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Bavarian State Research Center for Agriculture

Recommendations

for the application of the EU Hygiene Package
in the production, processing and marketing of
fishery products in Bavaria



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Recommendations

for the application of the EU Hygiene Package in the production, processing and marketing of fishery products in Bavaria

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Preface

The Recommendations for the application of the EU Hygiene Package in the production, processing and marketing of fishery products in Bavaria constitute a substantial contribution to the implementation of European and national legislation.

With these recommendations, owners of businesses manufacturing fishery products receive an overview of the hygienic and formal standards in the EU Hygiene Package, applicable in the production, processing and marketing of fishery products.

The recommendations have been compiled by a team of colleagues from veterinary administration, the Bavarian State Office for Health and Food Safety, professional representatives and colleagues from the Bavarian State Research Centre for Agriculture - Institute of Fisheries. The content has been coordinated with the Bavarian State Ministries for the Environment and Health as well as for Nutrition, Agriculture and Forestry.

The recommendations can also be found on the website of the Bavarian State Research Centre for Agriculture at www.LfL.bayern.de (under: Publikationen, LfL-Informationen - in German only) and also via a link on the website of the Bavarian State Ministry for Nutrition, Agriculture and Forestry at www.stmelf.bayern.de (under: Ernährung, Markt und Absatz, Direktvermarktung - in German only). As such, the recommendations are accessible to those within the fisheries industry, producers marketing their fish directly and public administration.

We would like to thank everybody who has contributed in putting together these recommendations and we hope that they can be used as practical guidelines.



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1 Introduction

A common hygiene law has been applicable in Europe since 1 January 2006. The so-called EU Hygiene Package (new EU regulations on the hygiene of foodstuffs) has replaced the German decree on the hygiene of foodstuffs and the German decree on fish hygiene which were mandatory until then. On the one hand, the Hygiene Package sets out general hygiene requirements in the areas of premises, facilities, personnel, cleaning and disinfection, pest control and waste disposal amongst others. On the other hand, it stipulates the registration and approval of establishments, dependent on their activity. The aim of the EU regulations is to achieve a high level of protection of human life and health.

According to these provisions, every owner of a fishery establishment is a food business operator responsible for the safety of its products. This means that the food business operator bears the primary responsibility for the safety of its products. In order to prevent health risks on a physical, biological and chemical level, controls based on a self-monitoring concept and a HACCP concept have to take place at the establishments.

A transitional period until 31 January 2009 has been granted for establishments registered prior to January 2006 which require approval. This means that these establishments must have obtained the appropriate approval from January 2010. In order to continue practising activities requiring approval unrestricted after this time limit, approval applications must be filed before 31 December 2009 at the absolute latest. Questions regarding approval obligations and procedures may be directed to the competent veterinary office.

These recommendations should assist owners of fishery establishments in the fulfilment of the food law requirements. The criteria for registrations or approval of an establishment are specified in Chapter 2. Hygiene requirements for establishments are outlined in Chapter 3. These recommendations also describe production processes and provide advice on fitting out premises as well as processes for the production of fishery products.

2 Registration, approval

Food business operators which produce, process and distribute food are obliged to **notify** the competent authority (local veterinary office or food supervision), in accordance with Article 6 of Regulation (EC) No 852/2004, in order to be registered or approved (see forms in appendix, which can also be found - in German - at

http://www.stmugv.bayern.de/lebensmittel/betriebe/doc/imbetriebe_meldung.pdf)

The rules concerning this registration/approval obligation are as follows:

1. primary production **not requiring** registration or approval:

Primary products are fresh or prepared fishery products the nature of which has not been substantially altered during the primary production phase (e.g. fishery, fish farming). Primary producers (e.g. fishermen or fish farmers) manufacture these products in a way that the manufacturing processes used do not exceed slaughter, exsanguination, evisceration, removal of the fins and gills, cooling or packaging the fish.

If only small amounts of primary products, i.e. common household amounts (Section 3 (2) No. 1 of the German decree concerning hygiene requirement in the production, treatment and placing into the market of certain food products of animal origin (*Verordnung über Anforderungen an die Hygiene beim Herstellen, Behandeln und Inverkehrbringen von bestimmten Lebensmitteln tierischen Ursprungs*, Tier-LMHV)/Section 5 (2) No. 1 of the German decree concerning hygiene requirements in the production, treatment and placing into the market of food (*Verordnung über Anforderungen an die Hygiene beim Herstellen, Behandeln und Inverkehrbringen von Lebensmitteln*, LMHV), neither registration nor approval under EU law is required. However, there are general and basic hygiene requirements (Section 5 LMHV and Section 3 Tier-LMHV) which must be observed.

The acquisition of slaughtered fish does not classify as primary production. The acquisition of live fish to put into the pool is irrelevant under food law.

2. Primary production and registration:

If the owner of the establishment intends to place more than small amounts of primary products on the market or to render more than small amounts to fish processing plants, registration is required. The requirements for industrial hygiene from Article 4 in conjunction with Annex I Part A of the Regulation (EC) No 852/2004 and (where applicable) Regulation (EC) No 853/2004, if applicable, must be observed.

3. Retail and registration:

Activities such as smoking, filleting, marinating or chopping up, substantially alter the nature of the fishery products such that no primary product remains (item 3.7 of the Guidance document on Regulation (EC) No 853/2004). Establishments which manufacture such products and sell them to the final consumer at the production site are retail establishments and in principle do not require approval (Article 1 Section 5 Regulation (EC) No. 853/2004). In accordance with the German decree concerning hygiene requirements in the production, treatment and placing into the market of animal products (Tier-LMHV), establishments which supply at the most 1/3 of the amount of food of animal origin produced to other retail establishments (including their own branches) within a radius of no more than 100 km, do not require approval (so-called 1/3 rule), provided that the remaining production quantity is supplied locally to the final consumer.

The production quantity relevant for the 1/3 rule provided for in Section 6 Tier-LMHV comprises all fish slaughtered within the establishment (possible acquisitions included). Exception: Fish which are supplied to retail establishments as primary products (= slaughtered). If the fish farmer supplies slaughtered (and therefore not processed) fish to retail, this amount is not included in the calculation of the 1/3 quantity.

Here are examples for this rule:

- The establishment places 100 kg slaughtered fish into the market. 50 kg go to the final consumer, 50 kg to retail. The amounts are supplied separately - half slaughtered (primary product) and half smoked (processed).
In calculating how much is 1/3, a production quantity of 100 kg - 25 kg (primary product to retail trader) = 75 kg is taken into account. The 25 kg supplied to retail (processed product) amount to a third of the relevant quantity of 75 kg. Approval is therefore not required.
- If out of 100 kg slaughtered fish, an establishment supplies the final consumer with 50 kg fish as primary product, another 20 kg to the final consumer as processed product and 30 kg to retail as processed product, the total 100 kg are included in the calculation of the production quantity. The 30 kg (supply to retail establishment) then represent somewhat less than a third of the 100 kg production quantity. Approval is not required in this case as well.

If processed fishery products are marketed via mobile sales stalls (market stalls) e.g. at local markets, the mobile sales stall classifies as part of the establishment.

1. Approval:

Establishments which produce fishery products and supply more than a third of the production quantity to other establishments require approval.

