COUNTRY PROFILE - PART I

Norway

Competent authority control systems in the areas of food and feed safety, animal health and animal welfare



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INTRODUCTION

This country profile has been drawn up by Norway in cooperation with the EFTA Surveillance Authority ('the Authority') to present in a summary form the latest information available on Norwegian control systems relating to food and feed safety, animal health and animal welfare. Plant health is not part of the country profile as it does not fall under the Agreement on the European Economic Area ('the EEA Agreement', 'the Agreement').

The information in the country profile has been compiled from:

- recent written submissions and background documentation provided by the Norwegian authorities, detailing how control systems are organised;
- the results of the EFTA Surveillance Authority's missions to Norway in recent years and, in particular, a general review mission in November 2016.

This country profile (Part 1) is presented in two main chapters:

<u>Chapter 1</u> describes the overall organisation of the Norwegian authorities and the respective responsibilities of the ministries and government agencies in relation to the different components of the control system.

<u>Chapter 2</u> provides a more detailed description of the different control systems that form the complete set of official controls in Norway, covering the whole chain of animal, feed and food production.

This country profile is to be updated at regular intervals pursuant to the EFTA Surveillance Authority's missions or additional relevant information being submitted by the Norwegian competent authorities.

Part 2 of the country profile will cover the current status of progress in implementation of corrective actions to recommendations issued by the EFTA Surveillance Authority

Acronyms are used extensively throughout this report for the sake of brevity. A list of acronyms, abbreviations and special terms is provided in Annex I.



1 COMPETENT AUTHORITIES AND IMPLEMENTATION OF REQUIREMENTS

1.1. Competent authorities

Ministries

The Ministry of Agriculture and Food, the Ministry of Trade, Industry and Fisheries, and the Ministry of Health and Care Services share responsibility for developing policy and legislation on food and feed safety, animal health and animal welfare in Norway.

Table 1. Division of	of res	nonsihility	in	relation t	o control	systems	and a	operational levels
	1100	ponsionny	in	i cianon i	o control	systems	unu	operational tevels.

Sector	Policy co-ordination	Coordination and implementation of controls	Risk assessment and scientific advice and laboratories
1. Animal health (including aquatic animal health)	Ministry of Agriculture and Food Ministry of Trade, Industry and Fisheries	NFSA	Norwegian Scientific Committee on Food Safety (VKM) Norwegian Veterinary Institute (VI) Norwegian Institute of Nutrition and Seafood Research (NIFES) Institute of Marine Research (IMR) Norwegian University of Life Sciences (NMBU) Labora AS Pharmac Analytic AS
2. Food of animal origin	Ministry of Agriculture and Food Ministry of Trade, Industry and Fisheries Ministry of Health and Care Services	NFSA	VKM Norwegian Institute of Public Health (NIPH) VI NIFES NMBU
3. Imports of animals and food of animal origin	Ministry of Agriculture and Food Ministry of Trade, Industry and Fisheries	NFSA	VI NIFES NMBU
4. Feeding stuffs	Ministry of Agriculture and Food	NFSA	VKM

			VI
	Ministry of Trade, Industry and Fisheries		NIFES
			Norwegian Institute of Bioeconomy Research (NIBIO)
			Acontrol Laboratories
5. TSE/Animal by- products(ABP)	Ministry of Agriculture and Food	NFSA	VI
F	Ministry of Trade,		NIFES
	Industry and Fisheries		ALcontrol Laboratories
			VKM
6. Veterinary medicines - authorisation,	Ministry of Agriculture and Food	NFSA	VKM
marketing and distribution	Ministry of Trade,		VI
Veterinary medicines residues	Industry and Fisheries		NIFES
	Ministry of Health and Care Services		LGC's Teddington laboratory, UK
7. Foodstuffs and food	Ministry of Agriculture	NFSA	VKM
hygiene,	and Food		NIPH
	Ministry of Trade, Industry and Fisheries		VI
	Ministry of Health and Care Services		NIFES
			NIBIO
			For food contact materials: the food department at the Danish Technical University (DTU)
8. Imports of food of plant origin	Ministry of Agriculture and Food	NFSA	
	Ministry of Health and Care Services		
9. Plant protection products –	Ministry of Agriculture and Food	NFSA	NIBIO
authorisation, marketing and use. Plant protection			Kimen Seed Laboratory VKM
products – residues 10. Plant health	Ministry of Agriculture	NFSA	NIBIO
	and Food		VKM
		•	·

The Ministry of Agriculture and Food

The Ministry is responsible for food and agricultural policymaking. The food policy of the Ministry aims to provide consumers with wholesome, high quality food products, and to ensure that the food production process is carried out with environmental, public health and animal welfare concerns in mind. The Ministry is responsible for terrestrial primary production.

In addition, the Ministry is administratively responsible for the Norwegian Food Safety Authority (NFSA), which is the central competent authority in Norway for food and feed safety, animal health and welfare.

The responsibility for shaping food policy and for the management of foodstuffs from production to delivery to the consumer is shared between the Ministry of Agriculture and Food, the Ministry of Trade, Industry and Fisheries and the Ministry of Health and Care Services.

