g. 1-3 different lots/raw materials/products, taking the scope and nature of operations into consideration. For example, there will be time to check more lots in a small-capacity establishment that only guts and fillets fish than in a large establishment that also manufactures processed products.

1. Approved establishments that handle fish and/or fishery products under dioxin derogation:

- Commercial documents bear the required indication of delivery restrictions.
- Compliance with delivery restrictions.
- Analysis certificate, if fish and/or fishery products under dioxin derogation have been delivered to countries other than those to which the derogation applies.
- Separation between fish under dioxin derogation and other fish
    - e.g. lots of salmon and lots of rainbow trout may not be mixed without keeping records of mixings

- clear, systematic management of marking and traceability can be demonstrated during storage and production.

2. Registered premises that receive fish under dioxin derogation and broker/sell it to other operators and/or (possibly) manufacture products from such fish:
- Compliance with delivery restrictions.
- Forward to the receiving operator the indication of delivery restrictions required in commercial documents.
- Management of commercial documents.
- Separate storage of documents demonstrating the management of dioxin derogation or some other form of records are not required, but the operator shall be able to demonstrate by means of commercial documents, if fish or products under dioxin derogation has been received and if it has been delivered further.
- Separation between fish under dioxin derogation and other fish
  - e.g. lots of salmon and lots of rainbow trout may not be mixed without keeping records of mixings.
  - clear, systematic management of separation and traceability can be demonstrated during storage and possible further delivery.

EXCELLENT

Operations comply with requirements.

1. Approved establishments:
- Commercial documents bear the required indication of delivery restrictions.
- Delivery restriction is complied with.
- If fish or fishery products under dioxin derogation have been delivered to countries other than those to which the derogation applies, an analysis certificate can be presented for each lot showing that the limit value for the dioxin level is not exceeded.
- Fish under dioxin derogation is not mixed with other fish at any point unless the mixing is documented.

2. Registered establishments:
- Compliance with delivery restrictions.
- Forward the indication of delivery restrictions required in commercial documents.
- Is able to demonstrate by means of commercial documents, if fish exempt from dioxin regulations has been received and if it has been delivered further.
- Fish under dioxin derogation is not mixed with other fish at any point unless the mixing is documented.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The operator's operations meet in the main parts the aforementioned requirements. There are some minor shortcomings, such as:

1. Approved establishments:

- The indication of delivery restrictions is provided in the document of each delivery lot with the exception of a random shortcoming (human error). As concerns such an exception, the operator is able to demonstrate by means of commercial documents, however, that the products have been delivered to Finland or Sweden (salmon Latvia) and the recipient has not delivered them further to a commercial operator.
- There are some minor inaccuracies in the operator's processes as regards the separation of fish under dioxin derogation to the extent that there is cause to improve the management of separation.

2. Registered establishments:

- For example, a small operator who has handled fish under dioxin derogation on a very random basis and has not had all the requirements laid down in dioxin derogation provisions under control. The operator is able to demonstrate by means of commercial documents, however, that the products have been delivered to Finland or Sweden (salmon Latvia) and the recipient has not delivered them further to a commercial operator.
- There are some minor inaccuracies in the operator's processes as regards the separation of fish under dioxin derogation to the extent that there is cause to improve the management of separation.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

Such defects/shortcomings include, for example:

1. Approved establishments:

- The operator does not use at all in commercial documents the indication of delivery restrictions on products on which it should be used. The operator is able to demonstrate by means of commercial documents, however, that the products have been delivered to Finland or Sweden (salmon Latvia) and the recipient has not delivered them further to a commercial operator.
- The operator's compliance with delivery restrictions cannot be satisfactorily demonstrated so as to make concrete improvements of operations unnecessary.
- Separation cannot be satisfactorily demonstrated for all lots.

2. Registered establishments:

- The operator's compliance with delivery restrictions cannot be satisfactorily demonstrated.
- Separation cannot be satisfactorily demonstrated for all lots.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Such issues include:

1. Approved establishments:
- The operator has itself delivered fish or fishery products under dioxin derogation to a country or countries other than Finland, Sweden or Latvia (salmon).
- The operator is not able to demonstrate where the products have been delivered to.
- The operator does not use at all the indication of delivery restrictions in documents in which it should be used and is unable to demonstrate that products have only been delivered to Finland, Sweden (or Latvia salmon).
- Separation cannot be verified at all for any of the lots.

2. Registered establishments:
- The operator has itself delivered fish or fishery products under dioxin derogation to a country or countries other than Finland, Sweden or Latvia (salmon).
- The operator is not able to demonstrate at all where the products have been delivered to.
- Separation cannot be verified at all for any of the lots.

In case of all the examples under the grade Poor, if one of the examples is realised, the controlling inspector of the establishment should inform Evira's Product Safety Unit about the matter without delay as well, to make it possible to forward information about the problem also to the central authority of the country of destination.

Legislation and guidelines (with any amendments) pertaining to the subject:
- Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs, Article 7
- Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; Articles 14, 17 and 18
- Commission Regulation (EC) 931/2011 on the traceability requirements set for food of animal origin, Article 3
- Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, Articles 14 and 15
- Regulation (EU) No 1379/2013 of the European Parliament and of the Council on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000, Article 5
- Commission Regulation (EU) No 589/2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin like PCBs in certain foodstuffs and repealing Regulation No 252/2012, Annex 1 Definitions and abbreviations, 1.11 "Lot"
- Finnish Food Act 23/2006, Section 17
- Decree 1424/2015 of the Ministry of Agriculture and Forestry on amending the Decree of the Ministry of Agriculture and Forestry on food hygiene at approved establishments
- Decree 795/2014 of the Ministry of Agriculture and Forestry on food hygiene at approved establishments, Sections 3 and 4
- Evira's Guide 16031/1 Indications or marks identifying fishery products, and documents to accompany fishery products Note. The Guide is not up-to-date as concerns the requirement of a rectangular mark for dioxin derogation.

- Evira's Guide 16023/3 Control of fishery products. Note. The Guide is not up-to-date as concerns the requirement of a rectangular mark for dioxin derogation.

Updates in version 2:

- Added: Decree 1424/2015 of the Ministry of Agriculture and Forestry on amending the Decree of the Ministry of Agriculture and Forestry on the food hygiene of establishments
- The requirement of a rectangular additional mark in labelling laid down in national legislation has been repealed (Decree 1424/2015 of the Ministry of Agriculture and Forestry -> References to the requirement of a rectangular mark and to the control of the use of the rectangular mark removed from this Guideline for control.
- Added: Commission Regulation (EU) No 589/2014
- Added: the definition of "lot" for an analysis certificate according to Regulation (EU) No 589/2014.
- Added: a requirement for presenting an analysis certificate, if fish or fishery products under dioxin deregation have been delivered to countries other than those to which the derogation applies.
- Added (registered food premises): a requirement to forward in the chain of operators the indication of delivery restrictions required in commercial documents.
- Added: the management of commercial documents.
- Added at the end: instructions for the controlling inspector, in case of all the examples under the grade Poor, if one of the examples is realised, to inform Evira's Product Safety Unit about the matter without delay as well.
- Removed: Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin, Article 5
- Removed: Regulation of the European Parliament and of the Council (EC) No 1069/2009
- Removed: Decree 1369/2011 of the Ministry of Agriculture and Forestry on food hygiene at approved establishments
- Removed: Evira's Guide 17067/1 Control of dioxin derogation provisions pertaining to fishery products
- Added: a mention related to Evira's Guides 16031/1 and 16023/3: Note. The Guide is not up-to-date as concerns the requirement of a rectangular mark for dioxin derogation.
- Added: instructions to contact Evira in case the grade Poor is awarded.

16 Traceability and Recalls

16.5 Management of and Preparedness for Special Situations

To be taken into consideration:

- This Guideline is applied to all approved establishments.
- The purpose of this point is to evaluate the management of and preparedness for abnormal situations that are relevant as regards the securing of the safety of foodstuffs and from the viewpoint of the establishment's own operation.
- Preparedness for abnormal situations should be based on a risk assessment carried out by the establishment.
- The management of abnormal situations refers to e.g. preventing products from reaching the market unless they can be proven to be safe, or e.g. the production facilities being cleaned thoroughly after an animal disease incident.
- Recalls of foodstuffs that have already reached the market, and preparedness for recalls are evaluated in point 16.6.
- Preparedness for abnormal situations refers to e.g. the operator taking into consideration the actions that will most probably be necessary due to an abnormal situation, such as where can foodstuffs be delivered to be destroyed.
- Situations that jeopardise the safety of food production in an unexpected and substantial manner can be considered to be abnormal situations. Abnormal situations can include, for example:
  - Electricity black-out and its effects on the production of foodstuffs.
  - Serious and exceptional disturbances related to the quality and safety ofwater, and the effects of such disturbances on foodstuffs to be manufactured or foodstuffs that have already been manufactured.
  - Process disturbances, such as failure of a production line.
  - Animal disease situations and their effects on food production processes, such as reception of live animals.
  - Other abnormal situations with potential to affect the safety of foodstuffs, such as accidents, floods, fires, biohazards, vandalism, etc.

Matters to be controlled:

- Written instructions for action in case of abnormal situations that are relevant to the establishment's own operations.
- Instructions for actions in abnormal situations regarding foodstuffs to be manufactured or foodstuffs that have already been manufactured.
- Securing food safety also after abnormal situations, e.g. cleaning activities.
- Implemented actions in possible abnormal situations; for example, destruction of contaminated foodstuff batches.
- Own-check records maintained of possible abnormal situations, and actions taken due to them.

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- The operator has written instructions for abnormal situations to ensure that no food safety risk is caused to the consumer.
- Actions concerning foodstuffs to be manufactured or foodstuffs that have already been manufactured have been taken into consideration in instructions and actions.
- Food safety also after abnormal situations has been taken into consideration in instructions and actions; e.g. cleaning of processes.
- The actions taken due to abnormal situations, if any, have been appropriate and adequate.
- Adequate own-check records have been maintained of abnormal situations, if any, and actions taken due to them.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- The operator has instructions for abnormal situations to ensure that no food safety risk is caused to the consumer.
- The actions taken due to abnormal situations have been appropriate and adequate, but there are some minor shortcomings in the own-check records maintained of abnormal situations and actions taken.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- The operator does not have instructions for abnormal situations to ensure that no food safety risk is caused to the consumer.
- The actions taken due to abnormal situations have not been appropriate or adequate, and food safety has been impaired.
- There are shortcomings in the records maintained of actions taken, and food safety has been impaired.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- The operator has failed to take corrective actions in abnormal situations, and food safety has been jeopardised.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Regulation (EC) No 854/2004 on official controls on products of animal origin
- Implementing Regulation (EC) No 2074/2005
- Finnish Food Act 23/2006

- Decree of the Ministry of Agriculture and Forestry on primary production 1368/2011
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Annex 3, Chapter 1, point 1.3(2.a) and (3.i)
- Decree of the Ministry of Agriculture and Forestry on meat controls 590/2014

16 Traceability and Recalls

16.6 Recalls

To be taken into consideration:

This point is to be controlled, when the operator

- manufactures, has manufactured for it and/or packages food products
- imports and/or brokers (from the internal market and/or third countries) food products
- stores, markets, serves or exports food products.

If the operator has not been an initiating or involved party in a recall process, the control only applies to the content of the own-check plan with respect to recalls.

Retail operators whose activities do not affect the packaging, labelling, safety or integrity of foodstuffs are not required to implement communication to consumers or authorities. However, they are required to take actions that promote the recall together with the operator responsible for the recall as well as authorities.

It is recommended that point 16.1 Traceability of Foodstuffs is controlled at the same time.

Matters to be controlled:

The implementation of in-house control is evaluated by controlling the following matters:

- Preparedness for recalls is included in the own-check plan.
- The changes necessary due to recalls have been made in own-check activities.
- Records and documents exist about the recalls that have been implemented.
- The lots of foodstuffs which the recall concerned are not mixed up with other lots of foodstuffs.

EXCELLENT

Operations comply with requirements.

Recall activities have been appropriate and adequate. Activities have been recorded and the records and documents related to recalls are stored for the period of time defined in provisions.

The own-check plan contains appropriate and adequate instructions for actions in case of recalls.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Recall activities have been appropriate and adequate, but there are some minor shortcomings in the records of activities. Such minor shortcomings include, for example

- there are only minor differences in the quantities of recalled products, and products that have been destroyed, returned and sold to consumers.

The records and documents related to recalls are stored for the period of time defined in provisions.

The instructions provided in the own-check plan for actions in case of recalls are slightly deficient. For example,
- the person responsible for communication to consumers is not indicated.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

Recall activities have not been recorded and documents have not been stored, although recall processes have been carried out. Recall activities have been slightly deficient. For example,
- the scope of communication to consumers has been inadequate
- the operator has not initiated a recall process although they have had cause to suspect that the product does not meet regulations related to the safety of foodstuffs.
- there is a risk of recalled products being mixed up with the operator's other products.
- there are significant differences in the quantities of recalled products, and products that have been destroyed, returned and sold to consumers.