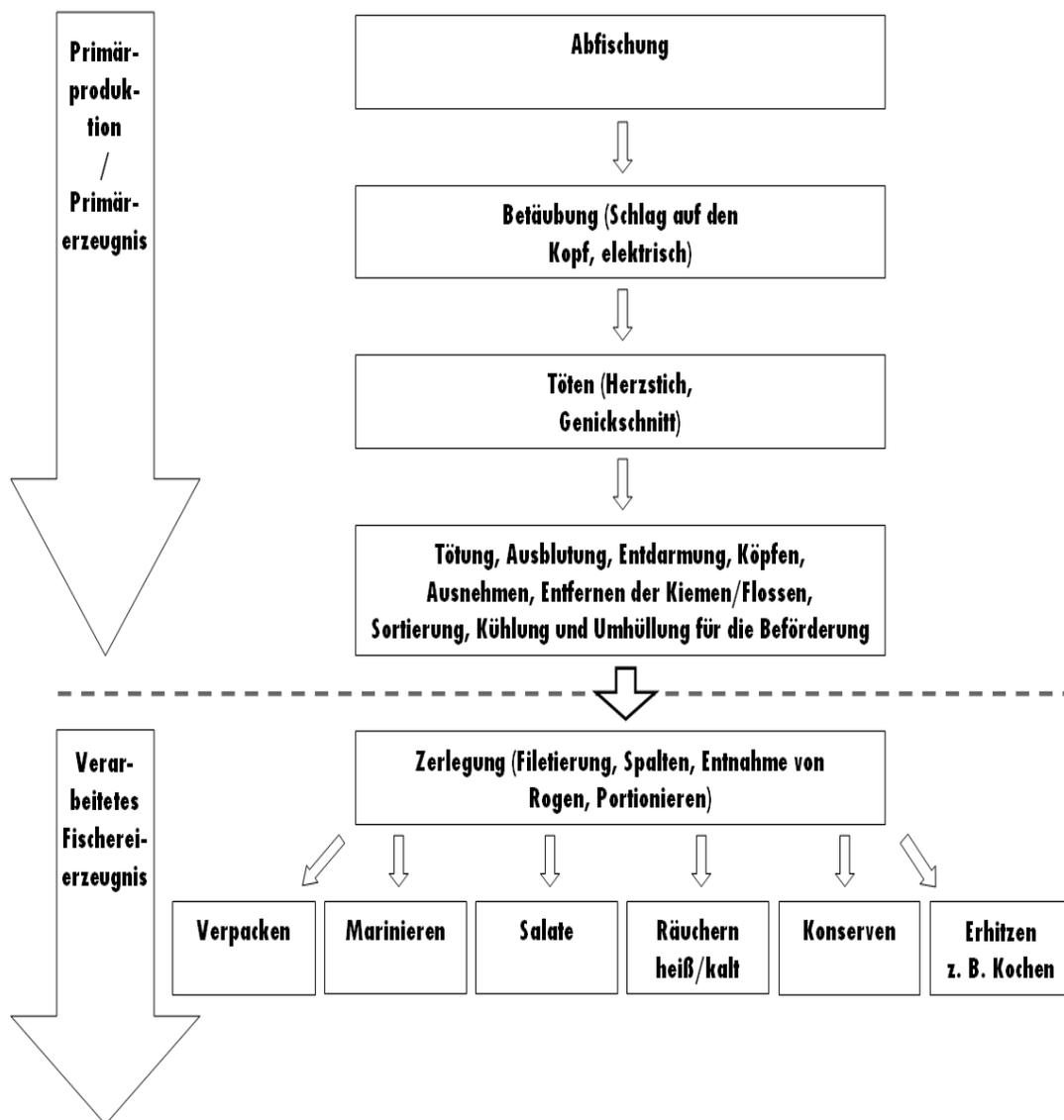
The following table provides an overview in order to classify the establishments.

Marketing of fishery products through fishermen and fish farmers

Production	Marketing			Registration/ Approval	Remarks
	How many?	Supply where?	Supply to whom?		
<p>Primary products, i.e. fishery products the nature of which has not substantially been altered. This comprises the following activities: Slaughter, bleeding, heading, gutting, removing fins, sorting, refrigeration and wrapping for transport.</p> <p>(Item 3 of the Guidance document on Regulation (EC) No 852/2004 and item 3.7 of the Guidance document on Regulation (EC) No 853/2004)</p>	<p>Supply of small quantities¹</p> <p>(Section 5 (2) No. 1 LMHV and Section 3 (2) No. 1 Tier-LMHV)</p>	<p>at the establishment, at the production site</p> <p>This also includes</p> <ul style="list-style-type: none"> by means of delivery/supply on a market stall at local markets 	<ul style="list-style-type: none"> final consumers local retail establishment² for supply to final consumers 	<p>Registration no Approval no</p> <p>(Article 1 (2) (c) of Regulation (EC) 852/2004 and Article 1 (3) (c) Regulation (EC) 853/2004</p>	<p>the retail establishment supplied may also process the fish</p> <p>Compliance with hygiene requirements in accordance with Section 5 LMHV and Section 3 (1) Tier-LMHV</p>
	<p>No longer a small quantity</p>	<p>no limitation</p> <p>(if primary products are supplied by producer at the establishment or via delivery)</p>	<p>no limitation</p>	<p>Registration yes Approval no</p> <p>(Article 6 (2) Regulation (EC) 852/2004)</p>	<p>Compliance with the requirements of Regulation (EC) No 852/2004</p>
<p>Fishery products whose nature has been <u>substantially altered</u>, so that the product no longer is a primary product, e.g. through smoking, filleting, chopping or marinating</p> <p>(Inverse conclusion from item 3 of the Guidance document on Regulation (EC) No 852/2004 and item 3.7 of the Guidance document on Regulation (EC) No 853/2004)</p>	<p>up to 1/3 of the production quantity of food of animal origin also to other retail establishments²</p> <p>(Section 6 Tier-LMHV in conjunction with Article 1 (5) (b) (ii) of Regulation (EC) 853/2004)</p>	<p>at the establishment, at the production site.</p> <p>This also includes</p> <ul style="list-style-type: none"> by means of delivery/supply on market stalls at local markets <p>(Guidance document on Regulation (EC) No 852/2004 No. 3.3)</p>	<ul style="list-style-type: none"> final consumers Retail establishments² within a radius of no more than 100 km 	<p>Registration yes Approval no</p> <p>(Article 6 Section 2 Regulation (EC) 852/2004)</p>	<p>All fishery products are food of animal origin. Exception quantity may not represent more than 1/3 of the production quantity of food of animal origin.</p> <p>Compliance with the requirements of Regulation (EC) No 852/2004 and Annex III Section VIII No. 2 of 853/2004 for retail establishments</p>
	<p>Exceeding 1/3 of the production quantity of food of animal origin supplied to other retail establishments²</p> <p>(Article 1 (5) (b) (ii) Regulation (EC) 853/2004 NOT met)</p>	<p>no limitation</p>	<p>no limitation</p>	<p>Approval, yes</p> <p>(Article 4 Regulation (EC) 853/2004)</p>	<p>Compliance with the requirements of Regulations (EC) No 852/2004 and 853/2004</p>

¹Small quantities = small quantities of live, fresh or prepared fishery products the nature of which has not substantially been altered: - in case of direct supply to the consumer: common household volumes, - in case of supply to retail establishments: common daily quantity supplied to consumers for the respective establishment (in accordance with Section 5 (2) LMHV), ²Retail establishments also include restaurants

2.1 Slaughter, filleting and smoking flow chart



German	English
Primärproduktion/Primärerzeugnis	Primary production / Primary product
Abfischung	Harvesting
Betäubung (Schlag auf den Kopf, elektrisch)	Stunning (hitting on the head, electrical)
Töten (Herzstich, Genickschnitt)	Slaughter (stabbing in chest, cutting neck)
Tötung, Ausblutung, Entdarmung, Köpfen, Ausnehmen, Entfernen der Kiemen/Flossen, Sortierung, Kühlung und Umhüllung für die Beförderung	Slaughter, exsanguination, evisceration, heading, gutting, removing gills / fins, grading, refrigeration and wrapping for transport
Zerlegung (Filetierung, Spalten, Entnahme von Rogen, Portionieren)	Cutting (filleting, splitting, roe removal, portioning)
Verarbeitetes Fischereierzeugnis	Processed fishery product
Verpacken	Packaging
Marinieren	Marinating
Salate	Salads
Räuchern heiß/kalt	Hot/Cold Smoking
Konserven	Canning
Erhitzen z.B. Kochen	Heating e.g. cooking

2.2 Necessary documents for the notification and registration of the establishment

Application (Appendix 1)

2.3 Necessary documents for the establishment approval application

The documents listed below are required for the application for approval of a food establishment according to Section 9 Tier-LMHV (see also Article 6 (3) of Regulation (EC) No 852/2004 in conjunction with Article 4 (2) of Regulation (EC) No 853/2004)

- Approval application (Appendix 2)
- Profile of the establishment with the relevant supplementary sheets according to Tier-LMHV [Annex 4 - Profile of the establishment (General information), Annex 5 - Supplementary sheet fishery products to the profile of the establishment (not including transloading goods)]
- Documentation concerning room use. For establishments structured as a handicraft business, a true-to-scale plan of the establishment with material flow and movement of staff as well as machine set-up is not required (Section 9 (1) last sentence Tier-LMHV).
- Proof of reliability of the food business operator, e.g. police certificate and/or extract from the Central Register of Companies, and/or self-disclosure (Appendix 3). Which evidence must be supplied is left to the discretion of the relevant regulatory authority.
- An extract from the land registry office (*Katasteramt*) may only be requested for establishments structured as a handicraft business in exceptional cases.

Additional documents:

The authorities may request additional necessary documents during the course of the approval process in individual cases.

Further information is available in the “Handbuch Zulassung” (Approval Manual, available in German only), issued by the Bavarian State Ministry for the Environment and Health.

http://www.stmug.bayern.de/lebensmittel/betriebe/doc/zulassung_metzgerei.pdf.

2.4 Self-monitoring

Self-monitoring is to be carried out to a reasonable extent according to the type and size of the establishment as well as according to its activity. Please refer to appendices 6 to 16 in this regard. The HACCP concept (Appendix 13) is to be appropriately adapted to the size of the establishment (cf. 3.2.6).

It is advisable to adhere to the Leitlinien für eine gute Hygienepaxis und für die Anwendung der Grundsätze des HACCP-Systems für das Herstellen, Behandeln und Inverkehrbringen von Fischereierzeugnissen 2005 (Guidance on good practice for hygiene and the application of the HACCP system principles for production, treatment and placing into the market of fishery products 2005, available in German only) issued by the German *Bundesverband der deutschen Fischindustrie und des Fischgroßhandels e.V.* (Federal Association of the German Fishing Industry and Fish Wholesale).

