Introductory regulations

§ 1 This Decree contains regulations that complement the Food Act (SFS 2006:804). The expressions and terms that are used in the Decree have the same meanings as in the Act.

EC Regulations

§ 2 The primary EC Regulations that, wholly or in part, are complemented by the Food Act (SFS 2006:804) are shown in a Government promulgation. In the case of EC regulations in such Regulations that fall within the scope of several acts, the regulations that are complemented by the Food Act are shown in the promulgation.

The National Food Administration may issue the regulations and make the decisions necessary to complement the EC regulations.

Drinking water in private households

§ 3 The National Food Administration may issue regulations that the Food Act (SFS 2006:804) shall be applied to drinking water in private households.

Treatment of food with ionising radiation

§ 4 Food may not be treated with ionising radiation. However, herbs, spices and vegetable seasonings may be treated with such radiation according to the conditions prescribed by the National Food Administration.

A food that has been treated with ionising radiation may be imported into Sweden or placed on the market in the country only if the treatment is
permitted here. The National Food Administration may issue regulations on further conditions for importation into the country of food from a country that is a member of the European Union.

The National Food Administration shall supply the Swedish Customs with a list of
1. the types of food that are irradiated abroad,
2. countries where food is irradiated or can be assumed to be irradiated.

**Prohibition on and conditions for the handling, etc. of food**

§ 5 If necessary to protect human life or health, the National Food Administration may issue regulations or in an individual case decide on

1. prohibition on or conditions for the handling, importation into the country or placing on the market of food, and
2. prohibition on the re-exportation of food that has been stored at a Border Inspection Post or a Customs warehouse or in a free zone or a free warehouse.

§ 6 If necessary to protect human life or health or otherwise to look after the interests of consumers, the National Food Administration may issue regulations on the nature or designation of food or on the use of products, substances or equipment in the handling of food or together with food.

**Labelling and presentation of food**

§ 7 The National Food Administration may issue regulations on the labelling and presentation of food.

**Personnel hygiene**

§ 8 If necessary for reasons of food hygiene, persons who are engaged in food handling shall be required to undergo a medical examination when requested to do so by the control authority. The cost of such an examination shall be reimbursed by the authority, unless it is to be reimbursed according to the Communicable Disease Act (SFS 2004:168).

§ 9 The National Food Administration may issue regulations on the obligation for a person who is engaged in food handling to show by means of a medical certificate that he/she is free from diseases or infections that can be transmitted to man via food.
The medical certificate shall be made out in the form which the National Food Administration stipulates after consultation with the National Board of Health and Welfare.

§ 10 After consultation with the National Board of Health and Welfare, the National Food Administration may issue regulations concerning the obligation for a person who is engaged in food handling to undergo a medical examination or other health control.

The food business operator shall decide on and pay for the health control.

§ 11 The National Food Administration may issue further regulations on personnel hygiene. If the regulations concern health control of personnel, the Administration shall consult the National Board of Health and Welfare.

Food establishments

§ 12 The National Food Administration may issue regulations that food may be handled or placed on the market only in an establishment that has been approved by the competent control authority. Furthermore, the National Food Administration may issue regulations on the requirements to be met in order for such approval to be granted and under which conditions the approval may be withdrawn.

§ 13 The National Food Administration may issue regulations on the registration of establishments.


§ 15 The National Food Administration and a municipal committee that performs tasks in the environment and health protection area shall maintain up-to-date lists of the approved and registered establishments over which the respective authority exercises control. In addition, the authorities shall carry out the tasks related to such establishments as are prescribed in Article 31 in Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules.
Measures against sabotage and other damage

§ 16 The National Food Administration may issue regulations on precautions aimed to prevent and repair the damaging effects of sabotage or other damage that can affect Sweden’s food supply.

Exemptions from prohibition on placing food on the market

§ 17 The National Food Administration may issue regulations on exemptions from the prohibition in § 10 of the Food Act (SFS 2006:804) on placing food on the market.

Competent authorities

§ 18 The National Food Administration shall carry out the tasks that are the responsibility of a competent authority according to the EC regulations that the Food Act (SFS 2006:804) complements, unless otherwise follows from § 15 or §§ 23-26 or the Government has decided otherwise.