The instructions provided in the own-check plan for actions in case of recalls are inadequate. For example,
- the person responsible for communication to authorities has not been appointed
- there are no advance plans for where to place recalled products in the operator's facilities.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The are no records of activities related to recalls and documents have not been stored, although recall processes have been carried out. Despite known incompliance of foodstuffs with regulations, the required activities have not been implemented at all, or incorrect or inadequate activities have been carried out. For example,
- authorities or consumers / other operators have not been informed, although it would have been necessary
- recalled lots of products have not been separated from other lots.

Recalls have not been taken into account in the own-check plan.

Provisions and guidelines pertaining to the topic:
- Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, 178/2002/EC, Articles 14 and 19
- Finnish Food Act 23/2006, Sections 9 and 10

16 Traceability and Recalls

16.8 Traceability of Meat of Swine, Sheep, Goats and Poultry

Food business operators shall have in place an identification and registration system ((EU) No 1337/2013, Article) which they use at each stage of the production and distribution of the meat referred to in the title of this Guideline to be able to indicate the country of origin or place of provenance of the meat. The system shall be applied in such a way as to ensure the link between the meat and the animal or group of animals from which it has been obtained. This applies to all the stages of the production and distribution of the meat, from slaughter to packaging. The requirements laid down for the identification and registration system include the following:

- Each food business operator is responsible for the application of the identification and registration system within the stage of production and distribution at which they operate.
- Each food business operator shall use the system to record, in particular, the arrival at and the departure from the establishment of the operator, of animals, carcases or cuts, as appropriate, and to ensure a correlation between arrivals and departures.
- Each operator shall verify the transmission of the information relating to the indications of the country of origin or place of provenance of the meat, as appropriate, together with the meat, to the operators at the subsequent stages of production and distribution.
- The food business operator who packs or labels the meat referred to in the title of this Guideline shall ensure the correlation between the batch code identifying the meat supplied to the consumer or mass caterer and the relevant batch or batches of meats from which the pack or labelled batch is constituted.

For the purposes of this Guideline, the identification and registration system refers to a structured and systematic manner in which the required information on the country of origin or place of provenance is identified, recorded and transmitted.

The size of a batch cannot exceed the production of one day. The use of the packaging date or some other date indication alone as the batch code is not recommended. A date indication can be considered an adequate batch code in cases where the operator only handles animals and/or the meat of animals originating in the same country of origin or place of provenance, and possibly also in other corresponding cases.

The control to be carried out in this point covers all stages of production and distribution in food business operations as far as fresh, chilled and frozen meat of swine, sheep, goats and poultry is concerned.

It is recommended that points 13.4 Labelling of Meat Required by Specific Legislation, and 16.1 Traceability of Foodstuffs are controlled at the same time.

Matters to be controlled:
The implementation of own-check is evaluated by random checks (on e.g. 1-3 different received batches, production batches or consignments, or products/packages, taking the scope and nature of operations into consideration) of the following matters:

- The use of the identification and registration system provided for in Regulation (EU) No 1337/2013, the clarity and systematic nature of documentation.
- Records: the arrival at and the departure from the establishment of the food business operator, of animals, carcases or cuts, as appropriate
- Correlation between arrivals and departures of animals, carcases or cuts.
- The transmission of information to the operators at the subsequent stages of production and distribution.

- As concerns food business operators who pack or label the meat referred to in the title of this Guideline, correlation between the batch code identifying the meat supplied to the consumer or mass caterer and the relevant batch or batches of meats from which the pack or labelled batch is constituted.

EXCELLENT

Operations comply with requirements.

The operator has an identification and registration system in place and uses it, and the controlling inspector becomes concinced that the requirements of the system are met.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The operator can be construed to use, in practice, the activities required by the identification and registration system. Some occasional shortcomings can be found in practical activities, but notwithstanding these, the accuracy of the information on the country of origin or place of provenance of the meat can be verified for all batches as well as the practices used to transmit the required information. Minor shortcomings can include, for example:

- An individual record or document is missing.
- However, the controlling inspector becomes concinced on the basis of records/ documentation related to the same batch that the information is accurate.
- Correlation between information on the arrival and departure of animals, carcases or cuts is not indicated in a completely systematic manner. However, the controlling inspector becomes concinced on the basis of other own-check records and commercial documents that the information is accurate.
- As concerns operators who pack or label the meat referred to in the title of this Guideline: the operator uses only a date indication as the batch code identifying the meat supplied to the consumer or mass caterer and is not able to present appropriate justification for the use of only a date indication.
- In general; minor shortcomings regarding a systematic approach in operation, or an individual inaccuracy in documentation, despite of which, however, the controlling inspector becomes concinced that the information on the country of origin or place of provenance of the meat is accurate for all lots.

TO BE CORRECTED

There are issues with the operations that are not in compliance with legislation or impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The operator has some clear shortcomings in the management and verification of traceability which need to be rectified within a set period of time. Such shortcomings may include, for example:

- The operator is of the opinion that they are using an identification and registration system, some documentation has been carried out, but the

controlling inspector does not become concinced that the operator is always able to reliably indicate the country of origin or place of provenance by means of the system.

- The operator has an identification and registration system in use, but records/indications are missing to the extent that makes it impossible to consider the use of the system systematic and therefore it is not possible to verify the fulfilment of requirements.
- Animals, carcases or cuts delivered to the operator's facilities have not in each case been accompanied by information on the country of origin or place of provenance and the operator is unable to demonstrate that they have observed the matter and reacted to it (e.g. a written complaint to the supplier). However, based on other evidence, the controlling inspector becomes concinced that information given related to information on the country of origin or place of provenance has not been misleading.
- In general; data is missing to the extent that it is no longer a question of an individual defect, and thereby the management of the identification and registration system and the fulfilment of requirements can not be satisfactorily demonstrated.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to rectify the issues within the set period of time.

Such issues include, for example:

- The operator has no information on the country of origin or place of provenance of meat batches.
- The operator has failed to transmit information on the country of origin or place of provenance of meat batches.
- As concerns operators who pack or label the meat referred to in the title of this Guideline: the operator uses only a date indication as the batch code identifying the meat supplied to the consumer or mass caterer, although meat batches with different information on the country of origin or place of provenance are packed continuously during the same day. As a result of this, the batch code identifying the meat and the relevant batch or batches of meat from which the pack or labelled batch is constituted do not correlate and it is not possible to verify the origin of the meat.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Commission Implementing Regulation (EU) No 1337/2013 laying down rules for the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry, Articles 1, 2, 3, 4
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, Articles 1, 2, 8, 9 and 26, and ANNEX XI

- Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; Articles 3 and 18
- Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs, Article 2
- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin, Articles 7, and ANNEX I, points 1.13, 1.16 and 1.17
- Finnish Food Act 23/2006, Sections 17 and 18

17 Food Testing

17.1 Sampling and Own-check Testing

To be taken into consideration:

- This Guideline is applied to establishments other than storage establishments.
- The competence of the laboratory used to analyse the samples is evaluated in point 1.6 "General Compliance of Own-check with Requirements".
- The own-check of water and ice is evaluated in point 17.3.
- The national salmonella own-check control of the meat sector is evaluated in point 17.4.
- EHEC own-check control is evaluated in point 17.5.
- Listeria own-check control is evaluated in point 17.6.
- Campylobacter own-check control is evaluated in point 17.7.
- The quality testing of raw milk is evaluated in point 17.9.
- The tests required pursuant to the Decree on raw milk for raw milk sold from a milk sector establishment for consumption as such are evaluated in point 17.6 and in this point.
- The shelf life tests of products are evaluated in point 17.10.
- Other Guidelines related to food testing: 17.8, 17.11-17.16 and 17.18.

Matters to be controlled:

Tests designed for verification of the safety of the foodstuffs, such as:

- Sampling for salmonella of meat products not included in the national salmonella control programme, such as minced meat, meat preparations, certain meat products, MSM, carcasses of horses, sheep and goats
- Sampling for salmonella of milk, egg and fishery products, as well as raw goat's milk intended for consumption as such
- *Cronobacter spp. (Enterobacter sakazakii)* of infant formulae
- Sampling of milk products for staphylococcal enterotoxin, when required due to the result of the process hygiene criteria
- Sampling for campylobacter and STEC of raw milk sold for consumption as such
- TSE sampling

Own-check tests concerning process hygiene, such as

- samples taken from the surface of carcasses for testing of slaughter hygiene
- sampling of minced meat, meat preparations and mechanically separated meat for aerobic micro-organisms and *E. coli*
- sampling of milk products for Enterobacter, coagulase positive staphylococcus, *E. coli* and *B. cereus*
- sampling of certain fishery products for Enterobacter, coagulase positive staphylococcus, and *E. coli*
- sampling of egg products for Enterobacter
- concentration of 3-OH-butyric acid in the dry matter of egg products, lactic acid content of raw material used in manufacture of egg products, and quantity of eggshell remains, egg membranes and any other particles in processed egg product.
- verification of the cleanliness of equipment, surfaces, and the production environment (surface cleanliness sampling)

Execution of sampling

- Frequency of sampling and number of sample units. Where appropriate, the derogations granted by the controlling inspector regarding the taking of sample units to be taken into consideration.
- Any deviations found in the tests referred to above, the implemented corrective actions, and the records of these
- Trend analysis carried out by the operator
- Sampling and handling of samples
- The adequacy and suitability of own-check, and the own-check plan (sampling and testing plan), if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The sampling and testing plan complies with requirements, or appropriate grounds are presented in it, or it complies with Evira's sampling recommendation. Sampling has been carried out according to plan.

Sampling has been carried out in a hygienic manner.

Own-check sampling related to process hygiene is carried out appropriately to demonstrate the acceptable effectiveness of the production process, i.e., the operator monitors the trends indicated by the sample results.

The corrective actions taken in case limit values have been exceeded in tests related to the safety of foodstuffs have been appropriate and adequate.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- The plan for the sampling of products and/or the production environment does not comply with requirements, or there are some minor shortcomings in the grounds presented in the plan. Or, the operator has opted to follow Evira's sampling recommendation, but the sampling plan of the operator is not completely consistent with the recommendation.
- The plans for the sampling of products and the production environment comply with requirements, or appropriate grounds are presented in the plans, or they comply with Evira's sampling recommendation. As a rule, sampling is carried out according to plans, but in some individual cases sampling has not been carried out.
- The number of sample units is not completely in compliance with requirements or with the grounds presented in the sampling plan, occasionally the number of tested sample units is too low.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There is no sampling plan at all, but sampling has been carried out to some extent.
- The sampling plan does not comply with requirements, or there are clear shortcomings in the grounds presented in the plan. Or, the operator has opted to follow Evira's sampling recommendation, but the sampling plan of the operator deviates significantly from the recommendation.
- The number of tested samples is considerably lower than the planned number.
- Sample units are not tested of the samples, or the number of tested sample units is continuously too low, without a sampling plan presenting sampling grounds.
- The hygiene level is not adequate in the sampling and handling and storage of samples, and samples may become contaminated or deteriorated.
- Own-check sampling related to process hygiene is not carried out to demonstrate the acceptable effectiveness of the production process. In case limit values are exceeded, no actions are taken to e.g. improve the hygiene level in the production of foodstuffs or in slaughtering operations.
- The majority of sampling of the production environment is carried out from surfaces that are not in contact with the product.
- The results of surface cleanliness sampling of equipment or other surfaces in contact with foodstuffs repeatedly exceed the limit values laid down in the own-check plan, but no actions are taken due to the results.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- No sampling is carried out or only to a very limited extent, although sampling should be carried out.
- As a rule, there are shortcomings in the sampling and handling or identification of samples that render the samples unusable for tests.
- Own-check sampling related to food safety is not carried out appropriately to demonstrate the safety of the foodstuffs. No actions are taken in case limit values are exceeded to investigate contamination, for example.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin, Annex III, Section X
- Commission Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs
- Finnish Food Act 23/2006, Sections 20, 39 and 50
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on raw milk, 699/2013, Section 14, Annex 3A
- Evira's Guide 10501 Microbiological criteria for foodstuffs, application of Commission Regulation (EC) 2073/2005

Updates in version 2:

- TSE sampling added in the point "Matters to be controlled"

17 Food Testing

17.3 Own-check Testing of Water and Ice

To be taken into consideration:

- This Guideline is applied to all establishments.
- This Guideline does not pertain to the control of the operator's own water source or the control of the supplier of domestic water.
- The use and own-check of domestic water and clean water in food processes is controlled by the food control authorities.
- The scope of the own-check plan and the frequency of the tests carried out depend on the type of the foodstuffs produced, the scope of operation (production volumes and seasonal nature) as well as the nature of the processes. The water source used (e.g. domestic water from a water utility company or domestic water from own well) as well as the cleaning methods used are also of relevance.
- Sampling should primarily be focused on the control of the water used for food processes and the water and ice used during the processes.
- The source of the domestic water used at the establishment and the potential contamination risk resulting from recycled water are evaluated in point 1.4 "Compliance of Domestic Water with Requirements".
- The source of the clean water used at the establishment is evaluated in point 1.5 "Compliance of Clean Water with Requirements".
- The competence of the laboratory used to analyse the samples is evaluated in point 1.6 "General Compliance of Own-check with Requirements".
- Serious disturbances related to the quality and safety of water, and the effects of such disturbances on foodstuffs to be manufactured or foodstuffs that have already been manufactured are evaluated in point 16.5 "Management of and Preparedness for Special Situations".

