

**NB: Unofficial translation**

**Legally binding texts are those in Finnish and Swedish**

**Decree of the Ministry of Agriculture and Forestry  
on Activities Concerning Fertiliser Products and Their Control  
(11/2012)**

Section 1 - *Scope*

- (1) This Decree lays down the provisions on the operator's obligation to notify and registration of certain operators relating to by-products of animal origin, obligation to keep a file, own check obligation, obligation to notify in advance, laboratory approval, and internal trade and import of fertiliser products. In addition, this Decree lays down the provisions on the approval of an establishment which manufactures, technically processes or stores organic fertiliser products or their raw materials as well as on organising the control concerning fertiliser products.

Section 2 - *Obligation to notify*

- (1) An operators who manufactures, technically processes, places on the market, imports and stores fertiliser products and, as applicable, their raw materials shall give a written notification to the Finnish Food Safety Authority on starting the activity and significant changes in the activity no later than one month prior to starting the activity or changes in it. Notification shall also be given on the termination of the activity no later than one month after the event. The information in Annex I shall be given in the notification. The notification shall be given using the official form of the Finnish Food Safety Authority. If the activity is seasonal in nature, the operator shall also indicate the period of the activity. The obligation to notify also applies to an operator who transports or stores by-products of animal origin and fertiliser products manufactured from these or their raw materials under Article 23 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption (Animal by-products Regulation). The obligation to notify also applies to farms using fertiliser products of animal origin mentioned in section 11(6) of the Decree of the Ministry of Agriculture and Forestry on Fertiliser Products (24/11) where the farm animals have access to land on which these have been spread or from which pasture vegetation intended for farm animal feed is harvested.
- (2) Obligation to notify does not apply to an operator who
  - 1) conveys or receives unprocessed or processed manure from one farm to another under a contract;
  - 2) conveys unprocessed manure or septic tank and wastewater sludge generated from living or other activity on the farm or other organic waste to an operator who has an environmental permit regarding these referred to in the Environmental Protection Act (86/2000);
  - 3) processes on the farm or in a joint manure storage facility for their own use manure, raw milk, eggshells and organic waste of plant origin produced on the farm or other waste produced in the activity of the farm excluding other Category 2 and 3 animal by-products than those listed above;
  - 4) processes on the farm for own use septic tank or wastewater sludge and dry toilet waste originating from living on the farm and from other activity of the farm by lime stabilising, composting, thermophilic digestion or mesophilic digestion when no environmental permit referred to in the Environmental Protection Act is required for the activity. Mesophilically

digested sludge shall be hygienised, composted, thermally dried or processed in other similar manner before or after the digestion;

- 5) conveys manure of the farm or joint manure storage facility loose directly from the farm as so-called direct sale when the manure involves no risk of spreading a serious infectious disease and no wild oat has been found on the farm or farms that share the joint manure storage facility; or
  - 6) is registered or approved to engage in transport under the Feed Act (86/2008) or approved under Article 24 of the Animal by-products Regulation or the Food Act (23/2006) and who transports by-products and products derived from these as a secondary occupation on behalf of an approved establishment or an operator registered and approved to transport by-products under the waste Act (646/2011).
- (3) The Finnish Food Safety Authority may, where necessary, request a copy of the entry of an operator to the waste management register from the Centre for Economic Development, Transport and the Environment in whose area of operation the activity is mainly practised.

### Section 3 - *Keeping a file*

- (1) A file under section 12 of the Fertiliser Product Act may be created by means of an automatic data processing system or by other similar appropriate means. Fertiliser products and their raw materials shall be traceable by product and by batch on the basis of the file. The file shall be kept up to date.
- (2) If import, placing on the market, manufacture, technical processing or conveyance of a fertiliser product or its raw material is prohibited, the operators shall enter in the file batch-specific information on the prohibition or enforcement order as well as on the place where the fertiliser product or its raw material is kept or the method, place and date of its disposal.
- (3) Obligation to keep a file also applies to an operator who conveys unprocessed manure to a technical processing establishment or to a biogas and composting establishment. In this case farm bookkeeping is sufficient as a file. Obligation to keep a file also applies to an operator who processes by-products of animal origin other than manure into fertiliser products for own use.
- (4) If an operator supplies processed wastewater sludge under points 1–3 of section 11 a(1) of the Decree of the Ministry of Agriculture and Forestry (24/11) to be used in agriculture, the file kept by the operator shall also contain the following information
  - 1) method of processing wastewater sludge to reduce the presence of pathogens and pests
  - 2) contracts concluded on the use of processed sludge
  - 3) recipients of processed sludge and places where sludge is used
  - 4) characteristics describing the quality of the agricultural land specified in accordance with Annex V of the above-mentioned Decree.