3 Special requirements for fisheries / hygiene requirements

The food law hygiene requirements are formulated flexibly. They are applicable for all types of establishment. The leeways they provide are used by the authorities. The type and size of an establishment, along with its respective activities are taken into consideration. In any case, the goal of hygienically producing safe food must be achieved.

In this chapter we will give a detailed presentation of the points relevant to hygiene. Annex 17 contains a table outlining the respective points. Please note that the ideal case is being presented, however alternatives can and must be assessed locally on an individual basis.

3.1 Division of work steps in slaughtering and processing

For the individual work steps of slaughtering, processing and marketing, the rooms should be separate in new builds. A potential alternative to this for smaller establishment or existing facilities is to have an adequate time gap between the work steps with intermediate cleaning (assessed on a case-by-case basis on site). Producers of primary products have to guarantee hygienic conditions regarding the production, transport and storage (*LMHV, Annex 2 No. 1 letter b*).

3.2 Working areas

Floors, walls, doors and work surfaces must be easy to clean and, where necessary, to disinfect. Flexible solutions are possible in order to implement these requirements in existing facilities.

Examples:

- floors: e.g. synthetic resin or alternatively: tiles, concrete coating;
- walls: e.g. light tiles or other flat surfaces up to the ceiling or alternatively: smooth and washable up to the working height, appropriate coating possible;
- surfaces: e.g. stainless steel, alternatively: smooth synthetic material;
- doors: e.g. stainless steel, alternatively: appropriate coating. (*Annex II Chapter II (1) of Regulation (EC) 852/2004, AVV LmH Annex 1.1, No. 1.8, 1.9, 1.12*).

Windows must be constructed to prevent the accumulation of dirt (no unnecessary scratches or cracks, smooth surface, no wood or only with appropriate coating, slanted window sills, insect-proof screens) (*AVV LmH Annex 1.1 No. 1.11*). Ceilings must be constructed and finished so as to prevent accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles (adequate ventilation, no unnecessary conduits and piping, level surfaces) (*Regulation (EC) No. 852/2004 Annex II Chapter II No. 1 c*).

Deviations are possible for floors and walls in ripening rooms and smoke chambers (*AVV LmH Annex 1.1, No. 1.8 and 1.9*).

Producers of primary products must maintain, regularly clean and, where necessary, disinfect walls, floors and work surfaces at operation facilities as well as retail facilities, containers and vehicles which may

come into contact with primary products. Wall surfaces must be smooth, washable, easy to clean and, where necessary, disinfected up to the working height, an appropriate coating is possible (*LMHV, Annex 2, No. 1 letter a*).

3.3 Equipment

Items, fittings and equipment which come into contact with food must be maintained, thoroughly cleaned and, where necessary, disinfected (*Regulation (EC) No 852/2004 Annex II Chapter V, No. 1*), they must be resistant to chemicals and corrosion. Knives are to be regularly changed during production and subsequently disinfected (e.g. in dishwasher). Other than in the ripening rooms and smoke chambers, no wood is to be stored (*AVV LmH Annex 1.1, No. 3.1*).

3.4 Shipping containers

Containers, e.g. E2 boxes containing unpacked food may not be placed directly onto the floor (*Regulation (EC) No 852/2004 Annex II Chapter IV No. 1 in conjunction with AVV LmH Annex 1.1, No. 2.1*).

3.5 Floor gullies

Floor gullies must be secured against rodents. The effluent disposal system must be odour-proof and must be covered with a rust-free material (metal, plastic). The flow direction of the water must run from a clean area into a contaminated area. Discharge channels are essential if contamination via non-effluent waste water is possible. In areas where dry processing steps take place (e.g. packaging), drainage channels may be dispensed with if the floors have an adequate slope (*Regulation (EC) No 852/2004 Annex II, Chapter I No. 8 in conjunction with AVV LmH Annex 1.1 No. 1.8*). Alternatively, in establishments structured as handicraft businesses, drainage channels are dispensable provided that contamination of unpacked food or spreading of a contamination to another area via waste water (e.g. cleaning water) is prevented with adequate certainty by means of an inclined floor (*AVV LmH Annex 1.4, No. 1.1.1*).

3.6 Ventilation and lighting

The rooms must be adequately ventilated so that the build up of condensation or the formation of mould is easily avoided (*Regulation (EC) No. 852/2004 Annex II Chapter I No. 5*). Furthermore, the working areas must be adequately lit in order for irregularities in the food to be easily detected (*Regulation (EC) No. 852/2004 Annex II Chapter I No. 7*). A minimum illumination 220 lx for work rooms and 110 lx for storage areas is recommended (*AVV LmH Annex 1.1, No. 1.5*).

3.7 Hand basins

Hand basins must be fitted with both hot and cold running water. They should be contact free and fitted directly next to the work space. Alternatively, a hand basin with hot and cold water connections may also be fitted with a single lever mixer tap or pivot-mounted arm. The hand basins should also be equipped with soap and/or disinfectant dispensers and disposable towels (*Regulation (EC) No 852/2004 Annex II Chapter I No. 4*). For producers of primary products, as a minimum, a hand

basin, soap, disposable towels or a clean hand towel are required (*DVO LMHV Annex 2 No. 2 letter d*). Separate facilities need to be established for washing food (*Regulation (EC) No 852/2004 Annex II, Chapter II, No. 3 in conjunction with AVV LmH Annex 1.1, No. 1.16*).

3.8 Water supply

There is to be an adequate supply of potable water; for cleaning uncut fish, clean water may also be used (*Regulation (EC) No 852/2004 Annex II Chapter VII No. 1 Letters a and b*). Immediately after gutting, fishery products must be thoroughly washed with potable water (*Regulation (EC) No 853/2004 Annex III, Section VIII, Chapter III A No. 2*).

3.9 Food waste

Food waste must be deposited in closable containers. Waste collection rooms must be kept free from animals and pests (*Regulation (EC) No 852/2004 Annex II Chapter VI No. 2 and No. 3*). Waste refrigeration (e.g. deep freezer, chest freezer) is recommended. A possible alternative is collection in open containers, which are placed in lockable rooms designated specifically for that purpose (*AVV LmH Annex 1.1, No. 4.1*). In order to eliminate contamination of the primary products, waste storage and disposal is also necessary at the primary production stage (*DVO LMHV Annex 2, No. 1 Letter d*).

3.10 Disposal of animal by-products and/or condemned material

Viscera such as intestines, bladder, genitals, kidneys, heart and all other parts which are not intended for human consumption, such as fins, skin and scales, if applicable, or the liver as well as fresh by-products from fish resulting from processing (fish sections), constitute Category 3 material in accordance with *Article 6 (1) (i) Regulation (EC) No 1774/2002* and are to be disposed of as per this Regulation.

Fish that died other than by being slaughtered, including fish killed to eradicate an epizootic disease, are classified as Category 2 material in accordance with *Article 5 (1) (e) Regulation (EC) No 1774/2002* and are to be disposed of accordingly.

Fish, which contain residues of veterinary drugs and contaminants listed in *Group B (1) and (2) of Annex I to Directive 96/23 EC* are classified as Category 2 material, if such residues exceed the permitted level laid down by Community legislation and must be disposed of pursuant to *Article 5 (1) (c) Regulation (EC) No 1774/2002*. In contrast, fish which have been administered substances prohibited under *Council Directive 96/22/EC* or contain residues of environmental contaminants or other substances listed in *Group B (3) of Annex I to Council Directive 96/23/EC*, classify as Category 1 material according to *Article 4 (1) (c) Regulation (EC) No 1774/2002*, if such residues exceed the permitted level.

Containers in which animal by-products are kept are to be marked with the corresponding categories: Category 3 - "Not for human consumption", Category 2 - "Not for animal consumption", Category 1 - "For disposal only". The food manufacturer is obligated to store commercial documentation from the waste disposal contractor (issued by them) according to *Annex II Chapters III and X Regulation (EC) No 1774/2002 and Section (1), (3) and (4) in conjunction with Annex I of the German Animal*

By-product Disposal Regulation (Tierische Nebenprodukte-Beseitigungs-Verordnung, TierNebV) and to keep records according to *Article 9 (1) in conjunction with Annex II, Chapter IV Regulation (EC) No 1774/2002 and/or Section 9 (5) in conjunction with Annex 2 TierNebV*. Commercial documentation and records must be kept for a period of at least two years (*Annex II Chapter V Regulation (EC) No 1774/2002*).

The consignor of animal by-products (food business operator) must keep the records according to Section (5) TierNebV according to the template given in Annex 2 and the following must be noted:

- date on which the material was collected;
- description of the material (animal species for Category 3 material), including category;
- material quantity;
- name and address of the shipping company (registration number);
- where known, name and address of the receiving establishment (approval number).

3.11 Refrigeration

Refrigeration capacities must correspond to the production quantities (*Regulation (EC) No 852/2004 Annex II Chapter I No. 2 (d)*). If, alternatively, household fridges are being used, checks must be carried out to verify that temperatures can be met.