Matters to be controlled:

- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".
- With regard to the quality control of domestic water, clean water (fishery sector establishments) and ice, the following are to be controlled:
  - Organoleptic monitoring of water
  - Storage of information requested/obtained from supplier of domestic water or municipal control authority regarding quality of domestic water
  - Risk-based monitoring of water quality (sampling and tests)
  - Corrective actions in abnormal situations, if any; for example, if sample results have been poor
  - Compliance with any instructions for use of water issued by control authorities or the water utility company

EXCELLENT

Operations comply with requirements.

The needs for own-check of water and ice have been appropriately assessed. The own-check plan is adequate taking the quality and quantity of the foodstuffs produced by the food establishment into consideration.

Own-check related to domestic water, clean water (fishery sector establishments) and ice has been carried out at the establishment according to plan.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are some minor shortcomings in the assessment of the needs for own-check of water and ice, but food safety is not impaired. The own-check plan is adequate in essence taking the quality and quantity of the foodstuffs produced by the food establishment into consideration, and food safety is not impaired.
- There are some minor shortcomings in the execution of the own-check plan related to domestic water, clean water (fishery sector establishments) and ice; for example, some individual samples have not been taken, but food safety is not impaired.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There are some minor shortcomings in the assessment of the needs for own-check of water and ice, and food safety is impaired. The own-check plan is not adequate taking the quality and quantity of the foodstuffs produced by the food establishment into consideration, and food safety is impaired.
- There is no own-check plan in place, but sampling has been carried out adequately, however.
- There are shortcomings in the execution of the own-check plan related to domestic water, clean water (fishery sector establishments) and ice resulting in impaired food safety; for example, several samples have not been taken.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- There are shortcomings in the assessment of the needs for own-check of water and ice, and food safety is jeopardised because of this. The own-check plan is not adequate taking the quality and quantity of the foodstuffs produced by the food establishment into consideration, and food safety is jeopardised.
- There are shortcomings in the execution of the own-check plan related to domestic water, clean water (fishery sector establishments) and ice, and the safety of foodstuffs is jeopardised because of this; for example, no sampling has been carried out at all.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Evira's Guide 16023: Control of fishery products
- EVI Guideline 3565/41/02: Own-check of water for human consumption and of ice in establishments referred to in Hygiene Act

17 Food Testing

17.4 National Salmonella Control in Meat Sector

To be taken into consideration:

- This Guideline is applied to slaughterhouses, low-capacity slaughterhouses and cutting plants which handle beef and the meat of swine, chicken, turkey, duck, goose, or guinea fowl, and the purpose of this point is to evaluate the implementation of the national salmonella control programme at these establishments. The sampling carried out at the aforementioned establishments within the national salmonella control programme shall cover:
  - Samples of lymphatic glands from swine and cattle, and surface swipe samples of carcasses (slaughterhouses)
  - Samples of cut/crushed meat from swine, cattle, ducks, geese, and guinea fowls (cutting plants)
  - Samples of neck skin from chickens, turkeys and hens (slaughterhouses)
  - Samples of skin/surface muscle from chickens, turkeys and hens (cutting plants)
- Salmonella sampling in compliance with the Regulation on microbiological criteria for foodstuffs is evaluated in point 17.1 "Sampling and Own-check Testing". Salmonella sampling in compliance with the Regulation on microbiological criteria for foodstuffs includes e.g. the salmonella samples taken in slaughterhouses from horses, sheep and goats, and the samples taken in meat sector establishments from minced meat and meat preparations (also as concerns e.g. chickens, turkeys and hens).
- The competence of the laboratory used to analyse the samples is evaluated in point 1.6 "General Compliance of Own-check with Requirements".
- Situations where animals need to be slaughtered separately due to salmonella or lack of salmonella test results are evaluated with respect to the operation of the animal shed in point 5.1 "General Hygiene in Food Production".
- The heating treatment of meat due to salmonella is evaluated with respect to the effectiveness of the heating treatment in point 6.5 "Temperature Management in Food Production Processes", and with respect to overall compliance with the heating requirement, handling hygiene and identification of carcasses in point 5.1 "General Hygiene in Food Production".
- Actions taken based on detection of salmonella (134/2012, Section 7) are evaluated e.g. in points 3.2 "Cleanliness of Surfaces, Fixtures, Equipment, and Utensils", and 16.1 "Traceability of Foodstuffs". However, the increase in sampling is evaluated in this point.
- Salmonella matters related to egg production are evaluated in point 15.2 "Management of Salmonella Certificates in Egg Production".

Matters to be controlled:

- The quantity of samples taken for testing and the distribution of sampling between different species and according to the country of origin of meat.
- The random nature and the distribution of sampling over time
- Sampling, and handling and identification of samples
- Information accompanying samples to the laboratory
- Increase in the quantity of samples taken after detection of salmonella
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

Salmonella control complies with requirements in relation to the matters evaluated in this point.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operations and the own-check plan comply with requirements in essence, but there are some minor shortcomings in them; however, these do not have any essential effect on the quality or quantity of the samples tested, or on the test results. The grade can be Good e.g. in cases where:

- The quantity of salmonella samples taken in one year is a little short of the quantity required by legislation or the quantity defined in the sampling plan prepared by Evira for the slaughterhouse.
- The proportion of samples taken from domestic and foreign meat at the cutting plant is slightly different than the proportion of meat cutting.
- Sometimes samples are taken from several successive animals in the slaughtering sequence, which makes sampling non-randomised.
- There are occasionally shortcomings in the information accompanying samples to the laboratory.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are shortcomings in operations and/or the own-check plan which have an essential effect on the quality or quantity of the samples tested, or on the test results. The grade can be To be corrected e.g. in cases where:

- There are significant or frequently occurring shortcomings in the quantities of samples taken for testing, or the quantity of samples has not been increased after detection of salmonella.
- A low-capacity slaughterhouse has failed to take one of the required two samples to be taken during one year.
- Sampling is not carried out on a random basis.
- Sampling for salmonella is not included in the own-check plan of the establishment, but operation complies with requirements.
- There are repeatedly major shortcomings in the information accompanying samples to the laboratory.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Sampling for salmonella has not been carried out or samples have not been sent for testing, or there are, as a rule, shortcomings in the handling or identification of samples, or in the information accompanying samples to the laboratory that render the samples unsuitable for testing.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation /EC) No 2073/2005 on microbiological criteria for foodstuffs
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Decree of the Ministry of Agriculture and Forestry on meat inspection 590/2014, Annex 1, Chapter 4, point 4.3
- Decree of the Ministry of Agriculture and Forestry on salmonella control at meat establishments, 134/2012
- Evira's Guide 10501: Microbiological criteria for foodstuffs, application of Commission Regulation (EC) 2073/2005, Guide for food business operators

Updates in version 2

- The title of the Guideline has been changed: "own-check" of salmonella has been changed into "national salmonella control"

17 Food Testing

17.5 Own-check of EHEC

To be taken into consideration:

- This Guideline is applied to faecal sampling for EHEC at slaughterhouses where bovine animals are slaughtered, and at low-capacity slaughterhouses where 100 or more than 100 bovine animals are slaughtered per year.
- The competence of the laboratory used to analyse the samples is evaluated in point 1.6 "General Compliance of Own-check with Requirements ".
- If surface swipe samples are taken for EHEC, the effectiveness of the heating treatment of the carcass tested EHEC positive based on the *surface swipe sample* is evaluated in point 6.5 "Temperature Management in Food Production Processes", and general compliance with the heating requirement, handling hygiene and identification of the carcass in point 5.1 "General Hygiene in Food Production".
- The consideration of the epidemiological situation on the location where the animals come from in the slaughtering arrangements is evaluated with respect to the operation of the animal shed in point 9.7 "Separation of Animals Delivered to Slaughterhouse", and with respect to the slaughtering process in point 5.1 "General Hygiene in Food Production".
- Matters related to the cleanness of the animals to be slaughtered are evaluated in points 5.1 "General Hygiene in Food Production", 9.3 "Animal Transport", and 9.7 "Separation of Animals Delivered to Slaughterhouse".

Matters to be controlled:

- Quantity of samples to be tested
- The random nature and the distribution of sampling over time
- Sampling, and handling and identification of samples
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

EHEC control complies with requirements in relation to the matters evaluated in this point.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operations and the own-check plan comply with requirements in essence, but there are some minor shortcomings in them; however, these do not have any essential effect on the quality or quantity of the samples tested, or on the test results. The grade can be Good e.g. in cases where:

- Sometimes samples are taken from several successive animals in the slaughtering order, making sampling non-randomised.

- The quantity of EHEC samples taken in one year is a little short of the quantity defined in the sampling plan prepared by Evira for the slaughterhouse.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set deadline.

There are shortcomings in operations and/or the own-check plan which have an essential effect on the quality or quantity of the samples tested, or on the test results. The grade can be To be corrected e.g. in cases where:

- Samples are repeatedly sent to the laboratory too late after sampling, which makes it impossible to test them within the required time limits due to reasons for which the slaughterhouse operator is responsible.
- There are significant shortcomings in the quantity of samples taken for testing or samples are taken in large quantities at once on a few days during the year.
- Sampling for EHEC is not included in the own-check plan of the establishment, but operation complies with requirements.
- A low-capacity slaughterhouse has failed to take one of the two required samples to be taken during one year.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Sampling for EHEC has not been carried out or samples have not been sent for testing, or as a rule, there are shortcomings in sampling, and handling or identification of samples that render the samples unusable for tests.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Annex 3, Chapter 2, point 2(2.1(10))
- Decree of the Ministry of Agriculture and Forestry on meat inspection 590/2014, Annex 1, Chapter 4, points 4.3 (4.3.1) and (4.3.3)
- Decree of the Ministry of Agriculture and Forestry on EHEC control, 24/EEO/2006
- Evira's Guide 5001/1: Prevention of EHEC bacteria at cattle farms and slaughterhouses

17 Food Testing

17.6 Own-check of Listeria

To be taken into consideration:

- This point is evaluated at establishments producing ready-to-eat foodstuffs. However, this point is not evaluated at establishments producing only preserves.
- The competence of the laboratory used to analyse the samples is evaluated in point 1.6 "General Compliance of Own-check with Requirements".

Matters to be controlled:

- Frequency of sampling and number of sample units. Where appropriate, the derogations granted by the controlling inspector regarding the taking of sample units to be taken into consideration.
- Frequency of sampling from the production environment.
- Any deviations found in the tests referred to above, the implemented corrective actions, and the records of these.
- The adequacy and suitability of own-check activities, and the own-check plan, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

Sampling plans for listeria from the products and the production environment present appropriate grounds or comply with Evira's sampling recommendations. Sampling has been carried out according to plan.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in the grounds presented in the sampling plan for listeria from the products and/or the production environment. Or, the operator has opted to follow Evira's sampling recommendation, but the sampling plan of the operator is not completely consistent with the recommendation.
- Sampling plans for listeria from the products and the production environment present appropriate grounds or comply with Evira's sampling recommendation. As a rule, sampling is carried out according to plans, but in some individual cases sampling has not been carried out.
- The number of sample units is not completely in compliance with requirements, occasionally the number of sample units that are tested is too low.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- There is no sampling plan at all, but sampling has been carried out to some extent.
- There are clear shortcomings in the grounds presented in the sampling plan for listeria from the products and/or the production environment. Or, the operator has opted to follow Evira's sampling recommendation, but the sampling plan of the operator deviates significantly from the recommendation.
- The number of tested samples is considerably lower than the planned number.
- Sampling is not carried out at all from some product group.
- Sample units are not tested of the samples, or the number of tested sample units is continuously too low.
- The majority of sampling of the production environment is carried out from surfaces that are not in contact with the product, and no grounds are presented for this.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- No sampling has been carried out or only to a very limited extent.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002/EY on food law
- Regulation (EC) No 2073/2005 on microbiological grounds for foodstuffs, Article 3
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Annex 3, Chapter 1.3
- Decree of the Ministry of Agriculture and Forestry on raw milk, 699/2013, Section 14, Annex 3
- Evira's Guide 10501, "Microbiological grounds for foodstuffs, application of Commission Regulation (EC) 2073/2005"

Updates in version 2:
The example related to samples from the production environment supplemented under the grade "To be corrected"

17 Food testing

17.7 Own-check of Campylobacter

To be taken into consideration:

- This Guideline is applied to chicken slaughterhouses, but not to low-capacity slaughterhouses.
- The purpose of this point is to evaluate in certain parts the fulfilment of the requirements laid down in the Decree of the Ministry of Agriculture and Forestry on control of campylobacter in chickens (10/EEO/2007).
- The competence of the laboratory used to analyse the samples is evaluated in point 1.6 "General Compliance of Own-check with Requirements ".
- *Practical arrangements* related to slaughtering animals as the last animals of the day when campylobacter has been found in the animals of one building of the holding place in successive slaughtering operations (10/EEO/2007, Section 7) are evaluated in point 9.7 "Separation of Animals Delivered to Slaughterhouse".