### Section 4 - *Own checks by an operator*

- (1) In the own checks the operator shall ensure that the factors which impact on the quality of fertiliser products are identified and that appropriate procedures are planned, implemented and monitored to reduce microbiological or other risks in the activity.
- (2) An own check plan shall show the nature of the activity, taking into account the information required in Annex II. An own check plan shall be up-dated when any significant changes take place in the activity and the up-dated own check plan shall be submitted to the Finnish Food Safety Authority as an annex to a notification of changes in the activity referred to in section 2.
- (3) The operator shall implement the own check plan in practice and keep a record of the implementation of own checks. To ensure the quality and safety of fertiliser products or their raw materials the documentation of own checks shall include analysis results and official certificates relating to the critical manufacturing and processing stages as well as documents of

exceptional situations and of measures taken to rectify them. For traceability purposes the documents relating to own checks shall be kept for five years. Where necessary, the documents shall be readily available when a control authority checks the operator's activity or requests the operator to submit copies of these for control.

- (4) The own check obligation does not apply to operators referred to in section 2(2) of this Decree or to operators who import fertiliser products from outside the European Union or from another Member State of the European Union only for the operator's own use.

#### Section 5 - *Approved establishment*

- (1) The requirement concerning the approval of an establishment under section 14 of the Fertiliser Product Act applies to establishments which manufacture organic fertiliser products referred to in Annex I of the Decree of the Ministry of Agriculture and Forestry (24/11) for placing on the market as follows:
- 1) establishments which manufacture or store organic fertiliser products of animal origin in accordance with the requirements of the Animal by-products Regulation;
  - 2) establishments which manufacture other organic fertiliser products in type designation groups 1B2, 3A2 and 3A5 except for establishments which engage in mechanical blending of organic raw material manufactured in an approved establishments and wastewater purification plants which process wastewater sludge into a by-product to be used as such as soil improver.
- (3) The approval of the establishment applies to manufacture for own use on a farm when processing animal by-products other than manure, raw milk of the farm or eggshells produced on the farm or when the activity is otherwise subject to the obligation to notify under section 11 of the Fertiliser Product Act.
- (4) An application for an approved establishment shall be made in writing to the Finnish Food Safety Authority using a form ratified by the Authority, and information required in section 14(1) of the Fertiliser Product Act shall be attached to it.
- (5) The Finnish Food Safety Authority functions as the evaluator of the applications concerning alternative processing methods for by-products of animal origin and fertiliser products derived from these under Article 20 of the Animal by-products Regulation and submits the results of the evaluation to the Commission.

#### Section 6 – *Registered establishment or operator*

- (1) The Finnish Food Safety Authority registers operators transporting by-products and fertiliser products manufactured from these and their raw materials on the basis of notification under section 2(1). Provisions on the conditions for the registration of operators are laid down in Chapter IV, point 3 of Annex IX of Commission Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Implementing Regulation), with subsequent amendments.
- (2) Only the registration obligation under Article 23 of the Animal by-products Regulation applies to the following establishments manufacturing fertiliser products:
- 1) establishments which only add a component or components to be mixed into processed meat-and-bone meal of Category 2 or processed animal protein of Category 3 as specified in Article 23 of the Animal by-products Regulation and re-package the product;
  - 2) establishment which re-packages a derived product of animal origin intended to be used as organic fertiliser in the construction of green areas or home gardens into retail packages with a maximum package size of 50 kg.