Filletts and slices must no remain on the worktables beyond the time necessary for their preparation and must be wrapped and chilled immediately after their preparation (*Regulation (EC) No 853/2004 Annex III Section VIII Chapter III A No. 3*).

The following storage and transport temperatures have to be complied with (*Regulation (EC) No 853/2004 Annex III Section VIII Chapter VII No. 1 and 2*):

- fresh fishery products: temperature approaching that of melting ice;
- frozen fishery products: - 18°C (short-term deviations up to 3°C are permissible),
- Recommendation for smoked fish: < 4°C (depending on the best before date and the product).

Ice must be made from potable water, for whole fish it may be made from clean water (*Regulation (EC) No. 852/2004 Annex II Chapter VII No. 4*). Melt water may not come into contact with the fishery products (*Regulation (EC) No 853/2004 Annex III Section VIII Chapter III A No. 4 in conjunction with Chapter VI No. 1 in conjunction with VIII No. 3*). For separate storage of raw materials and processed products, separate cold storage rooms or household fridges are to be used (*Regulation (EC) No. 852/2004 Annex II Chapter IX No. 5*). Alternatively, a physical (e.g. by means of Euroboxes or packaging) or a temporal separation is possible (*AVV LmH Annex 1.1, No. 6.3*).

Interpretation of *AVV LmH Annex 1.1 No. 6.3*, however, also permits in exceptional cases, collective storage of raw materials and processed products, as long as any cross contamination is avoided. The products may also be protected against contamination through separate storage in Euroboxes or temporal separation, for example.

3.12 Temperature records

Chill temperatures must be monitored daily with a thermometer or logger (*Regulation (EC) No 852/2004 Annex II Chapter I No. 2 letter d*). Record keeping is to comply with the self-monitoring concept, at least through recording of any deviations and measures taken.

For process stages such as heating and/or smoking (CCP), a work description on how to reliably reach and maintain the set-point temperatures with the procedures in place has to be drafted once.

It is sufficient if the actual temperatures taken during random sampling and any deviations are documented.

3.13 Outdoor smokers

Food transport in the open may only occur with a covering or in locked containers (*Regulation (EC) No 852/2004 Annex II Chapter IX No. 3*).

3.14 Access to the production sites

Access to the production sites from the outside must be via an access area with appropriate equipment such that there can be no contamination; for example, facilities for cleaning or changing footwear as well as facilities for hand washing and disinfecting (*Regulation (EC) No 852/2004 Annex II Chapter I No. 2 (a) in conjunction with AVV LmH Annex 1.1 No. 1.1*). Alternatives may be used in the access areas, e.g. bucket with water and a brush for cleaning shoes, a tub with disinfectant solution and a hand basin to wash and disinfect hands in the production area.

3.15 Cooling after smoking process

Cooling must take place in an appropriate, hygienic section or area (*Regulation (EC) No 852/2004 Annex II Chapter IX No. 3*). In case of cooling outdoors, protection from adverse impacts (flies, birds etc.) must be ensured e.g. through a canopy and partitioning with insect-proof screens.

3.16 Clothing

Hygiene clothing is to be used (light, clean, easily washable) and a head covering must be worn which completely covers the hair. In wet areas light footwear, e.g. boots, is to be worn. In dry areas, suitable, clean and easy to clean footwear is to be worn. Work clothes must be suitable and clean, e.g. a single-use or rubber apron (*Regulation (EC) No 852/2004 Annex II, Chapter VIII, No. 1 in conjunction with AVV LmH Annex 1.1, No. 5.1*). Primary producers must wear appropriate and clean work clothes and clean boots and a single-use or rubber apron, where necessary (*DVO LMHV Annex 2, No. 3 (b)*).

Alternatively, if the food is handled in front of the consumer and immediately supplied, a head covering and protective footgear can be waived (*AVV LmH Annex 1.1, No. 5.1*).

3.17 Cleaning and disinfecting

It is compulsory to draft a cleaning and disinfection plan. The frequency and scope are dependent on the areas or area sections concerned and the activities carried out in them. In general, cleaning takes place at the end of each work day as well as at the end of completed work step and as required. Only cleaning agents and disinfectants approved for food areas are to be used [products listed by the DVG (German Association of Veterinary Medicine)]. These must be stored separately from areas where food is handled (*Regulation (EC) No 852/2004 Annex II Chapter I No. 10*). Appropriate documentation of the measures taken by the respective staff member has to take place. In case of primary producers, documentation is not absolutely necessary, however it is strongly recommended within the scope of personal responsibility of the food business operator.

3.18 Pest control

Pest infestations should be effectively avoided by the use of insect-proof screens at external windows and tightly closing doors and windows (*Regulation (EC) No 852/2004 Annex II Chapter II No. 1 Letter b*). Identification of pests such as ants, cockroaches, mice, rats, flies is done essentially by eye, with the help of baits or pest control agents and traps (e.g. UV-fly traps or adhesive tape). Pest control firms have to be consulted, where necessary. There must be no cross contamination of food and pest control agents (*Regulation (EC) No 852/2004 Annex II Chapter IX No. 4 in conjunction with AVV LmH Annex 1.1, No. 6.2*). Pest prevention, primarily any infestation and measures taken, are to be documented. For primary production documentation is not mandatory.

3.19 Training

Only competent staff may be employed to slaughter fish (*Section 4 (1) TierSchlV*). Hygiene training of all employees must correspond to their areas of responsibility and activity respectively (*Regulation (EC) No 852/2004 Annex II Chapter XII No. 1*) and is to be repeated annually.

Proof of initial instruction according to *Section 43 (1)* of the German Infection Protection Act (*Infektionsschutzgesetz, IfSG*) issued by the Health Authority or commissioned doctor is to be deposited with the employer. Instructions in accordance with *Section 43 (4) IfSG* on prohibitions on carrying out certain activities according to *Section 42 (1) IfSG* have to be given annually (with a signature from the employee stating they have participated) by the food business operator or its representatives. Also, in case of primary producers is has to be ensured that staff are in good health and trained in matters of food hygiene (*Regulation (EC) No 852/2004 Annex I Part A Section II, No. 4 (e) in conjunction with DVO LMHV Annex II No. 3 a*).

3.20 Personnel

A high degree of personal hygiene is a prerequisite of working with food (*Regulation (EC) No 852/2004 Annex II Chapter VIII No. 1*). Adequate changing facilities must be available (*Regulation (EC) No 852/2004 Annex II Chapter I No. 9*). Protective clothing must be stored separately from other clothing items (e.g. split locker) (*AVV LmH Annex 1.1, No. 1.7*).

In exceptional cases the changing rooms may be in private areas (Annex 1.1 No. 1.7 AVV).

Staff toilets must be equipped with flushing and connection to an effective drainage system. Lavatories may not open directly into rooms in which food is handled (*Regulation (EC) No 852/2004 Annex II Chapter I No. 3*).

In small craft businesses, changing facilities and toilets may alternatively be used within private building areas (*AVV LmH Annex 1.1, No. 1.2*). Lavatories must be equipped with hand basins with soap and clean towels (*DVO LMHV Annex 2 No. 2 (d)*).

3.21 Retained samples

Storage of retained samples for an appropriate time period is particularly useful for easily perishable products handed out ready-to-eat (German Product Liability Act).

3.22 Best before date (BBD)

To state a BBD is only mandatory in case of finished packaged products available via self-service (*Section 3 (1) No. 4 of the German Ordinance on Food Labelling (Lebensmittelkennzeichnungsverordnung, LMKV)*). Responsibility for establishing best before dates lies with the food business operator. The food business operator performs analyses at its own discretion (potential stock tests; microbiological analyses, empirical data with corresponding safety margins) and establishes the BBD. It is not necessary to state the BBD in case of the sale of fresh batch goods.

3.23 Microbiological analyses

The food business operator is responsible for carrying out microbiological analyses. The criteria for these are determined in *Regulation (EC) No 2073/2005*. The food business operator in principle determines the scope and intensity of sampling.

1. Product:

The scope of sampling depends on the type and amount of products produced.

Test for *Listeria monocytogenes* in vacuum-packed smoked fish (*Regulation (EC) No 2073/2005 Annex I Chapter 1 No. 1.2*).

Proposal for registered establishments: For instance, analysis of three samples per year in the case of vacuum-packed products. In the case of positive results, the cause for the contamination should be identified. For this reason, it is usually necessary to increase the frequency of analyses for *L. monocytogenes*.

2. Environment:

Collecting *Listeria* samples from surfaces in the environment is recommended in case of production of products with an increased risk of *Listeria*, as is the case with vacuum-packed smoked fish (*Regulation (EC) No 2073/2005, recital 22*). Environmental analysis (contact/swab tests) on the overall bacterial count and enterobacteriaceae is recommended to verify cleaning and disinfecting (hygiene status).