Matters to be controlled:

- Quantity of slaughtering batches and slaughtered birds subjected to testing
- The random nature and the distribution of sampling over time
- Sampling, and handling and identification of samples
- Monitoring of slaughtering batches tested positive for campylobacter to enable the slaughterhouse operator to *identify* the buildings of the holding places where campylobacter has been found in the animals in two successive slaughtering operations.
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check ".

EXCELLENT

Operations comply with requirements.

Control of campylobacter complies with requirements at the slaughterhouse with respect to the matters controlled in this point.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Operations and the own-check plan comply with requirements in essence, but there are some minor shortcomings in them; however, these do not have any essential effect on the quality or quantity of the samples tested, or on the test results. The grade can be Good e.g. in cases where:

- Sometimes samples of slaughtering batches are taken from successive birds in the slaughtering sequence or sometimes sampling is in some other respect not evenly distributed in the whole slaughtering batch, which makes sampling non-randomised.
- The operator has failed to take some individual samples or samples from an individual slaughtering batch.

The slaughterhouse operators *identifies* also slaughtering batches that must be slaughtered as the last animals of the day based on the results of campylobacter tests of previous slaughtering batches received from the same building of the holding place.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are shortcomings in operations and/or the own-check plan which have an essential effect on the quality or quantity of the samples tested, or on the test results. The grade can be To be corrected e.g. in cases where:

- Samples are repeatedly sent to the laboratory too late after sampling, which makes it impossible to test them within the required time limits due to reasons for which the slaughterhouse operator is responsible.
- Sampling for campylobacter is not included in the own-check plan of the establishment, but operation complies with requirements.
- There are significant or frequently occurring shortcomings in the quantities of samples taken for testing.

The grade can also be To be corrected, if the slaughterhouse operator has failed to *identify* slaughtering batches that should have been slaughtered as the last animals of the day based on the results of campylobacter tests of previous slaughtering batches received from the same building of the holding place.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Sampling for campylobacter has not been carried out or samples have not been sent for testing, or as a rule, there are shortcomings in sampling, and handling or identification of samples that render the samples unusable for tests.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014, Annex 3, Chapter 2, point 2(2.2(8))
- Decree of the Ministry of Agriculture and Forestry on control of campylobacter in chickens, 10/EEO/2007, and justification memorandum for the draft decree

17. Food Testing

17.8 Own-check of Histamine in Fishery Products

To be taken into consideration:

This point is evaluated in fish sector establishments that handle fresh or processed tuna, mackerel or sardine.

Matters to be controlled:

- Frequency of sampling, product groups that are tested and number of sample units.
- Any deviations found in the tests referred to above, the implemented corrective actions, and the records of these.
- The adequacy and suitability of own-check activities, and the own-check plan, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The sampling plan for histamine presents appropriate grounds or complies with Evira' sampling recommendations. Sampling has been carried out according to plan.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

For example:

- There are some minor shortcomings in the grounds presented in the sampling plan. Or, the operator has opted to follow Evira's sampling recommendation, but the sampling plan of the operator is not completely consistent with the recommendation.
- The sampling plan presents appropriate grounds or complies with Evira's sampling recommendation. As a rule, sampling is carried out according to plans, but in some individual cases sampling has not been carried out.
- The number of sample units is not completely in compliance with requirements, occasionally the number of sample units that are tested is too low.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

For example:

- There is no sampling plan at all, but sampling has been carried out to some extent.
- There are clear shortcomings in the grounds presented in the sampling plan. Or, the operator has opted to follow Evira's sampling recommendation, but the sampling plan of the operator deviates significantly from the recommendation.
- The number of tested samples is considerably lower than the planned number.
- Sampling is not carried out at all from some product group.
- Sample units are not tested of the samples, or the number of tested sample units is continuously too low.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

For example:

- No sampling has been carried out or only to a very limited extent.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002/EY on food law
- Regulation (EC) No 2073/2005 on microbiological grounds for foodstuffs, Article 3
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Evira's Guide 10501: "Microbiological grounds for foodstuffs, application of Commission Regulation (EC) 2073/2005"
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Updates in version 2:

- The title of the Guideline has been changed: "control of histamine" has been changed into "own-check of histamine ".

17 Food Testing

17.9 Quality Testing of Raw Milk

To be taken into consideration:

- This Guideline is applied to the evaluation of the operation of an establishment that receives raw milk, with respect to the implementation of quality testing of raw milk. The milk sector operator shall initiate procedures to verify that the raw milk received at the establishment meets the criteria laid down in Regulation 853/2004 as regards plate count, somatic cell count and residues of conventional antibiotic substances tested using the Delvotest. Procedures refer to the establishment taking care of the implementation of the referred tests. If the supplier of the raw milk is responsible for the referred tests, the receiving establishment shall ensure that the test results are made available to the establishment on a regular basis.
- The residues of medicines and other substances in raw milk are evaluated more specifically in points 17.11 – 17.14.
- The implementation of the acceptance inspections of raw milk defined in the Decree on food hygiene at establishments (organoleptic determination of temperature, appearance and smell of received milk batches, as well as any residues of antimicrobials) is also evaluated.
- The own-check plan of the establishment shall provide descriptions of the implementation of the referred tests and inspections, as well as instructions for action in case quality deviations are detected, and instructions for reporting to the control authorities.

Matters to be controlled:

- Results of plate count and somatic cell count tests of the received raw milk produced at the place of primary production, as well as the testing of milk for residues of antimicrobials.
- Temperature of received raw milk, organoleptic assessment (appearance and smell) as well as testing of residues of antimicrobials.
- Any deviations found in the tests referred to above, the implemented corrective actions, and the records of these.
- Procedures defined in the own-check plan in case quality deviations are detected in raw milk, and instructions for reporting to control authorities.

EXCELLENT

Operations comply with requirements.

Quality testing of raw milk is implemented, operation is described in the own-check plan, records are maintained of actions taken, and reporting is implemented.

- Own-check records contain information on results of plate count and somatic cell count tests of the received raw milk produced at the place of primary production, as well as results of the testing of milk for residues of antimicrobials.
- The temperature of the received milk is measured, an organoleptic assessment is carried out of its appearance and smell, and it is tested for residues of antimicrobials. The arrangements of the acceptance inspection are described in the own-check plan and the plan is complied with.
- Records are available of any deviations found in the referred tests and corrective actions taken. Corrective actions have been adequate and appropriate.

- The own-check plan describes procedures for deviations and instructions for reporting to the control authority. Reporting to the authorities has been implemented.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The quality testing obligations are fulfilled with respect to raw milk, operation is described in the own-check plan, but records are not complete.

- Results of plate count and somatic cell count tests of raw milk, as well as results of the testing of raw milk for residues of antimicrobials have been monitored, but all the results are not included in the own-check records.
- The temperature of the received milk is measured, an organoleptic assessment is carried out (appearance and smell), and it is tested for residues of antimicrobials, but all the results are not included in the own-check records. The arrangements of the acceptance inspection are described in the own-check plan.
- There are some minor shortcomings in the records of deviations or corrective actions. However, corrective actions have been adequate.
- The own-check plan describes procedures for deviations and instructions for reporting to the control authorities. Reporting to the authorities has been implemented.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are shortcomings in the fulfilment of quality testing obligations with respect to raw milk, and in records and reporting. Operation and corrective actions are described in the own-check plan.

- Results of plate count and somatic cell count tests of raw milk, as well as results of the testing of milk for residues of antimicrobials have been monitored, but all the results are not included in the own-check records.
- The temperature of the received raw milk is measured, an organoleptic assessment is carried out (appearance and smell), and it is tested for residues of antimicrobials, but all the results are not included in own-check records. The arrangements for acceptance inspections are not described in the own-check plan.
- Deviations have not been recorded although it becomes known that deviations have occurred or corrective actions taken because of deviations have been inappropriate or inadequate.
- The own-check plan provides inadequate instructions for actions in case deviations are detected and for reporting to the control authorities. There are shortcomings in reporting to the authorities.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

There are serious shortcomings in the fulfilment of quality testing obligations with respect to raw milk, and in records and reporting. Operation and corrective actions are inadequately described in the own-check plan.

- Results of plate count and somatic cell count tests of raw milk, as well as results of the testing of milk for residues of antimicrobials are not monitored, and they are not included in the own-check records.
- Acceptance inspections are not carried out for raw milk. Arrangements for acceptance inspections are not described in the own-check plan.
- Deviations have not been recorded although it becomes known that deviations have occurred or corrective actions taken because of deviations have been inappropriate or inadequate.
- The own-check plan does not provide a description of quality criteria for raw milk, quality control and actions in case quality deviations are detected in raw milk. There are shortcomings in reporting to the authorities.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 853/2004 on hygiene rules for food of animal origin, Annex III, Section IX, Chapter I, Part III
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2015
- Decree on raw milk 699/2013

17. Food testing

17.11 Residues of Medicinal Products

This evaluation is at present not presented in the Oiva report, but only in the control report

The purpose of this topical area is to control that the operator has recognised the risks related to residues of medicinal products authorised to be used for production animals (also other medicines in addition to antimicrobials, such as pain killers or anti-parasite drugs) and substances banned from use for production animals, and the operator is taking actions for the management of these risks when receiving animals or foodstuffs of animal origin to the establishment. Typical methods for management include own-check tests and documentary controls. The operator shall report all detected or suspected shortcomings to the authority responsible for the control of the establishment, and take corrective actions to eliminate such shortcomings. The consideration of residues of medicinal products is part of the verification of the chemical safety of food.

To be taken into consideration:

- This point is to be evaluated for establishments, primarily slaughterhouses, low-capacity slaughterhouses and milk sector establishments. Where considered appropriate, the Guideline is also applied to other establishments that receive animals or foodstuffs of animal origin (e.g. poultry slaughterhouses, reindeer slaughterhouses, egg-packing centres, and fish sector establishments), taking into account the nature and scope of operations at the establishment.
- This point can also be controlled on discretionary basis when the operator manufactures, has manufactured for it, packs, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs for which regulatory maximum levels for residues of medicinal products have been set (e.g. any residues of anti-parasite drugs in beef).
- The purpose of this Guideline is to evaluate risk management related to any residues of medicinal products in raw milk (risk assessment and required management methods). The quality testing of raw milk is evaluated in point 17.9.
- The checking of information related to the food chain is evaluated in Guideline 9.2.
- The sampling and testing plan related to own-check testing (e.g. compliance of methods with requirements, and laboratories) is evaluated in Guideline 13.1.
- The checking of the identification documents of horses is evaluated in point 9.5.

Matters to be controlled:

The risks related to residues of medicinal products (also other medicines authorised to be used for production animals in addition to antimicrobials) and banned substances shall be identified as part of the establishment's own-check activities taking the nature and scope of the operation into account, and the means required to identify and eliminate these risks shall be included in the own-check plan of the establishment. It is also to be controlled that the operator has complied with its own-check plan in relation to residues of medical products, if any. In this point, control shall cover the whole topical area which comprises the following:

- When checking food chain information related to the animal received or information related to another foodstuff, the operator has also taken possible residues of medicinal products or banned substances into consideration. The checking and assessment of medication data

should be included in the assessment of the food chain information by the operator, in addition to the checking of the adequacy of the withdrawal period.

- Residues of medicinal products are also included in the establishment's sampling and testing plan. It shall particularly be controlled in this point that the tests for residues of antimicrobials included in own-check activities have been taken into account and the tests are carried out in compliance with the requirements laid down in provisions and in accordance with the plan. In some cases the operator can carry out checks related to residues of medicinal products as documentary controls (e.g. small-scale milk sector establishments or importers of foodstuffs / procurement agreements on foodstuffs).
- The own-check plan provides procedures to prevent food containing residues of medicinal products from being delivered for consumption when the food is suspected to contain, or found in e.g. own-check testing to contain residues of medicinal products in levels exceeding the limit values specified in legislation, or substances banned from use for production animals.
- Records are maintained of own-check tests and results of the tests, deviations and actions taken, including reporting to the authority responsible for the control of the establishment. It can be evaluated on the basis of the records if the corrective actions taken as needed due to test results or documentary controls have been adequately extensive and executed adequately swiftly, and if abnormal situations have been reported in compliance with sector-specific provisions to the authority responsible for the control of the establishment.
- The operator shall identify also for foodstuffs e that the operator has e.g. imported the most relevant risks related to residues of medicinal products in the foodstuffs concerned (e.g. foodstuffs imported from a third country where medicinal products not authorised in the EU are used for production animals). Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications. In addition, the operator is able to present, for example, analysis certificates or audit documents for the verification of risk management. NOTE! Batch-specific verification is not necessary The results of regulatory tests, if any, can also be utilised as part of the operator's own-check.

EXCELLENT

Operations comply with requirements.

Operations comply with requirements as regards the matters that are controlled. For example:

- Risks related to residues of medicinal products have been identified and the management of these risks is included in the own-check plan with respect to also other medicines in addition to antimicrobials through e.g. the statement that when food chain information is checked, medication data should be considered as a whole in addition to the adequacy of withdrawal periods, and that e.g. exceptionally and abnormally high use levels should be reported to the inspector controlling the establishment.