### Section 7 – *Report on own checks of an approved establishment*

- (1) A report on own checks shall include records on the implementation of the own check plan prepared in accordance with section 4 and Annex II of this Decree. The contents of the report may be specified in further detail in connection with the approval of the establishment.

### Section 8 – *Approved laboratory*

- (1) The official tests to ensure the quality of fertiliser products referred to in Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers (EC Fertiliser Regulation), Animal by-products Regulation, and in the Fertiliser Product Act or in statutes issued under it shall be performed at the laboratory of the Finnish Food Safety Authority, which functions as the national reference laboratory for the control of fertiliser products.
- (2) Samples from control by the authorities under the provisions mentioned above in subsection 1 shall be tested in an approved laboratory, which may also be other than the laboratory of the Finnish Food Safety Authority mentioned in subsection 1.
- (3) Before the approval a laboratory applying to become an approved laboratory shall request a statement from the Accreditation Unit of the Centre for Metrology and Accreditation (FINAS Accreditation Service) or another institution which meets the requirements of Standard EN/ISO IEC 17011. In Finland the FINAS Accreditation Service or another institution assesses whether the laboratory applying for approval meets the requirements of the international Standard EN/ISO IEC 17025 and the requirements laid down in the statutes referred to in subsection 1. The up-to-date statement shall be submitted to the Finnish Food Safety Authority, which shall approve a laboratory which meets the requirements.
- (4) For testing samples from own checks the operators may also use laboratories other than the approved laboratories. However, according to the Animal by-products Regulation microbiological analyses made in own checks by establishments approved under the Regulation shall be made in a laboratory approved by the Finnish Food Safety Authority.

### Section 9 – *Approved points of entry*

- (1) Fertiliser products and their raw materials included in the tariff heading groups 05, 12, 26, 27, 28 and 31 on which no provisions are laid down in the Chemical Act (744/1989) may be imported only via the points of entry listed in Annex III. Inspection of fertiliser products and their raw materials under the Fertiliser Product Act shall be performed at the point of entry.
- (2) By derogation from subsection 1, the import inspection of fertiliser products and their raw materials under the Fertiliser Product Act may also be performed at a point of entry other than those listed in Annex III. A written transfer permit issued by the Finnish Food Safety Authority is required for an inspection performed elsewhere than at a point of entry. In addition, the control authority may, upon request of the importer, order the fertiliser products or, where necessary, their raw materials to be transported to the customs warehouse to wait for an inspection under the Fertiliser Product Act if due to inspection techniques or other reasons the inspection cannot be performed in a sufficiently reliable manner at the point of entry.
- (3) By derogation from subsections 1 and 2, provisions on border crossings approved for the import of fertiliser products of animal origin and their raw materials are laid down in the Decree of the Ministry of Agriculture and Forestry on veterinary border inspections of foodstuffs and other products of animal origin (1370/2004) and Decree of the Ministry of Agriculture and Forestry on the conditions for import of animal by-products, derived products and other goods involving risk of spreading animal diseases from countries outside the European Union (1122/2011. Import of by-products of Category 2 in the Animal by-products

Regulation and products derived from these intended for use as fertiliser is prohibited. However, the prohibition does not apply to manure processed in accordance with the Animal by-products Regulation and processed manure products.

- (4) A fertiliser product consignment referred to in subsections 1–3 above may not be handed over to free circulation before the Finnish Food Safety Authority or an inspector authorised by it has notified the customs office at the point of entry that the consignment qualifies for import.