3.24 Inspection of goods (incoming/outgoing)

Inspection of goods (incoming/outgoing) is necessary in order to ensure that fishery products satisfy legal requirements (e.g. freshness criteria) (*Regulation (EC) No 852/2004 Annex II Chapter IX No. 1 in conjunction with Regulation (EC) No 853/2004 Annex III Section VIII Chapter V A*)

Recommendation for inspection of goods (incoming/outgoing)

- Sensory freshness test (smell, colour, taste and texture, if applicable), examination of external quality (for fresh fish: eyes, colour of the gills, slime coat on the skin and gills, pressure test);
- temperature;
- cleanliness of the delivery vehicle;
- integrity and cleanliness of the packaging;
- identity check (checking the goods are consistent with the shipping documents);
- quantity;
- best before date (BBD), where appropriate;
- analysis certificates, specification of goods, under certain circumstances;
- documentation, especially for rejects with reject reason specified.

3.25 Traceability

Documentation on the origin of all food received (e.g. spices) and customers of all food supplied (exception: customers are final consumers), e.g. through the organised filing of delivery notes and receipts, if required (*Regulation (EC) No 178/2002 Article 18*). This applies accordingly to the supply of primary products.

3.26 General notes

Food business operators rearing animals or producing primary products of animal origin must, according to *Annex I Part A III No. 7 of Regulation (EC) No 852/2004*, keep records on:

- the nature and origin of feed fed to the animals;
- veterinary medicinal products administered to the animals, waiting times (evidence on how the drugs were administered and prescriptions as well as a register are to be properly kept for food-delivering animals. Only registered drugs may be administered, waiting times are to be observed);
- where applicable, illnesses which may compromise food safety;
- reports of any examinations carried out on the animals or the animal products.

3.27 Hazard analysis - HACCP

The **Hazard Analysis and Critical Control Points** Concept (abbreviated: **HACCP** Concept, German: *Gefahrenanalyse kritischer Lenkungspunkte*) is a precautionary system, which should ensure the safety of food and consumers.

Every food business operator is obligated by law, through suitable measures and own controls, to ensure that the food it placed on the market does not pose any risks to the health of the consumer. The food business operator is entirely responsible for food safety. In legal disputes the burden of proof lies with the food business operator.

According to *Article 5 (1) in conjunction with (2) of Regulation (EC) No 853/2004* food business operators shall put in place, implement and maintain procedures based on HACCP principles. It is a matter of being able to flexibly put together a company-specific system which corresponds to the size and structure of the establishments. It has to be assessed whether critical control points (CCPs, e.g. monitoring of smoking temperature) are exist in an establishment which require the establishment of an HACCP system. If this is the case, they must be monitored. In the case of any deviations, appropriate measures must be taken.

It is also possible that no CCPs are identified in manufacturing processes of certain food business operators and that in this case, food safety is ensured through a good hygiene practice (GHP). In any case, a hazard analysis is to be carried out and documented.

Instead of an individually-generated HACCP concept, guidelines (e.g. the *Leitlinien für eine gute Hygienepraxis und für die Anwendung der Grundsätze des HACCP-Systems für das Herstellen, Behandeln und Inverkehrbringen von Fischereierzeugnissen 2005* (Guidance on good practice for hygiene and the application of the HACCP system principles for production, treatment and placing into the market of fishery products 2005, available in German only, issued by the German Federal Association of the German Fishing Industry and Fish Wholesale) which are appropriate for the establishment may be used.

Independent of the HACCP system, self-monitoring systems, like cold storage room temperature surveillance, pest control measures etc., are to be established, through which optimal food hygiene is ensured.

4 Appendix: Requisite forms, check lists, templates

Appendix 2

Approval application

Sender:

Via District

Office/Place.....

-Veterinary Office-

.....

.....

To the
government

.....

Place, date

Application for approval of my food establishment according to Article 6 (3) of the Regulation (EC) No 852/2004 in conjunction with Article 4 (2) of Regulation (EC) No 853/2004

Attachments

Profile of the establishment (general information) Fish supplementary sheet

Dear Madam or Sir,

I hereby apply for approval of my establishment in

.....
.....

for the operational areas stated in the profile of the establishment and the associated

supplementary sheets. With best regards

.....

Signature

Self-disclosure

Sender (Applicant/Stamp)

Address of competent authority

Declaration

I hereby declare that at the time of making this declaration, and in the previous five years, no criminal proceedings and no preliminary public prosecution proceedings, notably in regard to food law, is / has been pending or a sentence passed.

(Place, date)

(Applicant's signature)

Appendix 4

Profile of the establishment (general information)

Name of establishment

Approval No. Veterinary control number (where already available)

Registration number(where available)

Food business operator.....
(within the meaning of *Article 3 No. 3 of Regulation (EC) No 178/2002*)

Street

Postcode, place.....

Telephone no.

Fax.....

E-mail & Internet

Year of construction

Last conversion.....

Operational areas

Meat	yes / no
Milk	yes / no
Fish	yes / no
Live mussels	yes / no
Eggs/Egg products	yes / no
Fat and tallow	yes / no
Stomachs, bladders and intestines	yes / no
Gelatine/Collagen	yes / no
Other	yes / no

Personnel

Total workforce	male:	female:
thereof in production	male:	female:
External staff (e.g. cleaners)	male:	female:

Water supply

Public water supply
Own water supply (well)
Clean seawater

Environmentally-relevant permits

Washing station for means of transport	yes / no
Fat separator	yes / no
.....	yes / no

Note:

Provisions from other fields of law, e.g. emission control law, labour law, industrial law, water law etc., remain unaffected by an approval granted under *Regulation (EC) No 853/2004*.

Appendix 5

**Supplementary sheet fishery products to the profile
of the establishment (without transloading goods)**

Operation types

- Fishing vessel*) yes
 Freezer vessel*) yes
 Factory vessel*) yes
 Auction hall yes
 Wholesale fish market yes
 Establishment for the manufacture of fishery products yes

*) Specify port of registry (information in register of shipping):

Operational areas for

- fresh fishery products, whole fish yes
 prepared fishery products yes
 processed fishery products yes
 fishery products produced by mechanically separating the
 fish meat from the fish bone yes

1 Information about operational structure

Production all year round Seasonal work (from/to)

1.1 Fresh fishery products area, whole fish:

	in kg
Fish farming capacity	
Maximum slaughter capacity per hour	
Average slaughter capacity per week	

1.2 Prepared fishery products area:

(Quantity in kg per week)

Fresh water fish	
Salt water fish	
Crustaceans	
Shellfish	

Work steps

Gutting	<input type="checkbox"/> yes
Heading	<input type="checkbox"/> yes
Cutting, filleting, chopping	<input type="checkbox"/> yes
Packaging	<input type="checkbox"/> yes
Refrigeration	<input type="checkbox"/> yes
Deep freezing	<input type="checkbox"/> yes

1.3 Processed fishery products area:

(Quantity per product type (approx.) in kg per week)

Dried fishery products	
Cold-smoked fishery products	
Hot-smoked fishery products	
Salted fishery products	
Anchovies	
Marinades	
Heated fishery products (fried, boiled fish)	
Fishery products produced by mechanically separating the fish meat from the fish bone	

Appendix 6

Cleaning and disinfection overview

Location	Cleaning	Disinfection
Slaughter: floors	after use	after use
Slaughter: walls, doors	weekly	monthly
Slaughter: windows	monthly	---
Slaughter: equipment, tools, dishes	after use	after use
Cutting/production: floors	after use	monthly
Cutting/production: walls, doors	weekly	monthly
Cutting/production: windows	monthly	---
Cutting/production: equipment, tools, dishes	daily, after use	monthly
Cutting/production: ventilation, extractor hood	monthly	---
Cold storage rooms: floors	weekly	monthly
Cold storage rooms: walls, doors	monthly	monthly
Cold storage rooms: Racks	monthly	---
Shop cold storage room: meat grinder (minced meat production)	at least daily	daily
Freezer rooms and facilities (antifreeze agent)	quarterly	---
Shop: floor	daily	---
Shop: walls, doors	monthly	---
Shop: fittings, dishes	daily	---
Shop: cutting boards, knives, tools	several times a day	---
Kitchen: floor	daily	---
Kitchen: walls, doors, windows	fortnightly and as required	---
Kitchen: outdoor facilities	daily	weekly
Kitchen: inside cupboards	monthly	---
Containers used for food	after use	after use
Lavatories: floors, toilets, wash basins, door handles	daily	weekly
Lavatories: walls, doors	monthly	---
Social areas	weekly	---
Means of transportation	after use	at least monthly
Waste bins	daily	weekly
Room for condemned material	weekly	weekly

Appendix 7

Sample cleaning and disinfection plan

Location	Staff member responsible	Cleaning agents	Disinfecting agents
Slaughter: floors			
Slaughter: walls, doors			
Slaughter: windows			
Slaughter: equipment, tools, dishes			
Cutting/production: floors			
Cutting/production: walls, doors			
Cutting/production: windows			
Cutting/production: equipment, tools, dishes			
Cutting/production: ventilation, extractor hood			
Euroboxes			
Cold storage rooms: floors			
Cold storage rooms: walls, doors			
Cold storage rooms: racks			
Shop cold storage room: meat grinder (minced meat production)			
Freezer rooms and facilities (antifreeze agent)			
Shop: floor			
Shop: walls, doors			
Shop: fittings, dishes			
Shop: cutting boards, knives, tools			
Kitchen: floor			
Kitchen: walls, doors, windows			
Kitchen: outdoor facilities			
Kitchen: inside cupboards			
Toilets: floors, toilets, wash basins, door handles			
Toilets: walls, doors			
Social areas			
Means of transportation			
Waste bins			
Room for condemned material			

Manufacturer safety data sheets for the cleaning and disinfection agents are available in the establishment.