- Medication data have been checked as part of the food chain information for every animal or group of animals delivered to the slaughterhouse.
- If any deviations have been detected in the information in addition to inadequate withdrawal periods or for some other reason, these have also been reported to the authority responsible for the control of the establishment. Suspicion can be based on e.g. the available data indicating

an exceptionally high level of medication for the animal delivered for slaughter or fresh puncture marks detected in the animal already before meat inspection. Also when receiving foodstuffs of animal origin, the operator has taken actions to verify that the foodstuffs do not contain residues of medicinal products in levels exceeding the permissible limits.

- The sampling and testing plan of the establishment is adequate and at least the tests for antimicrobials required by sector-specific provisions are included in it. Tests have been carried out according to the plan on a regular basis and in an adequate scope.

- Animals delivered for slaughter have been sampled on a regular basis to test for residues of antimicrobials.
- A sample quantity that can be considered adequate is e.g. 0.2% of the number of slaughtered animals. At milk sector establishments, every batch of raw milk received at the establishment has been tested for residues of antimicrobials. A small-scale establishment can apply the relaxations allowed by provisions and instead of tests for antimicrobials, the establishment has checked for every milk batch the information provided by the supplier of the raw milk.
- The own-check plan provides clear procedures to prevent food containing residues of medicinal products from being delivered for consumption. For example, if a test for residues of antimicrobials gives a positive result in own-check, or it is suspected that the animal or foodstuff contains residues of medicinal products in levels exceeding the limit values, the animal or foodstuff concerned is set aside to await the completion of the analyses. Also other situations that are possible in the sector concerned are included in the plan (e.g. an animal has to be slaughtered during the withdrawal period for humane reasons, or a milk batch being delivered to the establishment is known to contain residues of medicinal products).

- Records have been maintained of own-check tests or documentary controls and their results.
- Records have also been maintained of any deviations that have been detected, and corrective actions taken due to them, including reporting to the authority responsible for the control of the establishment.
- Based on the records, it can be verified that, when necessary, the establishment has followed the procedures described in the own-check plan and the procedures have been made more specific in each case. If corrective actions have been taken, they have been initiated immediately and have been adequate in relation to the nature of the matter (e.g. foodstuff containing residues of medicinal products delivered for disposal, and recalls, if appropriate).

- The operator has identified relevant risks related to residues of medicinal products also as concerns foodstuffs imported by the operator.
- Quality criteria in terms of residues of medicinal products have been defined for foodstuffs in e.g. procurement agreements in case where the production site of the foodstuffs involves known risk factors. Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications. In addition, the operator is able to present, for example, analysis certificates or audit documents for the verification of risk

management. NOTE! The necessity of chemical analyses as well as the required tests and the analysis frequency are determined based on the nature and effectiveness of operation.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

Risks related to residues of medicinal products have been identified at least with respect to antimicrobials, and the management of the risks is included in the own-check plan. For example:

- Medication data including adequacy of withdrawal periods are checked, as a rule, as part of food chain information for animals or groups of animals delivered to the slaughterhouse, and inadequate withdrawal periods are reported appropriately to the authority responsible for the control of the establishment.
- No individual cases of suspected shortcomings have been reported to the controlling inspector. Also when receiving foodstuffs of animal origin, the operator has taken actions to verify that the foodstuffs do not contain residues of antimicrobials in levels exceeding the permissible limits.
- The sampling and testing plan is adequate and the tests for antimicrobials required by sector-specific provisions are included in it. Testing has as a rule been carried out according to the plan, but in some parts tests have been made irregularly or in slightly lower numbers than planned. However, food safety has not been jeopardised.

- The own-check plan provides procedures to prevent food containing residues of medicinal products from being delivered for consumption.
- As a rule, the procedures have been followed and action taken has prevented the food from being delivered for consumption. Sometimes the case has been reported to the authority responsible for the control of the establishment after a short delay, and the start of corrective actions may also have been slightly delayed because of this.
- Records have been maintained of own-check tests or documentary controls and their results, but there are some occasional inaccuracies in the records. For example, all results have not been recorded, if they have been acceptable. As a rule, records have also been maintained of any deviations that have been detected, and corrective actions taken due to them, including reporting to the authority responsible for the control of the establishment, but the corrective actions taken have in some cases been described somewhat inaccurately, making it difficult to verify that they have been adequate.

- The operator has identified relevant risks related to residues of medicinal products also as concerns foodstuffs imported by the operator.
- If appropriate, quality criteria with respect to residues of medicinal products have been defined in e.g. procurement agreements, but the operator is unable to present any evidence to support this, e.g. analysis certificates.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

Risks related to residues of medicinal products have not been adequately identified even with respect to antimicrobials, and the risks are not adequately included in the own-check plan of the establishment. For example:

- Medication data have been checked irregularly as part of food chain information for animals or groups of animals delivered to the slaughterhouse.
- Inadequate withdrawal periods have been reported to the authority responsible for the control of the establishment in most cases, but often after a delay. Food safety is impaired.
- Suspicions of shortcomings have only rarely been reported to the authority responsible for the control of the establishment. When receiving foodstuffs of animal origin, the operator has not taken any actions to verify that the foodstuffs do not contain residues of antimicrobials in levels exceeding the permissible limits.

- Testing for residues of antimicrobials is included in the sampling and testing plan, but it does not meet sector-specific requirements due to e.g. inadequate numbers of samples.
- Tests/controls have been carried out, but on an irregular basis and/or in lower numbers than planned.
- The own-check plan does not provide clear procedures for cases where food is found to contain residues of medicinal products. The establishment aims at preventing such food from being delivered for consumption, but this cannot be verified. The cases are mostly reported to the controlling inspector after a long delay, which has clearly delayed the start of corrective actions or it has not been possible to take any actions.

- Records have been maintained of own-check tests or documentary controls and their results, but there are several inaccuracies and shortcomings in the records.
- Records have been maintained on a random basis of any deviations that have been detected, and corrective actions taken due to them, including reporting to the authority responsible for the control of the establishment, but the corrective actions taken have been described inaccurately and deficiently, making it impossible to verify that they have been adequate.
- The operator has not considered the possible risks related to residues of medicinal products as concerns foodstuffs imported by the operator. Quality criteria with respect to residues of medicinal products have not been defined for foodstuffs in e.g. procurement agreements and the operator is unable to present any kind of analysis certificates to support risk management.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Risks related to residues of medicinal products have not been identified and the management of the risks is not included in any way in the inown-check plan of the establishment. Food safety is jeopardised.

- The operator has controlled medication data as part of food chain information on a random basis. Inadequate withdrawal periods are only occasionally reported to the controlling inspector, although the matter has been pointed out to the operator. Food safety is jeopardised.

- The sampling and testing plan of the establishment does not specifically include tests for antimicrobials, although they are required by sector-specific provisions.
- Testing has been carried out, however, but only occasionally. Food safety is jeopardised.
- The own-check plan does not provide procedures for cases where foodstuffs are found to contain residues of medicinal products and this is not considered in operations in any specific way. Deviations have been reported to the authority responsible for the control of the establishment on a random basis or not at all, although deviations have been detected. Food safety is jeopardised.

- Records have been maintained of the results of own-check tests on a random basis or not at all.
- There are no records of detected deviations or any corrective actions taken due to them, including reporting to the authority responsible for the control of the establishment, to make it possible to review operations later.
- Quality criteria for foodstuffs with respect to residues of medicinal products are not under control. Shortcomings requiring immediate rectification include, for example, cases where the chemical analysis of a foodstuff has shown that the maximum regulatory level of a medicinal product is exceeded, but no corrective actions have been taken in the operation, or the action taken has been inappropriate or inadequate. Food safety is jeopardised.

- The operator has failed to fulfil the orders issued with the grade To be corrected.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EC) No 178/2002 on food law
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Finnish Food Act 23/2006
- Decree of the Ministry of Agriculture and Forestry on food hygiene at establishments 795/2014
- Detection of antimicrobials in meat inspection using a microbiological method 21/EEO/2001
- Finnish Act on the Medication of Animals 387/2014
- Regulation (EC) No. 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin

- Commission Regulation (EU) 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
- Evira's Guideline 17069: Chemical analyses for demonstration of compliance of foodstuffs with requirements

17. Food Testing

17.12 Residues of Plant Protection Products

To be taken into consideration:

This point is to be controlled when the operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business)

- Foods intended for infants or young children (incl. baby foods, infant formulae, follow-on formulae and foods for special medical purposes intended for infants)
- Significant quantities of fruit and/or berries (e.g. fresh, frozen and dried) (e.g. food premises and establishments that handle >500 000 kg of these products per year)
- Significant quantities of vegetables (e.g. fresh, frozen and dried) (e.g. food premises and establishments that handle >500 000 kg of these products per year)
- Significant quantities of nuts and/or seeds (e.g. food premises and establishments that handle >10 000 kg of these products per year)
- Significant quantities of spices (e.g. food premises and establishments that handle >10 000 kg of these products per year)
- Significant quantities of tea and/or herbal infusions (e.g. food premises and establishments that handle >10 000 kg of these products per year)

This point can also be controlled on discretionary basis, when the operator manufactures, has manufactured for it, imports (from the internal market and/or third countries) or brokers foodstuffs or ingredients of foodstuffs for which regulatory maximum levels for pesticide residues have been fixed:

- Fruit and berries
- Vegetables
- Dried leguminous vegetables
- Nuts
- Spices
- Cereals
- Oil seeds and oil seed plants
- Sugar plants
- Coffee, tea, herbal infusions and cocoa
- Hops
- Terrestrial animal products
- Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals; other processed products such as sausages and food preparations based on these
    - Milk and cream (not concentrated, nor containing added sugar or sweetening matter), butter and other fats derived from milk, cheese and curd
    - Birds' eggs (fresh preserved or cooked), shelled eggs and egg yolks (fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter)
    - Honey and other terrestrial animal products

This Guideline is applied on discretionary basis only to retail stores and serving facilities that import the aforementioned foodstuffs (from the internal market and/or third countries).

Matters to be controlled:

The implementation of own-check activities is evaluated (where necessary, by random checks on e.g. 1-3 products, taking the scope and nature of operations into consideration) by checking the following matters:

Foodstuffs containing residues of plant protection products in levels exceeding the fixed maximum level are not placed on the market or used as ingredients in food products.

- The operator identifies the relevant hazards related to residues of plant protection products and has these hazards under control.
- Risk management related to food products or raw materials of food products can be demonstrated (by means of e.g. procurement contracts or product specifications) and verified (based on e.g. analysis certificates or audits).
- NOTE! Batch-specific verification is not required. The scope and effectiveness of operation determine the frequency of analysis. Testing results from sampling carried out by authorities can also be utilised.

EXCELLENT

Operations comply with requirements.

The operator identifies the hazards which are relevant to foodstuffs and related to residues of plant protection products and has these hazards under control.

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications. In addition, the operator is able to present, for example, analysis certificates or audit documents for the verification of risk management.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The management of residues of plant protection products complies in main parts with the aforementioned requirements. There are some minor shortcomings, such as:

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications, but this cannot be supported by presentation of e.g. analysis certificates.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are clear shortcomings in the management of risks related to residues of plant protection products. Shortcomings include, for example:

- Risk management cannot be demonstrated in any way.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Risks related to plant protection products are not under control. Such shortcomings requiring immediate rectification or recall include:

- A chemical analysis has shown that the maximum level fixed in legislation is exceeded or an active substance that is not authorised in the EU is used in the plant protection product, but no corrective actions have been taken or the actions taken have not been adequate.
- The operator is unable to present any evidence to demonstrate risk management despite being requested or ordered to do so.

Legislation and guidelines pertaining to the topic:

- Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (incl. amendments)
- Decree of the Ministry of Trade and Industry on pesticide residues in children's foods, 1215/2007
- Decree KTM 1216/2007 of the Ministry of Trade and Industry on infant formulae and follow-on formulae
- Chemical hazards of foodstuffs and domestic water (Evira publication 13/2013)

Updates in version 4:

- The terminology related to children's foods revised to be consistent with new legislation.

17 Food Testing

17.13 Environmental Contaminants

To be taken into consideration:

This point is to be controlled when the operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business)

- children's foods (incl. infant formulae, follow-on formulae, foodstuffs intended for the particular nutritional use of infants, and beverages intended for infants and young children)
- significant quantities of wild-caught fish or fishery products thereof (e.g. food premises and establishments that handle >50 000 kg of these products per year)
- significant quantities of rice or rice products (e.g. food premises and establishments that handle >50 000 kg of these products per year)
- significant quantities of wild berries or mushrooms (e.g. food premises and establishments that handle >50 000 kg of these products per year)

Where wild-caught fish is concerned, it is recommended that Guideline 16.4. (Traceability of Fish and Fishery Products Exempt from Dioxin Regulations) is controlled at the same time.

This point can also be controlled on discretionary basis, when the operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs for which regulatory maximum levels for environmental contaminants have been set:

- e.g. milk and dairy products, meat and meat products, offals, fish and fishery products, eggs and egg products, crustaceans, molluscs, legumes, cereals, vegetables, mushrooms, fruits, berries, fats and oils, food supplements, soybeans, cocoa and chocolate products, canned beverages, fruit juices, fruit juice concentrates and fruit nectars, honey, rice, rice waffles, rice waffle biscuits, rice biscuits and rice cakes[1,2].