§ 19 The National Food Administration shall

1. carry out the task that is the responsibility of a Member State according to Article 4 in Council Regulation (EC) No 104/2000 of 17 December 1999 on the common organisation of the market in fishery and aquaculture products,
2. carry out the tasks that are the responsibility of a Member State according to Article 21 in Commission Regulation (EC) No 753/2002 of 29 April 2002 laying down certain rules for applying Council Regulation (EC) No 1493/1999 as regards the description, designation, presentation and protection of certain wine sector products,

§ 20 The National Food Administration shall carry out the tasks that are the responsibility of a Member State according to Article 18 in Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 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.

The municipal committee or committees that performs tasks in the environment and health protection area within the municipality shall carry out the tasks that are the responsibility of an independent control body
according to Article 16 in Regulation (EC) No 1760/2000 of the European Parliament and of the Council. However, at the establishments that are under the direct control of the National Food Administration these tasks shall be carried out by the Administration.

§ 21 The National Food Administration shall consult the Swedish Animal Welfare Agency before giving permission for destruction or slaughter according to Chapter VI, Section II or point 3, Section III in Appendix III to Regulation (EC) No 853/2004 of the European Parliament and of the Council.

§ 22 The National Food Administration shall carry out the inspections that are necessary to see to it that in the food area Sweden fulfils the obligations that follow from its membership of the European Union.

§ 23 Unless otherwise follows from the second paragraph, the following authorities are competent to examine questions of approval of food establishments or to register food establishments.

<table>
<thead>
<tr>
<th>Type of food establishment</th>
<th>Examining authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Slaughterhouses and game handling Establishments</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>2. Cutting establishments and establishments for ground meat that produce more than 5 tonnes per week</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>3. Refrigerated and cold stores, except those that store and regroup meat products for distribution solely in retail trade</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>4. Meat product establishments and meat preparation establishments that produce more than 7.5 tonnes per week</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>5. Milk and milk product establishments that produce milk products from more than 2 000 000 litres of milk per year</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>Type of food establishment</td>
<td>Examining authority</td>
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<tr>
<td>----------------------------------------------------------------</td>
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</tr>
<tr>
<td>6. Fish establishments that produce more than 250 tonnes per year and fish wholesale establishments that handle more than 500 tonnes per year</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>7. Egg packing establishments that are covered by Council Regulation (EEC) No 1907/90 of 26 June 1990 on certain marketing standards for eggs</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>8. Egg product establishments</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>9. Food establishments in railway carriages, aircraft and factory ships and also chilled tankboats for fish</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>10. Manufacturing establishments for spirit drinks, wine, aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>11. Food establishments that are run by the retail company referred to in Chapter 5, § 2 of the Alcohol Act (SFS 1994:1738)</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>12. Export-controlled establishments as referred to the Decree on Control on the Exportation of Food (SFS 1974:271)</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>13. Establishments for treating food with ionising radiation</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>Type of food establishment</td>
<td>Examining authority</td>
</tr>
<tr>
<td>----------------------------</td>
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</tr>
<tr>
<td>14. Ship chandler’s stores, Customs warehouses, free warehouses and establishments in a free zone in which food that is not approved from a veterinary standpoint for free distribution is stored</td>
<td>National Food Administration</td>
</tr>
<tr>
<td>15. Establishments for supplying drinking water</td>
<td>A municipal committee as referred to in the Food Act (SFS 2006:804)</td>
</tr>
<tr>
<td>16. Establishments manufacturing snuff and chewing tobacco</td>
<td>A municipal committee as referred to in the Food Act (SFS 2006:804)</td>
</tr>
<tr>
<td>17. Other food establishments, including establishments for manufacturing additives, flavorings and processing aids and also primary producers of food</td>
<td>A municipal committee as referred to in the Food Act (SFS 2006:804)</td>
</tr>
</tbody>
</table>

If responsibility for control of the operations in an establishment is transferred from a municipal committee to the National Food Administration under the provisions of §15 or §17 of the Food Act (SFS 2006:804), the Administration shall thereafter examine the question of approval or registration of the establishment.

Approval of establishments for the manufacture of snuff and chewing tobacco and water establishments may be withdrawn by the authority that examines the question of approval of the establishments.

**Control authorities**

§ 25 Unless it otherwise follows from § 26 or § 27 or from the regulations in the Decree on official control of food that has been imported from a third country (SFS 2006:812), the authority that is competent to exercise official control is the authority that examines the question of approval of an establishment or that registers it.

§ 26 If responsibility for control of a certain establishment has been transferred from the National Food Administration to a municipal committee under the provisions of § 16 of the Food Act (SFS 2006:804), the municipal committee is the competent authority to exercise official control.