Appendix 8

Cleaning and disinfection - room:**Month:**

Day	Floor	Walls	Doors	Windows	Work surfaces	Machines	Tools
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
26							
27							
28							
29							
30							
31							

Cleaning is confirmed by the staff member performing it by entering its initials in the appropriate box.

If the area has also been disinfected, an additional "D" is added.

Pest detection and control

Example:

Structural conditions have been created for the prevention of pests:

- repair of cracks in masonry work;
- insect-proof screens on all windows;
- tightly shutting doors;
- rodent-secure gullies.

Pest detection is carried out by the owner of the establishment or a contractor.

For this purpose, traps are set for various pests according to plan:

- mouse traps;
- rat bait in outside areas (product®);
- adhesive traps with chemical attractant for ants and cockroaches (product.....®);
- UV fly trap.

No infestation determined to date.

Should an infestation occur, a specialist firm will be commissioned with pest control.

Staff training documentation

Date: Duration:

Trainer:

Topic (check):

- Instruction under the German Infection Protection Act
- Food hygiene risks
- Basic microbiological principles:
 - growth of germs under different conditions (temperature, time, nutrients, humidity)
 - Types of germs (spoilage micro-organisms, pathogens)
 - Procedures to inhibit germ growth
 - Procedures to kill germs
- Temperature ranges to adhere to
- Hygiene in cold storage rooms (separation of various foodstuffs, wrapping, etc.)
- Behaviour during illness: gastrointestinal diseases, wounds
- Staff hygiene: work clothes, proper hand washing, jewellery
- Workplace-related rules of conduct when handling food
- Personal responsibility of individual employees
- Incoming goods inspection
- Correct use of cleaning agents and disinfectants
- Pests: Risks, detection, prevention
- Waste disposal
- Operational self-monitoring strategy, HACCP system

Comments:

HACCP system

(Hazard Analysis and Critical Control Points)

As a basis, available on site:

Leitlinien für eine gute Hygienepraxis und für die Anwendung der Grundsätze des HACCP-Systems für das Herstellen, Behandeln und Inverkehrbringen von Fischereierzeugnissen 2005 (Guidance on good practice for hygiene and the application of the HACCP system principles for production, treatment and placing into the market of fishery products 2005, available in German only) issued by the German Bundesverband der deutschen Fischindustrie und des Fischgroßhandels e.V. (Federal Association of the German Fishing Industry and Fish Wholesale)

Based on this an own, establishment-specific self-monitoring strategy is developed which is adapted to the size of the establishment.

All employees are informed about the HACCP strategy of the establishment in the course of annual training programmes and as required.

Appendix 14

Documentation of incoming goods

All fish deliveries received are checked and the results are documented in a check list and a corresponding note is added to the invoice.

Incoming goods form

Delivery received on:

Company:

Goods:

Quantity of goods:

Reference temperature Fresh fish: max. +2°C		Actual temperature:.... °C
Wrapping	O.K.	Complaint:
Delivery vehicle	O.K.	Complaint:
External quality	O.K.	Complaint:
Freshness test	O.K.	Complaint:
Identity check	O.K.	Complaint:
Quantity	O.K.	Complaint:
Certificates	O.K.	Complaint:

Goods accepted:

Goods rejected:

Reason:

.....

Signature:

Appendix 15

Chill temperatures, room:

Month: Required temperature:°C (threshold: ±.....°C)

Day	Temperature measured	Reason for deviations	Measures in case of deviation	Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				

Appendix 16

Microbiological self-monitoring

The establishment performs the following microbiological self-monitoring measures on a regular basis in order to improve process hygiene and verify the self-monitoring system.

What is being sampled?	Analyses	Minimum scope

Samples are collected by a laboratory employee. The laboratory interprets the results.

In the case of objectionable results, the reasons for this are determined, necessary measures taken and sampling increased until all problems are solved. This is also documented.

Appendix 17

Area	Hygiene requirements in establishments for processing fishery products	Alternative solution e.g. for smaller establishments (Case-by-case assessment on site)	Minimum requirements for establishments supplying only small quantities of primary products from their own production and/or catch
1. Separation of work steps	<p>physical separation (different rooms or areas in the room) for:</p> <ul style="list-style-type: none"> - slaughtering - filleting - processing (e.g. smoking) 	<p>temporal separation with intermediate cleaning possible for:</p> <ul style="list-style-type: none"> - slaughtering - filleting - processing (e.g. smoking) 	<p>hygienic production, transport and storage conditions;</p> <p><i>LMHV, Annex 2, No. 1 (b)</i></p> <p>Products resulting from smoking, packaging under vacuum and filleting are not primary products</p> <p><i>(Guidance document on Regulation (EC) No 852/2004, 3.2, Remarks on primary products)</i></p>
2. Working areas	<p>Floors, walls, doors and surfaces must be easy to clean and, where necessary, to disinfect.</p> <p>Windows must be constructed so as to prevent accumulation of dirt</p> <p>(no unnecessary scratches and cracks, smooth surface, no wood, slanted window sills <i>AVV LmH Annex 1.1, No. 1.11</i>)</p> <p>Ceilings must be constructed and finished so as to prevent accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles (adequate ventilation, no unnecessary conduits and piping, level surfaces).</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter II, No. 1</i></p> <p>Deviations are possible for floors and walls in ripening rooms and smoke chambers!</p> <p><i>AVV LmH Annex 1.1, No. 1.8 and 1.9</i></p>	<p>see left</p> <p>see left</p> <p>see left</p> <p>see left</p>	<p>Walls, floors and work surfaces in operation facilities as well as in retail facilities, containers, vehicles, which may come into contact with primary products must be well maintained and regularly cleaned and disinfected.</p> <p>Walls: smooth, washable, up to the working height; easy to clean and disinfect (where appropriate); coating possible</p> <p><i>DVO LMHV, Annex 2, No. 1 (a)</i></p>
3. Equipment	<p>Items, fittings and equipment which come into contact with food must be maintained, thoroughly cleaned and, where necessary, disinfected</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter V, No. 1</i></p> <p>They must be resistant to chemicals and corrosion. Other than in the ripening rooms and smoke chambers, no wood is to be stored.</p> <p><i>AVV LmH Annex 1.1, No. 3.1</i></p>	<p>see left</p> <p>e.g. Regular switch of knives during production and disinfection after use (e.g. in dishwasher)</p>	<p>see left</p> <p><i>DVO LMHV, Annex 2, No. 1 (a)</i></p>
4. Shipping containers	<p>E2 boxes may not to be placed directly on the floor (stored on trolleys or mats)</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter IV, No. 1 in conjunction with AVV LmH Annex 1.1, No. 2.1</i></p>	<p>see left</p>	<p>see left</p>

Area	Hygiene requirements in establishments for processing fishery products	Alternative solution e.g. for smaller establishments (Case-by-case assessment on site)	Minimum requirements for establishments supplying only small quantities of primary products from their own production and/or catch
5. Floor gullies	<p>Rodent-secure, odour-proof effluent disposal system with covering from rust-free material (metal, plastic);</p> <p>The flow direction of the water must run from a clean area into a contaminated area;</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter I, No. 8 in conjunction with AVV LmH Annex 1.1, No. 1.6</i></p> <p>Drainage channels are required if contamination via non-effluent waste water is possible; in areas where dry process steps take place (e.g. packaging), drainage may not be necessary if the floors have an adequate slope</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter I, No. 8 in conjunction with AVV LmH Annex 1.1, No. 1.8</i></p>	<p>see left</p> <p>In establishments structured as handicraft businesses, drainage channels are dispensable provided that contamination of unpacked food is prevented by means of an inclined floor</p> <p><i>AVV LmH Annex 1.4, No. 1.1.1</i></p>	<p>see left</p> <p><i>DVO LMHV, Annex 2, No. 1 (b)</i></p>
6. Ventilation and lighting	<p>The rooms must be adequately ventilated so that the build up of condensation or the formation of mould is easily avoided.</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter I, No. 5</i></p> <p>The working areas must be adequately lit</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter I, No. 7</i></p> <p>A minimum illumination 220 lx for work rooms and 110 lx for storage areas is recommended</p> <p><i>AVV LmH Annex 1.1, No. 1.5</i></p>	<p>see left</p>	<p>see left</p>
7. Hand basins	<p>Hand basins fitted with both hot and cold running water; contact free fittings</p> <p>Directly next to the work space; easily accessible;</p> <p>soap dispensers; disposable towels;</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter I, No. 4</i></p> <p>extra wash basin for washing food,</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter II, No. 3 in conjunction with AVV LmH Annex 1.1, No. 1.16</i></p>	<p>Hand basins fitted with both warm and cold running water;</p> <p>hand washing facility must be designed in a way that any contamination cannot be further spread, e.g. fitted with a single lever mixer tap or pivot-mounted arm;</p> <p>see left</p>	<p>Hand basins, soap, disposable towels or clean towel</p> <p><i>DVO LMHV, Annex 2, No. 2 (d)</i></p>
8. Water supply	<p>There is to be an adequate supply of potable water; for cleaning uncut fish, clean water may also be used;</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter VII, No. 1 (a) and (b)</i></p>	<p>see left</p>	<p>see left</p> <p><i>DVO Tier-LMHV, Annex 1, No. 1.4</i></p>