This Guideline is applied on discretionary basis only to retail stores and serving facilities that import the aforementioned foodstuffs (from the internal market and/or third countries).

Matters to be controlled:

The implementation of own-check activities is evaluated (where necessary, by random checks on e.g. 1-3 products, taking the scope and nature of operations into consideration) by checking the following matters:

Foodstuffs containing environmental contaminants (heavy metals, dioxins and PCBs, radioactive substances) in levels exceeding the maximum levels set are not placed on the market or used as ingredients in food products.

- The operator identifies the relevant hazards related to environmental contaminants that are to be particularly taken into account for the food product (e.g. wild-caught fish - heavy metals, particularly mercury; wild berries and mushrooms – radioactive substances; rice – inorganic arsenic) and has these hazards under control.
- Risk management related to food products or raw materials of food products can be demonstrated (by means of e.g. procurement contracts or product specifications) and verified (based on e.g. analysis certificates or audits).

- NOTE! Batch-specific verification is not required. The scope and effectiveness of operation determine the frequency of analysis – testing results from sampling carried out by authorities can also be utilised. The analysis certificates are not necessary for fish and fishery products exempt from dioxin regulations, provided the food products are intended to the markets to which the derogation applies.

EXCELLENT

Operations comply with requirements.

The operator identifies the hazards related to environmental contaminants and has these hazards under control.

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications. In addition, the operator is able to present, for example, analysis certificates or audit documents for the verification of risk management.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The management of environmental contaminants complies in main parts with the aforementioned requirements. There are some minor shortcomings, such as:

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications, but this cannot be supported by presentation of e.g. analysis certificates.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are clear shortcomings in the management of risks related to environmental contaminants. Shortcomings include, for example:

- Risk management cannot be demonstrated in any way.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Risks related to environmental contaminants are not under control. Such shortcomings requiring immediate rectification or recall include:

- A chemical analysis has shown that the maximum level set in legislation is exceeded, but no corrective actions have been taken or the actions taken have not been adequate.
- The operator is unable to present any evidence to demonstrate risk management despite being requested or ordered to do so.

Legislation and guidelines (with any amendments) pertaining to the subject:

- [1]Commission Regulation setting maximum levels for certain contaminants in foodstuffs, (EC) No 1881/2006
- [2]Commission Recommendation on the protection and information of the public with regard to exposure resulting from the continued radioactive caesium contamination of certain wild food products as a consequence of the accident at the Chernobyl nuclear power station (2003/274/Euratom)
- Council Regulation laying down Community procedures for contaminants in food (EEC) No 315/93
- Chemical hazards of foodstuffs and domestic water (Evira publication 13/2013)

Updates in version 2:

- matters to be controlled and the criteria for the grade Excellent specified with respect to the demonstration and verification of risk management
- added in the scope of the Guideline; beverages intended for infants and young children
- included in the Guideline; control of inorganic arsenic in rice and rice products
- list of food products to be controlled on procurement basis supplemented (added: fruit juices, fruit juice concentrates and fruit nectars, honey, rice, rice waffles, rice waffle biscuits, rice biscuits, and rice cakes).

17 Food Testing

17.14 Mycotoxins

To be taken into consideration:

This point is to be controlled when the operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business)

- children's foods (incl. infant formulae, follow-on formulae and foodstuffs intended for the particular nutritional use of infants)
- significant quantities of cereals or cereal products (e.g. food premises and establishments that handle >500 000 kg of these products per year)
- significant quantities of nuts, peanuts, dried fruits or maize, and products thereof (e.g. food premises and establishments that handle >10 000 kg of these products per year
- significant quantities of fruit juices, fruit juice concentrates or -nectars (e.g. food premises and establishments that handle >500 000 kg of these products per year).

This point can also be controlled on discretionary basis, when the operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs for which regulatory maximum levels for mycotoxins or ergot sclerotia have been set:

- e.g. peanuts and other oil seeds, almonds, pistachios, apricot seeds, hazel nuts, Brazil nuts, other nuts, dried fruits, cereal and cereal products (incl. maize and rice), raw milk, heat-treated milk, spices and spice mixtures, raisins, coffee (roasted coffee beans, ground roasted coffee, instant coffee) grape juice (incl. grape juice concentrates and nectars), liquorice (incl. liquorice roots and liquorice extract), wheat gluten not sold directly to consumers, fruit juices (incl. fruit juice concentrates and nectars), solid apple products (incl. apple compote and apple puree), pasta, bread, cakes, pastries, biscuits, cookies, cereal snacks, breakfast cereals, refined maize oil, red rice food supplements[1].

This Guideline is applied on discretionary basis only to retail stores and serving facilities that import the aforementioned foodstuffs (from the internal market and/or third countries).

Matters to be controlled:

The implementation of own-check activities is evaluated (where necessary, by random checks on e.g. 1-3 products, taking the scope and nature of operations into consideration) by checking the following matters:

Foodstuffs containing mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, citrinin) and/or ergot sclerotia in levels exceeding the maximum levels set are not placed on the market or used as ingredients in food products.

- The operator identifies the relevant hazards related to mycotoxins and ergot sclerotia that are to be particularly taken into account for the food product (e.g. cereals and cereal products – deoxynivalenol/ochratoxin A/zearalenone, maize and maize products – fumonisins/aflatoxins, nuts – aflatoxins, fruit juices – patulin, unprocessed cereals – ergot sclerotia) and has these hazards under control.
- Risk management related to food products or raw materials of food products can be demonstrated (by means of e.g. procurement contracts or product specifications) and verified (based on e.g. analysis certificates or audits).

- NOTE! Batch-specific verification is not required. The scope and effectiveness of operation determine the frequency of analysis – testing results from sampling carried out by authorities can also be utilised.

EXCELLENT

Operations comply with requirements.

The operator identifies the hazards related to mycotoxins and/or ergot sclerotia and has these hazards under control.

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications. In addition, the operator is able to present, for example, analysis certificates or audit documents for the verification of risk management.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The management of mycotoxins and/or ergot sclerotia complies in main parts with the aforementioned requirements. There are some minor shortcomings, such as:

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications, but this cannot be supported by presentation of e.g. analysis certificates.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are clear shortcomings in the management of risks related to mycotoxins and/or ergot sclerotia. Shortcomings include, for example:

- Risk management cannot be demonstrated in any way.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Risks related to mycotoxins and/or ergot sclerotia are not under control. Such shortcomings requiring immediate rectification or recall include:

- A chemical analysis (a microscopic analysis for ergot sclerotia) has shown that the maximum level set in legislation is exceeded, but no corrective actions have been taken or the actions taken have not been appropriate/adequate.
- The operator is unable to present any evidence to demonstrate risk management despite being requested or ordered to do so.

Legislation and guidelines (with any amendments) pertaining to the subject:

- [1]Commission Regulation setting maximum levels for certain contaminants in foodstuffs, (EC) No 1881/2006
- Council Regulation laying down Community procedures for contaminants in food (EEC) No 315/93
- Chemical hazards of foodstuffs and domestic water (Evira publication 13/2013)

Updates in version 2:

- matters to be controlled and the criteria for the grade Excellent specified with respect to the demonstration and verification of risk management
- control of ergot sclerotia included in the Guideline (and the associated technical changes made).

17 Food Testing

17.15 Process Contaminants

To be taken into consideration:

This point is to be controlled when the operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business)

- children's foods (incl. infant formulae, follow-on formulae and foodstuffs intended for the particular nutritional use of infants)
- foodstuffs produced using traditional smoking processes (NOTE! The Guideline does not pertain to foodstuffs manufactured using smoke flavourings, e.g. liquid smoke, or to the ingredients of such foods).

This point can also be controlled on discretionary basis, when the operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs for which regulatory maximum levels for process contaminants have been set:

- e.g. smoked meat and products thereof, smoked fish, smoked fishery products, oils and fats, cocoa beans and products thereof, molluscs, hydrolysed plant protein, soy sauce[1].

This Guideline is applied to retail stores and serving facilities where traditional smoking is carried out. In addition, this Guideline is applied on discretionary basis only to retail stores and serving facilities that import the aforementioned foodstuffs (from the internal market and/or third countries).

Matters to be controlled:

The implementation of own-check activities is evaluated (where necessary, by random checks on e.g. 1-3 products, taking the scope and nature of operations into consideration) by checking the following matters:

Foodstuffs containing process contaminants (PAH compounds, 3-MCPD) in levels exceeding the maximum levels set are not placed on the market or used as ingredients in food products.

Operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs:

- The operator identifies the relevant hazards related to process contaminants that are to be particularly taken into account for the food product (e.g. smoked products – PAH compounds, soy sauce – 3-MCPD) and has these hazards under control.
- Risk management related to food products or raw materials of food products can be demonstrated (by means of e.g. procurement contracts or product specifications) and verified (based on e.g. analysis certificates or audits).
- NOTE! Batch-specific verification is not required. The scope and effectiveness of operation determine the frequency of analysis – testing results from sampling carried out by authorities can also be utilised.

Operator smokes foodstuffs itself:

- The cleanliness of the smoking equipment is looked after.
- The instructions for use provided by the equipment manufacturer as well as good manufacturing practices (e.g. avoiding "over-smoking") are complied with.

- Analyses related to own-check activities have been carried out (NOTE! The scope and effectiveness of operation determine the frequency of analysis); testing results from sampling carried out by authorities can also be utilised.
- An analysis certificate demonstrating compliance with regulations is the strongest assurance of risk management.

EXCELLENT

Operations comply with requirements.

The operator identifies the hazards related to process contaminants and has these hazards under control.

Operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs:

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications. In addition, the operator is able to present, for example, analysis certificates or audit documents for the verification of risk management.

Operator smokes foodstuffs itself:

- The cleanliness of the smoking equipment is looked after.
- The instructions for use provided by the equipment manufacturer and/or good manufacturing practices are complied with.
- Chemical analyses have been carried out to support risk management.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The management of process contaminants complies in main parts with the aforementioned requirements. There are some minor shortcomings, such as:

Operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs:

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications, but this cannot be supported by presentation of e.g. analysis certificates.

Operator smokes foodstuffs itself:

- There are some minor shortcomings in the cleanliness of the smoking equipment, but it is clean in the main parts.
- Good manufacturing practices are complied with in the main parts, but some minor shortcomings are found; however, they do not impair food safety.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are clear shortcomings in the management of risks related to process contaminants. Shortcomings include, for example:

Operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs:

- Risk management cannot be demonstrated in any way.

Operator smokes foodstuffs itself:

- The smoking equipment is visibly extremely dirty.
- The instructions for use for the smoking equipment are not known.
- Good manufacturing practices are not complied with in smoking (e.g. "over-smoking").

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Risks related to process contaminants are not under control. Such shortcomings requiring immediate rectification or recall include:

Operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs:

- A chemical analysis has shown that the maximum level set in legislation is exceeded, but no corrective actions have been taken or the actions taken have not been adequate.
- The operator is unable to present any evidence to demonstrate risk management despite being requested or ordered to do so.

Operator smokes foodstuffs itself:

- A chemical analysis has shown that the maximum level set in legislation is exceeded, but no corrective actions have been taken or the actions taken have not been adequate.

Legislation and guidelines (with any amendments) pertaining to the subject:

- [1]Commission Regulation setting maximum levels for certain contaminants in foodstuffs, (EC) No 1881/2006
- Council Regulation laying down Community procedures for contaminants in food (EEC) No 315/93
- Chemical hazards of foodstuffs and domestic water (Evira publication 13/2013)
- Guidelines to reduce PAH compounds: (http://www.evira.fi/files/attachments/fi/elintarvikkeet/valmistus_ja_myynti/valvonta/tutkimukset_ja_projektit/pah_hanke/liite_6_ohjeita_pah-yhdisteiden_vahentamiseksi.pdf)

Updates in version 2:

- matters to be controlled and the criteria for the grade Excellent specified with respect to the demonstration and verification of risk management.

17 Food Testing

17.16 Other Contaminants

To be taken into consideration:

This point is to be controlled when the operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business)

- children's foods (incl. infant formulae, follow-on formulae and foodstuffs intended for the particular nutritional use of infants)
- significant quantities of spinach, fresh lettuce, Iceberg-type lettuces or rucola (e.g. food premises and establishments that handle >50 000 kg of these products per year)
- significant quantities of vegetable oils and fats (e.g. food premises and establishments that handle >100 000 kg of these products per year)

This point can also be controlled on discretionary basis, when the operator manufactures, has manufactured for it, packages, imports (from the internal market and/or third countries) or brokers (e.g. agency business) foodstuffs or ingredients of foodstuffs for which regulatory maximum levels for nitrate, erucic acid or tropane alkaloids have been set:

- spinach, fresh lettuce, Iceberg-type lettuces, rucola, vegetable oils and fats, foodstuffs containing vegetable oils and fats, as well as children's foods containing sorghum, millet or buckwheat[1].

This Guideline is applied on discretionary basis only to retail stores and serving facilities that import the aforementioned foodstuffs (from the internal market and/or third countries).