#### Section 10 – *Internal market trade of fertiliser products*

- (1) In internal market trade fertiliser products and their raw materials included in the tariff heading groups 05, 12, 26, 27, 28 and 31 on which no provisions are laid down in the Chemical Act (744/1989) and for which advance notification under section 21 of the Fertiliser Product Act is required may be inspected at a border crossing in Annex III or other location approved by the Finnish Food Safety Authority.
- (2) Provisions on the import and export within the internal market of by-products of animal origin which as such are finished fertiliser products or from which fertiliser products or their raw materials are manufactured are laid down in the Decree of the Ministry of Agriculture and Forestry on the animal disease requirements of certain live animals, animal by-products and certain goods on the internal market of the European Community (1002/2010). Import within the internal market of by-products of Category 2 in the Animal by-products Regulation and products derived from these intended for use as fertiliser is prohibited in accordance with section 19(2) of the Decree. However, the prohibition does not apply to manure processed in accordance with the Animal by-products Regulation and processed manure products. In addition, provisions on the inspections of products referred to in this subsection are laid down in the Decree of the Ministry of Agriculture and Forestry on inspections performed to combat animal diseases in the internal market of the European Community (977/2006).
- (3) In addition, the provisions of Regulation (EC) No 764/2008 of the European Parliament and of the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC shall be complied with in the internal market trade of fertiliser products.

#### Section 11 - *Advance notification*

- (1) An operator importing fertiliser products or their raw materials from a country outside the European Union shall give an advance notification regarding this to the Finnish Food Safety Authority. Advance notification of individual batches is not required for raw materials of fertiliser products which fall within the scope of the Chemical Act (744/1989). The notification shall be given sufficiently early for organising a possible fertiliser control inspection to establish that the fertiliser product or its raw materials qualify for import, but not less than three working days prior to the arrival of the goods at the point of entry. Information in Annex IV shall be given in the advance notification
- (3) An operator importing fertiliser products or their raw materials from another Member State of the European Union shall provide the information in Annex IV to the Finnish Food Safety Authority. The advance notification may be given as part of the obligation to notify under section 2 or separately not less than three working days prior to the arrival of the goods.
- (4) In addition, the provisions of Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste shall be complied with in the shipment of a fertiliser product or its raw material classified as waste from one country to another.
- (5) The Finnish Food Safety Authority shall notify of the decision concerning the return of fertiliser products or their raw materials in accordance with the procedure laid down in the Waste Shipment Regulation. In addition, in accordance with the Waste Shipment Regulation, the Finnish Food Safety Authority shall notify of the return to the sending state of a fertiliser

product or its raw materials prohibited under section 33 of the Fertiliser Product Act and submit the decision made by it to the Finnish Environment Institute for information.

#### Section 12 - *Control and publication of the control results*

- (1) The Finnish Food Safety Authority shall submit the control plan under section 23 of the Fertiliser Product Act to the Ministry of Agriculture and Forestry annually by the end of March. In addition to the provisions in section 23 of the Fertiliser Product Act, the control plan shall take into account the control results from the previous years and correct timing of annual inspections for the production period.
- (2) Sampling of organic and inorganic fertilisers and sending and processing of the samples shall be carried out in accordance with the EC Fertiliser Regulation, sampling of liming materials in accordance with Standard SFS-EN 1482 and sampling of soil improvers and substrates in accordance with Standard SFS-EN 12579. In the analysis of samples relating to the control of fertiliser products the analysis methods in control by the authorities specific to type designations referred to in the Decree of the Ministry of Agriculture and Forestry (24/11) and in the national type designation list of fertiliser products kept by the Finnish Food Safety Authority shall be complied with.
- (3) The Finnish Food Safety Authority shall keep a list of establishments and operators approved and registered in Finland under the Animal by-products Regulation and establishments approved nationally on its website.
- (4) The Finnish Food Safety Authority is tasked with assessing the national guides to good practice referred to in Article 30 of the Animal by-products Regulation.
- (5) The requirements for use on farms concerning wastewater sludge in points 1-3 of section 11 a(1) of the Decree of the Ministry of Agriculture and Forestry (24/11) are controlled by the Centres for Economic Development, Transport and the Environment as part of the control of the compliance with the Government Decree on the control of the requirements for good agricultural and environmental condition and statutory management requirements relating to the environment 636/2007.

#### Section 13 - *Entry into force*

- (1) This Decree enters into force on 10 May 2012.
- (2) This Decree repeals the Decree of the Ministry of Agriculture and Forestry on Activities Concerning Fertiliser Products and Their Control (13/07), with subsequent amendments.
- (3) An establishment or operator obliged to register under section 6 shall provide the notification under section 2(1) to the Finnish Food Safety Authority not later than on 1 October 2012.