Area	Hygiene requirements in establishments for processing fishery products	Alternative solution e.g. for smaller establishments (Case-by-case assessment on site)	Minimum requirements for establishments supplying only small quantities of primary products from their own production and/or catch
	Immediately after gutting, fishery products must be thoroughly washed with potable water. <i>Regulation (EC) No 853/2004 Annex III, Section VIII, Chapter III, No. 4</i>		see left <i>DVO Tier-LMHV, Annex 1, No. 2.3</i>
9. Food waste	Collection in closable containers; waste collection rooms must be kept free from animals and pests. <i>Regulation (EC) No 852/2004 Annex II, Chapter VI, No. 2 and No. 3</i> Recommendation: Waste refrigeration (e.g. deep freezer, chest freezer)	Collection in open containers, which are placed in lockable rooms designated specifically for that purpose, is possible <i>AVV LmH Annex 1.1, No. 4.1</i>	Waste to be stored and disposed of in such a way that no contamination of primary products is possible <i>DVO LMHV, Annex 2, No. 1 (d)</i>
10. Disposal of condemned material	Disposal obligation Fish waste classified as Category 3, in case of an epidemic Category 2; labelling of container “Not for human consumption”; Keeping commercial documentation from waste disposal contractors and appropriate records according to <i>TierNebV</i> <i>Regulation (EC) 1774/2002, Annex II</i>	see left	see left
11. Refrigeration	Refrigeration capacities must correspond to the production quantities; <i>Regulation (EC) No 852/2004 Annex II, Chapter I, No. 2 (d)</i> Fillets and slices must not remain on the worktables beyond the time necessary for their preparation and must be wrapped and chilled immediately after their preparation; <i>Regulation (EC) No 853/2004 Annex III, Section VIII, Chapter III, A, No. 3</i> The following storage and transport temperatures have to be complied with (fresh fishery products: temperature approaching that of melting ice, frozen fishery products: - 18°C, short-term deviations up to 3°C are permissible; recommendation: smoked fish < + 4°C storage, depending on the best before date and the product); <i>Regulation (EC) No 853/2004 Annex III, paragraph VIII, Chapter VII, No. 1 and 2</i> (permissible range, temperatures to be applied accordingly in retail) Ice must be made from potable water, for whole fish it may be made from clean water; <i>Regulation (EC) No 852/2004 Annex II, Chapter VII, No. 4</i>	see left If household fridges are being used, it must be verified that the corresponding criteria can be met.	In the event of storage, chilling capacities must correspond to the production quantities; Necessary temperatures must be reliably complied with <i>DVO LMHV, Annex 2, No. 2 (f)</i>

Area	Hygiene requirements in establishments for processing fishery products	Alternative solution e.g. for smaller establishments (Case-by-case assessment on site)	Minimum requirements for establishments supplying only small quantities of primary products from their own production and/or catch
	<p>Suitable draining of running melt water so that it does not come into contact with the fishery products;</p> <p><i>Regulation (EC) No 853/2004 Annex III, Section VIII, Chapter III, A, No. 4 in conjunction with Chapter VI, No. 1 in conjunction with Chapter VIII, No. 3</i></p> <p>Separate cold storage rooms for separate storage of raw materials and processed products</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter IX, No. 5</i></p>	<p>also physical or temporal separation possible by means of Euroboxes or packaging</p> <p><i>AVV LmH Annex 1.1, No. 6.3</i></p>	
12. Temperature records	<p>Equipment for monitoring and recording storage temperatures of food which must be kept cold must be available; chill temperatures are to be taken and recorded at least once a day (either manually or with logger);</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter I, No. 2 (d)</i></p> <p>Heating/Smoking temperatures (CCP): description on how the set-point temperatures are reliably reached with the procedures in place has to be drafted once; documentation only for random samples and in case of deviations</p>	see left	<p>Recommendation: Manually record chill temperatures in a list</p>
13. Outdoor smokers	<p>Food transport in the open may only occur with a covering;</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter IX, No. 3</i></p> <p>Access to the production sites from the outside: Hygiene lock with the opportunity to clean or change footwear and to clean and disinfect hands</p> <p><i>Regulation (EC) No. 852/2004 Annex II, Chapter I, No. 2 (c) in conjunction with AVV LmH Annex 1.1, No. 1.1</i></p>	<p>see left</p> <p>Facility in the sense of a hygiene lock: e.g. bucket with water and brush for cleaning shoes, tub with disinfectant solution, hand basins in the production room</p>	Not applicable since smoking is no primary production
14. Cooling after smoking process	<p>Cooling in suitable, hygienic room / area</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter IX, No. 3</i></p>	<p>In case of cooling outdoors, protection from adverse impacts (flies, birds etc.) must be ensured e.g. through a canopy and partitioning with insect-proof screens</p>	not applicable
15. Clothing	<p>Hygiene clothing (light, easily washable, clean); head covering (hair must be completely covered); light boots (wet area) or appropriate, clean and easy to clean footwear (dry area); single-use or rubber apron</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter VIII, No. 1 in conjunction with AVV LmH 1.1, No. 5.1</i></p>	<p>see left</p> <p>If the food is handled in front of the consumer and immediately supplied, a head covering and protective footwear can be waived</p> <p><i>AVV LmH Annex 1.1, No. 5.1</i></p>	<p>appropriate and clean work clothes; clean boots and single-use or rubber apron as required</p> <p><i>DVO LMHV, Annex 2, No. 3 (b)</i></p>

Area	Hygiene requirements in establishments for processing fishery products	Alternative solution e.g. for smaller establishments (Case-by-case assessment on site)	Minimum requirements for establishments supplying only small quantities of primary products from their own production and/or catch
16. Cleaning and disinfecting	<p>Drafting a cleaning and disinfection plan; frequency and scope is dependent on the areas or area sections concerned and the activities carried out in them; Cleaning (amongst other things) at the end of the working day and after completed work steps and as required; Documentation of the measures taken by the staff carrying out that work; <i>Regulation (EC) No. 852/2004 Annex II, Chapter I, No. 1</i> Use of the disinfectants (D) permitted for food areas (Recommendation: DVG listed products); Cleaning and disinfectant agents to be stored separately from food <i>Regulation (EC) No. 852/2004 Annex II, Chapter I, No. 10</i></p>	<p>see left;</p> <p>simplified documentation, e.g. a company-produced cleaning and disinfection plan.</p> <p>see left</p>	<p>see left, however no documentation needed</p>
17. Pests	<p>Insect-proof screens in front of external windows; tightly closing doors and windows; <i>Regulation (EC) No 852/2004 Annex II, Chapter II, No. 1 (d)</i></p> <p>Pest control through baits / traps: ants, cockroaches, mice, rats, flies (e.g. UV fly trap or adhesive tape) to detect pests; no contamination of food with pest control agents; <i>Regulation (EC) No 852/2004 Annex II, Chapter IX, No. 4 in conjunction with AVV LmH Annex 1.1, No. 6.2</i> appropriate documentation of the infestation and the measures taken</p>	<p>see left</p>	<p>see left, however no documentation needed <i>Regulation (EC) No 852/2004 Annex I, Part A, No. 4 (f)</i></p>
18. Training	<p>Slaughter staff must be competent; <i>Section 4 (1) TierSchlV</i></p> <p>Hygiene training for all employees corresponding to their area of responsibility and field of activity; <i>Regulation (EC) No 852/2004 Annex II, Chapter XII, No. 1</i></p> <p>training according to Section 43 (4) IfSG on prohibitions on carrying out certain activities according to Section 42 (1) once a year, signed by the employees, proof of initial instruction according to Section 43 (1) IfSG issued by the Health Authority or commissioned doctor is to be deposited with the employer</p>	<p>see left</p> <p>see left</p> <p>see left</p>	<p>see left</p> <p>It must be ensured that the staff is healthy and trained in health risks and food hygiene matters. <i>Regulation (EC) No 852/2004 Annex I, Part A, Section II, No. 4 (e) in conjunction with DVO LMHV Annex 2, No. 3 a)</i></p>