Matters to be controlled:

The implementation of own-check activities is evaluated (where necessary, by random checks on e.g. 1-3 products, taking the scope and nature of operations into consideration) by checking the following matters:

Foodstuffs containing nitrate, erucic acid or tropane alkaloids in levels exceeding the maximum levels set are not placed on the market or used as ingredients in food products.

- The operator identifies the relevant hazards related to nitrate, erucic acid or tropane alkaloids that are to be particularly taken into account for the food product (e.g. spinach, lettuces, rucola – nitrate; vegetable oils and fats and foodstuffs containing them – erucic acid; children's foods containing sorghum, millet or buckwheat – tropane alkaloids) and has these hazards under control.
- Risk management related to food products or raw materials of food products can be demonstrated (by means of e.g. procurement contracts or product specifications) and verified (based on e.g. analysis certificates or audits).
- NOTE! Batch-specific verification is not required. The scope and effectiveness of operation determine the frequency of analysis – testing results from sampling carried out by authorities can also be utilised.

EXCELLENT

Operations comply with requirements.

The operator identifies the hazards related to nitrate, erucic acid or tropane alkaloids and has these hazards under control.

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications. In addition, the operator is able to present, for example, analysis certificates or audit documents for the verification of risk management.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The management of nitrate, erucic acid or tropane alkaloids complies in main parts with the aforementioned requirements. There are some minor shortcomings, such as:

- Risk management can be demonstrated on the basis of e.g. procurement contracts or product specifications, but this cannot be supported by presentation of e.g. analysis certificates.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

There are clear shortcomings in the management of risks related to nitrate, erucic acid or tropane alkaloids. Shortcomings include, for example:

- Risk management cannot be demonstrated in any way.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

Risks related to nitrate, erucic acid or tropane alkaloids are not under control. Such shortcomings requiring immediate rectification or recall include:

- A chemical analysis has shown that the maximum level set in legislation is exceeded, but no corrective actions have been taken or the actions taken have not been adequate.
- The operator is unable to present any evidence to demonstrate risk management despite being requested or ordered to do so.

Legislation and guidelines (with any amendments) pertaining to the subject:

- [1]Commission Regulation setting maximum levels for certain contaminants in foodstuffs, (EC) No 1881/2006
- Council Regulation laying down Community procedures for contaminants in food (EEC) No 315/93
- Chemical hazards of foodstuffs and domestic water (Evira publication 13/2013)

Updates in version 3:

- control of tropane alkaloids included in the Guideline (and the associated technical changes made)

18 Display of the Oiva report

18.1 Display of the Oiva report

To be taken into consideration:

- The Oiva report shall be displayed in the immediate vicinity of the main entrance to the food premises or establishment, or in some other place that is relevant to the consumer, and at a height where it is easy to notice, as defined in the Evira Regulation 2/2016, when the consumers visit the food premises or establishment.

- All food premises and establishments that sell products online must publish the Oiva report on the front page of their website. In this case the front page of the website is equivalent to the entrance of an establishment.

- All food premises and establishments that market their products online must publish the Oiva report on their website.

Matters to be controlled:

- Display of the Oiva report
  - at the entrance
  - in connection with online sales or marketing

EXCELLENT

Operations comply with requirements.

The latest Oiva report is displayed according to Evira's regulations.

- The Oiva report is posted at the main entrance at a suitable height where it is clearly discernible and easy to read, or if it is posted somewhere else in the food premises or establishment, the location is appropriate and the report is easy to read there.
- In online sales the Oiva report is clearly discernible before the decision of purchasing and payment is being done.
- In online marketing the Oiva report is clearly discernible on the website.

GOOD

There are minor issues with operations. The issues do not impair food safety or mislead consumers.

The latest Oiva report has not been displayed according to Evira's regulations. The Oiva report is posted in a place where the consumer cannot read it, or the report is illegible.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade given at the previous control inspection for the display of the Oiva report was “Good” and the shortcoming found then in the display of the report has not been rectified.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade given at the previous control inspection for the display of the Oiva report was “To be corrected” and the shortcoming found then in the display of the report has not been rectified.

The displayed Oiva report is not consistent with the latest Oiva report issued by the authority which misleads the consumer.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Finnish Food Act 23/2006 Section 21
- Regulation of the Finnish Food Safety Authority on the Method of Fulfilling the Notification and Communication Obligation of the Food Control Authority and on the Publication of Control Information, Evira/2074/0900/2016

Updates in version 2

- Matters to the controlled made more specific, and online marketing and online sales added under the grade Excellent.
- Reference to Evira's Regulation updated.

19 Marketing Requirements

19.1 Quality and Weight Grading of Eggs

This evaluation is at present not presented in the Oiva report, but only in the control report

To be taken into consideration:

- This Guideline is applied to egg-packing centres that carry out quality and weight grading of eggs.
- It is recommended that point 19.2 "Stamping and Labelling of Eggs" and point 19.3 "Stock Records at Egg-packing Centres" are controlled at the same time.
- The grades issued for controls related to marketing do not affect the Oiva grade issued for controls related to food legislation.

Matters to be controlled:

- The correctness of the quality grading carried out by the packing centre is controlled by controlling (candling) from each weight grade randomly selected egg batches that have already been quality graded. The recommended numbers of eggs to be selected for the control of the correctness of quality grading are presented in Evira's Guide 16047/1.
- The correctness of the weight grading carried out by the packing centre is controlled by selecting from the stock of the packing centre an egg batch of 10 eggs randomly from each weight grade. The eggs of the selected batch are checked for their weight per egg.
- Quality and weighing records from quality and weight grading as part of own-check.
- Deviations in temperatures, corrective actions and records of corrective actions.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The quality and weight grading of the egg batches controlled by the control authority meet regulatory requirements. Quality defects and weight grading are within the regulatory tolerances in the egg batches.

Quality deviations of eggs do not exceed 5% in the controlled batch.

The total deviation in the weights per egg does not exceed 10% in the controlled batch, and the proportion of underweight eggs does not exceed 5%. Where the controlled batch contains fewer than 180 eggs, the percentages for quality and weight deviations shall be doubled.

The egg-packing centre monitors quality and weight grading on a regular basis.

The monitoring results regarding quality and weight grading meet regulatory requirements at the packing centre.

The records related to quality and weight grading are available for control at the packing centre.

The grading of eggs takes place within ten days of laying.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are some minor shortcomings in how the monitoring of the quality grading of eggs is implemented at the egg-packing centre. For example, quality grading has not been carried out on some isolated occasions and/or some individual monitoring results have not been recorded.

- There have been some minor shortcomings regarding the monitoring frequency of the weight grading of eggs carried out at the packing centre.
- For example, weight grading has not been monitored on some isolated occasions and/or some individual monitoring results have not been recorded.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- Quality defects in quality grading have systematically exceeded the deviations allowed by legislation.
- The proportion of eggs of the next lower weight grade systematically exceeds the allowed 5% deviation in the individual weighting results in weight grading.
- The quality and weight grading of eggs has not been monitored on a regular basis according to the own-check plan.
- There has been a malfunction in the quality and/or weight grading equipment which has not been detected.
- The grading of eggs has repeatedly taken place later than within 10 days of laying.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The control results of quality grading have not met regulatory requirements and the operator has failed to correct the adjustments of the quality grading equipment.
- Quality grading has not been monitored at all.
- The control results of weight grading have not met regulatory requirements and the operator has failed to calibrate the weighing equipment.
- Weight grading has not been monitored at all.

- The controlling inspector has during several control visits made comments about shortcomings in the operation of the quality grading and/or weight grading equipment, but the operator has failed to take necessary actions.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EU) No. 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) 992/72, (EEC) No 1037/2001 and (EC) No 1234/2007, Articles 1, 74 and 78, Annex I Part XIX, Annex II Part VII, and Annex VII, Part VI
- Commission Regulation (EC) No 589/2008 laying down detailed rules for implementing Council Regulation (EC) No. 1234/2007 as regards marketing standards for eggs
- Act on the organisation of the markets in agricultural products 999/2012 (incl. amendment 1194/2013), Section 58 c
- Evira's Guide 16034/3 Production and marketing of eggs and other bird's eggs
- Evira's Guide 16047/1 Marketing requirements subject to control at egg-packing centres

19 Marketing Requirements

19.2 Stamping and Labelling of Eggs

This evaluation is at present not presented in the Oiva report, but only in the control report

To be taken into consideration:

- This Guideline is applied to egg-packing centres that stamp and/or pack eggs for end-users and mass caterers.
- It is recommended that points 13.1 "General Labelling" (name of foodstuff and labelling in Finnish and Swedish), 19.1 "Quality and Weight Grading of Eggs", and 19.3 "Stock Records at Egg-packing Centres" are controlled at the same time.
- The general labelling of egg packages is evaluated in point 13.1.
- The grades issued for controls related to marketing do not affect the Oiva grade for controls related to food legislation.

Matters to be controlled:

- Stamping of eggs
    - The correctness of the marking/stamping of eggs carried out at the egg-packing centre is controlled by selecting from the stock of the packing centre an egg batch of 10 eggs randomly from each weight grade that has already been quality and weight graded. The correctness of stamping can be controlled using the same eggs used to control the correctness of weight grading.
    - The production code to be stamped on eggs = the code of the poultry farm consists of the number indicating the farming method, the country code and the number identifying the poultry farm. The producer code shall be easily visible, clearly legible and be at least 2 mm high. The stamping ink used for eggs shall be suitable for food use.
    - In the control of egg batches, a tolerance of 20% of eggs with marks that are illegible is allowed. Stamps are considered illegible, if they are e.g. missing in part or in whole, or are unclear or incorrect.

- The compliance of the labelling of eggs with requirements is evaluated by means of random sampling, taking the nature and scope of operation into consideration.
    - *The packaging of eggs marketed to consumers in quality and weight graded retail packages shall bear at least the following labelling:* name of food (general labelling requirement) (eggs), name, address and code of egg-packing centre, quality grading (class A or the letter A), weight grading, net quantity, minimum durability, or best-before date, storage instructions, farming method, explanation of the producer code stamped on the egg (= poultry farm code) (as well as a voluntary indication "extra" or "extra fresh").

- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The stamping of the egg batches controlled by the control authority meet regulatory requirements.

Marking errors found in the egg batches are within the tolerances allowed by legislation. A tolerance of 20% of eggs with erroneous markings is allowed in the controlled batch.

The labelling of eggs meets regulatory requirements.

The information is marked in such a way as to be easily visible.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are some minor shortcomings in how the monitoring of the correctness of stamping of eggs is implemented at the egg-packing centre. For example, the correctness of stamping has not been monitored on some isolated occasions and/or some individual monitoring results have not been recorded.
- As a rule, the labelling of eggs meets regulatory requirements.
- There are some minor shortcomings in labelling; for example, the address of the egg-packing centre is not complete.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- The control carried out by the controlling inspector shows that the proportion of marking errors in the controlled eggs exceeds the 20% deviation allowed by law.
- The correctness of the stamping of eggs has not been monitored on a regular basis according to the own-check plan.
- There has been a malfunction in the stamping equipment which has not been detected.
- There are essential defects or shortcomings in the labelling of eggs, such as a misleading name, packing centre information is missing or incomplete, farming method is not indicated, no explanation is provided of the poultry farm code stamped on the egg, best-before date is missing or has been calculated incorrectly from the laying date or the first day of the period of laying.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The control results of the stamping of eggs do not meet regulatory requirements. The 20% tolerance allowed by legislation is repeatedly exceeded and the operator has failed to take actions to rectify the problem.
- The correctness of the stamps has not been monitored at all.
- There are constantly malfunctions in the egg stamping equipment which have not been rectified.
- Labelling is completely missing from eggs or there are defects which require immediate rectification or recall, such as incorrect indication of farming method, e.g. eggs from caged hens are stamped as organically produced eggs.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EU) No. 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) 992/72, (EEC) No 1037/2001 and (EC) No 1234/2007, Articles 1, 74 and 78, Annex I Part XIX, Annex II Part VII, and Annex VII, Part VI
- Commission Regulation (EC) No 589/2008 laying down detailed rules for implementing Council Regulation (EC) No. 1234/2007 as regards marketing standards for eggs
- Act on the organisation of the markets in agricultural products 999/2012 (incl. amendment 1194/2013), Section 58 c
- Finnish Food Act 23/2006, Section 9
- Evira's Guide 16034/3 Production and marketing of eggs and other bird's eggs
- Evira's Guide 16047/1 Marketing requirements subject to control at egg-packing centres

19 Marketing Requirements

19.3 Stock Records at Egg-packing Centres

This evaluation is at present not presented in the Oiva report, but only in the control report

To be taken into consideration:

- This point is applied to all egg-packing centres.
- It is recommended that points 19.1 "Quality and Weight Grading of Eggs" and 19.2 "Stamping and Labelling of Eggs" are controlled at the same time.
- Records related to salmonella control are controlled in point 15.2. Controlling point 15.2 together with this point 19.3 would be a natural thing to do.
- The grades issued for controls related to marketing do not affect the Oiva grade for controls related to food legislation.