## ANNEX I

## INFORMATION REQUIRED IN THE WRITTEN NOTIFICATION

The notification shall state whether it concerns the starting of, changes to or termination of the activity. On the basis of an initial notification, the operator is entered in a register of operators; on the basis of a notification of changes, the data in the register are updated, and on the basis of a notification of termination, the operator is entered in the register as having terminated the activity.

The notification shall include information on items 1-5 and, as appropriate, information on items 6-8:

- 1) name, address and business ID of the operator;
- 2) places of manufacture and permanent or established places of sales and storage and other places of business;
- 3) contact details of persons in charge at the operator's business;
- 4) a description of the nature of the activity (manufacture, import, marketing, etc.) and an estimate of the extent of the activity;
- 5) date of starting of, changes to or termination of the activity;
- 6) information on the place of manufacture, sales and storage, and contact details of contractors and sub-contractors used by the operator for manufacture, sales and storage of a fertiliser product;
- 7) a written own check plan when starting the activity; and
- 8) information on marketed fertiliser products;
  - a) type designations and trade names, information required to be included in the product label,
  - b) except for inorganic fertilisers, a description of the chemical composition of the product or the raw materials used for it, technical processing or other manufacturing method.

A description in respect of point 8 b) is not needed for imported EC fertilisers.

## ANNEX II

## INFORMATION REQUIRED FOR AN OPERATOR'S OWN CHECK PLAN

The operator's own check plan shall contain the following information:

- 1) persons in charge of the activity and a plan for induction training of personnel;
- 2) product-specific raw materials of fertiliser products to be placed on the market and their origin and type;
- 3) batch-specific confirmation of traceability;
- 4) production and operating process and its
  - a) critical control points and reference points for action
  - b) remedial action taken when the reference points for action are exceeded
  - c) information on available premises, machinery and equipment and on their
    - maintenance
    - calibration of measuring equipment
    - method and frequency of cleaning
    - pest control;
- 5) instructions for action in case of disturbances;
- 6) quality control and sampling plan regarding raw materials, production and end product;
- 7) action taken if a fertiliser product or its raw materials do not fulfil the quality requirements set for it or they are outdated; and
- 8) information on warehousing, storage and transport of fertiliser products and their raw materials.

**POINTS OF ENTRY**

Points of entry referred to in section 9(1) of this Decree are the following customs offices:

*Eckerö, Hamina-Kotka, Hanko, Helsinki, Imatra, Inkoo, Kalajoki, Karigasniemi, Kaskinen, Kemi, Kokkola, Kristiinankaupunki, Lappeenranta, Loviisa, Maarianhamina, Merikarvia, Naantali, Niirala, Nuijamaa, Oulu, Pietarsaari, Pori, Porvoo, Raahe, Raja-Jooseppi, Rauma, Tampere, Tornio, Turku, Uusikaupunki, Vaalimaa, Vaasa, Vainikkala, Vantaa and Vartius.*

However, consignments on which a veterinary border inspection is performed in Finland shall be imported to Finland via the border crossing points listed in Annex I of Decree of the Ministry of Agriculture and Forestry 1370/2004.

## INFORMATION REQUIRED IN ADVANCE NOTIFICATION

Advance notification shall contain the following information:

- 1) importer's name,
- 2) origin of the fertiliser product or its raw material to be imported,
- 3) customs heading or, for import within the internal market, type designation of the fertiliser product,
- 4) quantity,
- 5) destination, and
- 6) purpose of use of the product (fertiliser product/raw material).

Advance notification of an individual batch of a fertiliser product consignment shall be accompanied by copies of:

- 1) invoice relating to the consignment or other similar document,
- 2) official certificate showing the cadmium content of the fertiliser product and, where necessary, health certificate of by-products of animal origin or certificate of processing in an approved establishment,
- 3) other documents which may be needed in import of a fertiliser product consignment.

In the case of inorganic fertilisers a certificate of the cadmium content of the fertiliser product is required only for phosphorus fertilisers.