Area	Hygiene requirements in establishments for processing fishery products	Alternative solution e.g. for smaller establishments (Case-by-case assessment on site)	Minimum requirements for establishments supplying only small quantities of primary products from their own production and/or catch
19. Personnel	<p>High degree of personal hygiene; <i>Regulation (EC) No 852/2004 Annex II, Chapter VIII, No. 1</i> appropriate changing facilities;</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter I, No. 9</i> with storage of clean PSE separate from other clothing items (e.g. split locker) <i>AVV LmH Annex 1.1, No. 1.7</i> Flushing toilets with connection to an effective drainage system, lavatories may not open directly into areas where food is handled</p> <p><i>Regulation (EC) No 852/2004 Annex II, Chapter I, No. 3</i></p>	<p>in family businesses, changing rooms and lavatories also in privately used part of the building <i>AVV LmH Annex 1.1, No. 1.2</i></p>	<p>appropriate changing facilities; lavatories with hand basins; <i>DVO LMHV, Annex 2, No. 2 (d)</i></p>
20. Retained samples	<p>Only reasonable for easily perishable, ready-to-eat products; (German Product Liability Act)</p>	<p>see left</p>	<p>Not applicable as no supply as ready-to-eat product</p>
21. BBD	<p>It is only mandatory to state the BBD in case of finished packaged products available via self-service; <i>Section 3 (1), No. 4 LMKV</i> Responsibility for establishing best before dates lies with the establishment, it establishes the BBD itself and performs analyses at its own discretion (potential stock tests; microbiological analysis)</p>	<p>see left</p>	<p>not required for sale of fresh products; responsibility for the BBD lies with the establishment; it establishes the BBD independently (e.g. empirical values with corresponding safety margins)</p>
22. Microbiological analyses of products	<p><u>Product:</u> Scope depends on turnover und manufactured products; Test for <i>Listeria monocytogenes</i> in vacuum-packed smoked fish (suggestion for registered establishments: 3 samples a year, in case listeria are found frequency of testing for <i>Listeria monocytogenes</i> might be increased, and particularly when cold smoking) <i>Regulation (EC) No 2073/2005 Annex I, Chapter I, No. 1.2</i></p> <p><u>Environment:</u> Collecting <i>Listeria</i> samples from surfaces in the environment is recommended in case of production of products with an increased risk of <i>Listeria</i> (vacuum-packed smoked fish); <i>Regulation (EC) No 2073/2005, Recital 22</i> Environmental analysis (contact/swab tests) on the overall bacterial count and enterobacteriaceae is recommended to verify cleaning and disinfecting (hygiene status)</p>	<p>see left (Reduction of the number of samples to: 1 sample per year)</p> <p>if the microbiological analyses of the product do not indicate any issue with <i>Listeria</i>; collecting <i>Listeria</i> samples from surfaces may be waived in individual cases; overall bacterial count and enterobacteriaceae see left (1 x yearly if no deviations)</p>	<p>no tests necessary as no ready-to-eat products are supplied</p> <p>collecting samples from surfaces is not absolutely necessary</p>

Area	Hygiene requirements in establishments for processing fishery products	Alternative solution e.g. for smaller establishments (Case-by-case assessment on site)	Minimum requirements for establishments supplying only small quantities of primary products from their own production and/or catch
23. Inspection of goods (incoming/outgoing)	<p>Inspection in order to ensure that fishery products satisfy freshness criteria (incoming/outgoing goods)</p> <p><i>Regulation (EC) No 853/2004 Annex III, Section VIII, Chapter V, A</i></p> <p><u>Recommendation for inspection of goods (incoming/outgoing)</u></p> <ul style="list-style-type: none"> - External quality (eyes, gill colour, slime coat on skin and gills, pressure test) - Sensory freshness test (smell, colour, taste and texture, if applicable) - Temperature - Cleanliness of the transport vehicle - Packaging integrity and cleanliness - Identity check (checking the goods are consistent with the shipping documents) - Quantity - BBD - analysis certificates, specification of goods, under certain circumstances <p><i>Regulation (EC) No 852/2004 Annex II, Chapter IX, No. 1</i></p> <ul style="list-style-type: none"> - Documentation, especially for rejects 	see left	<p>Incoming goods inspection not applicable since no acquisition possible</p> <p><u>Outgoing goods inspection:</u></p> <p>Fishery products must be fresh when assessed based on look, smell and texture.</p> <p><i>DVO Tier-LMHV, Annex 1, No. 2.4</i></p>
24. Traceability	<p>Documentation on the origin of all animals received for slaughter and food received (e.g. spices) and customers of all animals supplied for slaughter or food supplied (exception: delivery to the final consumer) e.g. through the organised filing of delivery notes and receipts</p> <p><i>Regulation (EC) No 178/2002 Article 18</i></p>	see left	<p>Documentation of all animals for slaughter / food obtained (exception: supply to final consumer)</p> <p>e.g. through the regular filing of delivery notes and documents</p> <p><i>Regulation (EC) No 178/2002 Article 18</i></p>
25. General notes	<p>for food business operators rearing animals or producing primary products of animal origin, on:</p> <ul style="list-style-type: none"> - the nature and origin of feed fed to the animals; - Any veterinary medicinal products administered to the animals, waiting times (evidence on how the drugs were administered and prescriptions as well as a register are to be properly kept for food-delivering animals. Only registered drugs may be administered, waiting times are to be observed); - where applicable, illnesses which may compromise food safety. 	see left	see left

Area	Hygiene requirements in establishments for processing fishery products	Alternative solution e.g. for smaller establishments (Case-by-case assessment on site)	Minimum requirements for establishments supplying only small quantities of primary products from their own production and/or catch
	<p>- reports of any examinations carried out on the animals or the animal products, if applicable</p> <p><i>Regulation (EC) No 852/2004 Annex I, Section A, No. 7</i></p>		
26. Hazard analysis	<p>Food business operators shall put in place, implement and maintain procedures based on HACCP principles. It is a matter of a company-specific scheme (e.g. monitoring of smoking temperature as a critical checkpoint);</p> <p><i>Regulation (EC) No 852/2004 Article 5, Sections 1 and 2</i></p> <p>Reference:</p> <p>Leitlinien für eine gute Hygienepraxis und für die Anwendung der Grundsätze des HACCP-Systems für das Herstellen, Behandeln und Inverkehrbringen von Fischereierzeugnissen 2005 (Guidance on good practice for hygiene and the application of the HACCP system principles for production, treatment and placing into the market of fishery products 2005, available in German only) issued by the German Bundesverband der deutschen Fischindustrie und des Fischgroßhandels e.V. (Federal Association of the German Fishing Industry and Fish Wholesale)</p>	see left	Not to be implemented in general yet
27. Residues	<p>Compliance with the maximum level of Benzo(a)pyrene in the muscle meat of smoked fish = 5 µg/kg</p> <p><i>Regulation (EC) No 1881/2006 Annex Section 6</i></p>	see left	not applicable
28. Total Volatile Basic Nitrogen (TVB-N) limits	<p>Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:</p> <p>a) 25 mg of nitrogen/100 g of flesh for <i>Sebastes</i> spp., <i>Helicolenus dactylopterus</i>, <i>Sebastichthys capensis</i></p> <p>b) 30 mg of nitrogen/100 g of flesh for species belonging to the <i>Pleuronectidae</i> family (with the exception of halibut: <i>Hippoglossus</i> spp.)</p> <p>c) 35 mg of nitrogen/100 g of flesh for <i>Salmo salar</i>, species belonging to the <i>Merlucciidae</i> family, species belonging to the <i>Gadidae</i> family.</p> <p><i>Regulation (EC) No 2074/2005 Annex II, Section II, Chapter I, No. 1 and Chapter II</i></p>	see left	see left

5 Legal framework

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 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

REGULATION (EC) No. 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the hygiene of foodstuffs

REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs

COMMISSION REGULATION (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

REGULATION (EC) No 1774/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption

Regulation implementing the provisions of community food hygiene law with

Article 1: German decree concerning hygiene requirements in the production, treatment and placing into the market of food

(Decree on the hygiene of foodstuffs - LMHV)

Article 2: German decree concerning hygiene requirements in the production, treatment and placing into the market of certain food products of animal origin

(Decree on the hygiene of foodstuffs or animal origin - Tier-LMHV)

Regulation implementing the German Act on the disposal of animal by-products

(Animal By-Product Disposal Regulation - TierNebV)

German Animal Welfare Slaughter Ordinance (TierSchlV)

Act on the prevention of and control of infectious diseases in people (Infection Protection Act - IfSG)

German Ordinance on Food Labelling (LMKV)

Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

General administrative regulations on how to officially monitor compliance with hygiene regulations for food of animal origin and examination processes from the good working practice guidelines (AVV Food Hygiene - AVV LmH) of 12 September 2007

Note:

- Administrative regulations only constitute internal administrative advice on how to construe legal provisions. They may prove helpful in the interpretation of legal provisions and decrees, ordinances and regulations.
- Legal sources are presented in italics in the text.