Matters to be controlled:

- Control of the records of the egg-packing centre by farming method and on a daily basis.
  - the quantity of ungraded eggs received from each producer, the name, address and producer code of the producer, and the laying date or period
  - quantity of eggs by quality and weight class after grading
  - quantities of graded eggs delivered from other packing centres, and the code of these packing centres and the minimum durability date for the eggs.
  - quantities of ungraded eggs delivered to other packing centres, broken down by producer, including the code of the other packing centres as well as the laying date or period.
  - quantity and/or weight of delivered eggs broken down by quality and weight class, and for class B eggs by packing date, and for class A eggs by minimum durability date, and purchaser (name and address of purchaser to be indicated).
- Controlling that records are kept for at least 12 months from the date of their creation.
- The adequacy and suitability of own-check activities, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The egg-packing centre has updated records regarding the aforementioned matters.

Records are available for control over a period of at least 12 months.

Records are made available to the controlling authority on request.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There have been some minor shortcomings or inaccuracies in records, e.g. in daily records, name and address information on purchasers, but the quantities of eggs received, graded and delivered for marketing are consistent by farming method
- Some individual records cannot be found after e.g. 10 months.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- There are no records of the quantities of eggs received from and/or delivered to other packing centres.
- No laying date or period is indicated for eggs received at the packing centre.
- The quantity of eggs after quality and weight grading is not consistent with the quantity of eggs received at the packing centre.
- Records are only available over a period of e.g. six months.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- There are several shortcomings in the records making it impossible to verify that all required records have been kept and are up-to-date.
- Records have not been made available for control despite the controlling inspector's request.
- No records have been kept.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EU) No. 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) 992/72, (EEC) No 1037/2001 and (EC) No 1234/2007, Articles 1, 74 and 78, Annex I Part XIX, Annex II Part VII, and Annex VII, Part VI
- Commission Regulation (EC) No 589/2008 laying down detailed rules for implementing Council Regulation (EC) No. 1234/2007 as regards marketing standards for eggs
- Act on the organisation of the markets in agricultural products 999/2012 (incl. amendment 1194/2013), Section 58 c
- Evira's Guide 16034/3 Production and marketing of eggs and other bird's eggs
- Evira's Guide 16047/1 Marketing requirements subject to control at egg-packing centres

19 Marketing requirements

19.4 Milk and milk products

This evaluation is at present not presented in the Oiva report, but only in the control report

To be taken into consideration:
This point pertaining to milk and milk products is to be controlled, when the operator

- manufactures, has manufactured for it and/or packages
- imports and/or brokers (from the internal market and/or third countries).

The designations used in the marketing of milk and milk products, such as cream, cheese and yogurt, and their natural composition are protected by the Regulation (1308/2013) of the European Parliament and of the Council which defines the meaning of milk and milk products. The designations milk and milk products may be used provided they meet the requirements laid down in legislation (Regulation 1308/2013, Sections 74, 78, Annex VII, Parts III and IV).

In derogation of this, the protected designations of milk and milk products may also be used to the designation of products the exact nature of which is clear from traditional usage and/or when the designations are clearly used to describe a characteristic quality of the product (Commission Decision 88/566/EEC, Commission Regulation (EC) No 445/2007). In Finland derogations related to the use of the Finnish word for butter include: *kaakaovoi (cocoa butter), maapähkinävoi (peanut butter), voleipäkeksi (cracker), voitatti (Suillus luteus) and voileipäkakku (savoury sandwich cake).* Derogations have been granted also to other countries regarding the designations cream, cheese and milk. The Finnish word *munavoi (chopped egg mixed in butter)* has also been granted a derogation (Commission Regulation (EC) No 445/2007).

Butter is controlled in point 19.6 Spreadable Fats.

It is recommended that points 13.1 General Labelling and 13.2 Nutrition Labelling, and where applicable, point 12.3 Foodstuffs with Protected Status are controlled at the same time, because the designations of milk products are also protected by EU's name protection schemes (e.g. feta cheese).

Matters to be controlled:
The implementation of own-check activities is evaluated by random checks on e.g. 1-3 packages of different products and/or batches, taking the scope and nature of operations into consideration. The purpose of the control is to evaluate, if the designations and product descriptions of milk and milk products, and foods used like milk products comply with the provisions laid down for designations of milk and milk products.

Compliance with requirements can be verified by means of, for example:

- inspections of labelling, recipes and documents
- where necessary, analysis certificates and/or own-check activity tests.

EXCELLENT

Operations comply with requirements.

Milk and milk products are manufactured and designated in compliance with the definition of the designation of the relevant milk or milk product. The designation of the foodstuff laid down in provisions is clearly visible on the labelling.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The manufacture and designation of milk and milk products takes place in compliance with the definition of the designation of the relevant milk or milk product. For example
the designation of the product is not clearly visible on the labelling
minor shortcomings are found in the minimum/maximum fat content defined for the sales designations of whole milk / semi-skimmed milk / skimmed milk.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The manufacture and designation of milk and milk products does not take place in compliance with the definition of the designation of the relevant milk or milk product. For example

- shortcomings are found regarding the minimum/maximum fat content defined for the sales designations of whole milk / semi-skimmed milk / skimmed milk.
- the origin (animal) of milk is not indicated for milk other than cow's milk
- the designation like milk / like cheese is used for a product that does not contain any milk, or one ingredient of milk has been substituted with some other substance
- the designation milk or milk product is used for a product manufactured using some other substance than milk, or one ingredient of milk has been substituted with some other substance
- the designation semi-skimmed milk is used for a product with a reduced protein content.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

There are repeatedly major shortcomings in the manufacture or designation of milk or milk products compared with the definition of the designation of the relevant milk product. For example

- the monitoring of the minimum/maximum fat content defined for the sales designations of whole milk / semi-skimmed milk / skimmed milk has been repeatedly neglected

- the designations of milk or milk products are repeatedly/intentionally misused.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EU) No. 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) 992/72, (EEC) No 1037/2001 and (EC) No 1234/2007, Articles 1, 74 and 78, Annex I Part XVI, and Annex VII, Parts III and IV
- Commission Decision (EEC) 566/88 listing the products referred to in the second subparagraph of Article 3 (1) of Council Regulation (EEC) No 1898/87
- Commission Regulation (EC) No 445/2007 laying down certain detailed rules for the application of Council Regulation (EC) No 2991/94 laying down standards for spreadable fats and of Council Regulation (EEC) No 1898/87 on the protection of designations used in the marketing of milk and milk products
- Act on the organisation of the markets in agricultural products 999/2012 (incl. amendment 1194/2013), Section 58 c
- Finnish Food Act 23/2006, Section 9

Updates in version 2:

- The title of the Guideline changed: Protected status of designation of milk products -> Milk and milk products, which is the expression used in the provisions.

19 Marketing requirements

19.6 Spreadable fats

This evaluation is at present not presented in the Oiva report, but only in the control report

To be taken into consideration:
This point pertaining to spreadable fats is to be controlled, when the operator

- manufactures, has manufactured for it and/or packages
- imports and/or brokers (from the internal market and/or third countries).

The sales designations used in the marketing of spreadable fats intended for human consumption, such as butter, margarine and fat blend, and their composition are protected by the Regulation (1308/2013) of the European Parliament and of the Council. The Regulation defines the meaning of the different spreadable fats. The sales designations provided for spreadable fats may only be used in the marketing of products that comply with the definition and product category of the relevant product (Regulation 1308/2013, Articles 74-75, 78, Annex VII, Part VII and Appendix II to Part VII, Spreadable fats.

In derogation of this, the protected designation of butter may also be used to the designation of products the exact nature of which is clear from traditional usage and/or when the designations are clearly used to describe a characteristic quality of the product (Commission Decision 88/566/EEC, Commission Regulation (EC) No 445/2007). In Finland derogations related to the use of the Finnish word for butter include: kaakaovoi (cocoa butter), maapähkinävoi (peanut butter), voleipäkeksi (cracker), voitatti (Suillus luteus) and voileipäkakku (savoury sandwich cake). The Finnish word *munavoi* (chopped egg mixed in butter) has also been granted a derogation (Commission Regulation (EC) No 445/2007).

It is recommended that points 13.1 General labelling and 13.2 Nutrition labelling as well as 19.4 Milk and milk products are controlled at the same time.

Matters to be controlled:

The implementation of own-check activities is evaluated by random checks on e.g. 1-3 packages of different products and/or batches, taking the scope and nature of operations into consideration. The purpose of the control is to evaluate, if the designations and product categories used in the marketing of spreadable fats comply with the provisions laid down for designations of spreadable fats.

Compliance with requirements can be verified by means of, for example:

- inspections of labelling, recipes and documents
- where necessary, analysis certificates and/or own-check activity tests.

EXCELLENT

Operations comply with requirements.

Spreadable fat is manufactured and designated in compliance with the definition of the sales designation of the relevant product and the description of the product category is consistent with the definition.

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GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The manufacture and designation of spreadable fat takes place in compliance with the definition of the sales designation of the relevant product. There are some minor shortcomings in labelling, such as

- A product with a milk-fat content of 38 percent is designated as half fat butter.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The manufacture and designation of spreadable fat does not take place in compliance with the definition of the sales designation of the relevant product. For example

- A product with a fat content of 60 percent is designated as margarine.
- The expression traditional is falsely used for a three-quarter or half fat butter product.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

There are major shortcomings in the manufacture or designation of spreadable fat compared with the definition of the relevant sales designation. For example

- A product containing no milk-fat or in which part of the milk-fat is substituted with other fats is designated as butter
- Three-quarter or half fat butter is falsely designated as traditional butter.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Regulation (EU) No. 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) 992/72, (EEC) No 1037/2001 and (EC) No 1234/2007, Articles 74, 75 and 78, Annex VII, Part VII and Appendix II to Part VII
- Commission Decision (EEC) 566/88 listing the products referred to in the second subparagraph of Article 3 (1) of Council Regulation (EEC) No 1898/87
- Commission Regulation (EC) No 445/2007 laying down certain detailed rules for the application of Council Regulation (EC) No 2991/94 laying down standards for spreadable fats and of Council Regulation (EEC) No 1898/87 on the protection of designations used in the marketing of milk and milk products
- Act on the organisation of the markets in agricultural products 999/2012 (incl. amendment 1194/2013), Section 58 c
- Finnish Food Act 23/2006, Section 9

Updates in version 2:

- the title of the Guideline changed: Edible fats -> Spreadable fats, which is the expression used in the provisions.

19 Marketing Requirements

19.7 Monitoring Water Content of Poultry

This evaluation is at present not presented in the Oiva report, but only in the control report

To be taken into consideration:

- The purpose of this point is to evaluate the monitoring of the water content of chickens and turkeys from carcasses.

Matters to be controlled:

- Weighing of birds before and after chilling
- Use of an automatic weighing line, if appropriate
- Weighing records related to water content monitoring as part of own-check
- Deviations, corrective actions and records of corrective actions
- The adequacy and suitability of own-check, and the own-check plan, if appropriate, are controlled applying the Annex to Guideline 1.6: "Adequacy and Suitability of Own-check".

EXCELLENT

Operations comply with requirements.

The water content is monitored on a regular basis and at a frequency that meets regulatory requirements.

Water content weighing results comply with regulatory requirements.

Weighing records are available for control and kept for one year.

All poultry batches are marked with an identification that makes it possible to determine the slaughtering date.

GOOD

There are small issues with the operations which do not impair food safety or mislead consumers.

The grade can be Good e.g. in cases where:

- There are some minor shortcomings in the implementation of weighing.
- There have been some minor shortcomings in the monitoring frequency of water content.
- The control results of water content do not meet regulatory requirements. The operator has used such batches in meat preparations or meat products as specified in regulatory requirements, and has taken actions to rectify the process.

TO BE CORRECTED

There are issues with the operations which impair food safety or mislead consumers. These issues must be rectified within a set period of time.

The grade can be To be corrected e.g. in cases where:

- The control results of water content do not meet regulatory requirements. However, the operator has failed to report the matter to the official veterinarian who has therefore not taken any control actions.
- Water content has not been monitored on a regular basis according to the own-check plan.
- There has been a malfunction in the automatic weighing equipment which has not been detected.

POOR

There are issues with the operations which jeopardise food safety or considerably mislead consumers, or the operator has failed to comply with orders that have been issued. These issues must be rectified with immediate effect.

The grade can be Poor e.g. in cases where:

- The control results of water content do not meet regulatory requirements. However, the operator has failed to report the matter to the official veterinarian. The operator has also failed to take actions to rectify the process, or has marketed the batch concerned as fresh or frozen meat in violation to legislation.
- Water content has not been monitored at all.
- There is a malfunction in the automatic weighing equipment which has not been rectified, or the measuring results of the automatic equipment have not been recorded.

Legislation and guidelines (with any amendments) pertaining to the subject:

- Commission Regulation (EC) No 543/2008 laying down detailed rules for implementing Council Regulation (EC) No. 1234/2007 as regards the marketing standards for poultry meat
- Act on market arrangements of agricultural products 999/2012
- Evira's Guide 16046 Management of water content of poultry meat at poultry slaughterhouses and cutting plants operating in conjunction with poultry slaughterhouses

Updates in version 2

- Added in the list of guidelines: Evira's Guide 16046/1 Management of water content of poultry meat at poultry slaughterhouses and cutting plants operating in conjunction with poultry slaughterhouses