§ 27 The Surgeon-General is the competent authority to exercise official control within the Armed Forces.

§ 28 The county administrative boards exercise official control within each county by coordinating the activities of the municipalities and providing them with support, advice and guidance.

§ 29 The National Food Administration coordinates the activities of the other control authorities and provides support, advice and guidance in the activities.

**Regulations on controls**

§ 30 The National Food Administration may issue regulations on how official controls are to be exercised. This authority includes the right to issue regulations on the extent to which company employees may assist the official veterinarian in official control at slaughterhouses.

§ 31 The National Food Administration may issue regulations on

1. the obligation on a control authority or control body that is engaged in the official control to provide information to the Administration or a county administrative board about the control activities that are carried out,

2. the obligation on a food business operator to exercise internal control (self-checking) appropriate to the operations, and
3. the obligation on a person who presents animals for slaughter to provide information.

Other regulations on controls

§ 32 A county administrative board and a municipal committee that performs tasks in the environment and health protection area shall assist with special sampling and examinations decided by the National Food Administration.

§ 33 A county administrative board and the municipalities that are situated in the county shall consult each other in a coordination group established for the purpose. The county administrative boards shall be responsible for calling the groups together.

§ 34 The costs that arise for a control authority as a result of measures according to § 24 of the Food Act (SFS 2006:804) shall be reimbursed by the owner of the food when it was seized.

Laboratories

§ 35 To the extent that follows from Article 12 in Regulation (EC) No 882/2004 of the European Parliament and of the Council, laboratories that carry out examination of food shall be accredited by the Swedish Board for Accreditation and Conformity Assessment (SWEDAC) or another equivalent accreditation body.

The National Food Administration may issue regulations that laboratories that are not required to be accredited according to the first paragraph shall be accredited or approved by the Administration. The National Food Administration may also issue regulations on the requirements that shall be placed on laboratories that the Administration shall approve.

§ 36 SWEDAC is responsible for supervision of accredited laboratories according to the Act on Technical Control (SFS 1992:1119).

The National Food Administration is responsible for supervision of laboratories that the Administration has approved.

SWEDAC and the National Food Administration shall consult each other on questions of supervision of food laboratories and as regards regulations for such laboratories.
Reporting obligations

§ 37 If salmonella is shown to be present when food is examined in internal control, this shall be reported to the control authority without delay. If the control authority is a municipal committee, the committee shall inform the National Food Administration as soon as possible.

§ 38 A municipal committee that in its control activities finds that a food can constitute a serious direct or indirect risk for human health shall report the matter to the National Food Administration at once.

The National Food Administration may issue regulations on the information that shall be included in such a report.

§ 39 If necessary from a public health point of view and if the National Food Administration so requires, a food business operator and the owner or manager of a laboratory shall report when pathogenic bacteria or foreign substances have been found on examination of foods and other control samples. Such a report shall be made to the National Food Administration and to the Swedish Institute for Infectious Disease Control.

A physician or veterinarian who has good reason to assume that food poisoning has been caused by the contamination of food with pathogenic bacteria or a foreign substance during commercial handling shall report the matter to the county administrative board, the medical officer responsible for infectious disease control or the control authority that exercises control according to the Food Act (SFS 2006:804)

A physician who has good reason to assume that a person who is occupationally engaged in the handling of unpackaged food has a disease, infection, wound or other injury that can render the food he/she handles unsafe as food shall report the matter to the authority that exercises control over the operations in question and to the medical officer responsible for infectious disease control. The report shall contain information about the person’s name and place of work. The control authority shall inform the medical officer responsible for infectious disease control without delay about observations that can be of importance for protecting humans against infectious diseases.

Other regulations

§ 40 The National Food Administration may issue further regulations for the application of regulations in the Food Act (SFS 2006:804) and this Decree.
However, regulations concerning the application of the Act to the Armed Forces are issued by the Surgeon-General after consultation with the National Food Administration and regulations concerning the obligation to report according to § 39, second paragraph, are issued by the National Board of Health and Welfare after consultation with the National Food Administration.

§ 41 Regulations on appeals are contained in §§ 31 and 32 of the Food Act (SFS 2006:804).

This Decree comes into force on 1 July 2006. Through this Decree the Food Decree (SFS 1971:807) is repealed.

On behalf of the Government

ANN-CHRISTIN NYKVIST

Anders Perklev
(Ministry of Agriculture, Fisheries and Food)