The Ministry of Health and Care Services

The Ministry is responsible for policymaking on drinking water and foodstuffs. The production and marketing of safe and wholesome food is an essential principle in this regard, as is the avoidance of misleading practices and ensuring of honest information to consumers.

The Ministry of Trade, Industry and Fisheries

The Ministry designates and creates a framework for administers policy regarding Norwegian business activities as well as other industrial and seafood policy instruments and policy for the shipping industry. The Ministry promotes trade, research, innovation and entrepreneurial spirit. In addition the Ministry aids in coordinating the efforts of the various ministries in order to ensure a sound, unified, future-oriented industrial and seafood policy.

The Norwegian Food Safety Authority (NFSA)

The NFSA is the designated competent authority for food and feed safety, animal health and animal welfare. Operating nationwide under the auspice of the above mentioned ministries, its aim is to ensure safe food and drinking water, as well as promotion of good health and welfare for animals, fish and plants.

The NFSA's organisation

The NFSA is organised into two administrative levels, the head office and the regions. The head office carries out directorate and governance tasks. The regional level consists of five regions, each divided into local departments (with 70 office locations altogether). The regional level normally carries out official control activities and makes initial decisions. Appeal cases are considered by the head office. **Picture 1.** *NFSA organisation chart*





The head office issues guidelines for how official control is to be exercised. These guidelines are communicated through the quality system (QS) and the NFSA's food safety supervision system MATS. Interregional expert forums support and promote professional coordination between the regions. The NFSA appoints an Animal Protection Committee, which contributes to animal welfare issues. The police, Norwegian Customs, the Norwegian Coast Guard and the municipalities are obliged to assist the NFSA on request in connection with official controls.

Delegation of authority to control bodies

The NFSA carries out most of the official control activities itself, but it has delegated authority to the following organisations in specific areas:

Debio (Organic Certification Organisation)

Debio is a member-based organisation whose objective is to ensure and promote organic and sustainable production, sales and consumption. Membership is open to all national organisations that have a positive attitude to the development of organic production. The organisation's members fall into three categories:

- organisations related to primary production
- organisations related to processing, import and sales
- organisations related to environmental protection, animal welfare and consumption.

Establishments subject to certification by Debio cannot be members. All membership categories are equally represented on Debio's board of directors and at its annual general meeting.

Debio has been delegated authority to carry out official control and make individual decisions about the production and sale of organic products pursuant to the Regulations of 14 October 2010 No 1103 relating to organic production and labelling of organic agricultural products and foodstuffs, and the Regulations of 7 July 2015 No 879 relating to organic aquaculture production and labelling of organic aquaculture products.

County governors and municipalities

EFTA SURVEILLANCE

As public administrative bodies, the county governors and municipalities have been delegated authority to hold examinations and issue certificates of authorisation for the use of pesticides pursuant to Section 8 of the Regulation (NO) of 6 May 2015 No 455 relating to pesticides. The municipalities have been delegated the authority to make decisions about permits for spraying pesticides from aircraft pursuant to Section 17 of the same regulation.

County governors and municipalities have been authorised to carry out official control tasks relating to wild oats pursuant to Section 2 of the Regulation of 25 March 1988 No 251 relating to wild oats.

Knowledge support

Norwegian Scientific Committee for Food Safety (VKM)

The Norwegian Scientific Committee for Food Safety (VKM), which is part of the Norwegian Institute of Public Health, carries out independent risk assessments for the NFSA across the Authority's field of responsibility, as well as environmental risk assessments of genetically modified organisms, alien organisms, micro-organisms and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) for the Norwegian Environment Agency (Miljødirektoratet).

Knowledge support institutions

The following public institutions provide independent knowledge support to the NFSA:

- Norwegian Veterinary Institute (VI) (animal health and welfare, fish health and food safety)
- Norwegian Institute of Public Health (NIPH) (food safety and epidemiology)
- National Institute of Nutrition and Seafood Research (NIFES) (food safety and nutrition)
- Norwegian Institute of Bio-economy Research (NIBIO) (plant health)
- Norwegian Institute of Marine Research (IMR) (fish health and fish welfare)
- Kimen, Seed Laboratory (seeds)
- ALcontrol (feed for terrestrial animals)

These knowledge institutions usually perform the functions of national reference laboratories (NRL).

Official laboratories are selected by the NFSA based on a tender and assessment procedure. Accreditation according to EN ISO 17025 is a prerequisite for participation in competitive tenders. The laboratories have a two-year contract with the NFSA. This agreement can be renewed once, after which there is a new competitive tender procedure.

Research-ba	sed advisory institutions	Website
VI	The Norwegian Veterinary Institute	www.vetinst.no
Bioforsk	The Norwegian Institute for Agricultural and Environmental Research	www.bioforsk
NIFES	The National Institute of Nutrition and	www.nifes.no

Table 2. List of designated laboratories involved in controls on food, feed and animal health

	Seafood Research			
NIPH	The Norwegian Institute of Public Health	www.fhi.no		
IMR	The Norwegian Institute of Marine Research	www.imr.no		
NMBU	The Norwegian School of Veterinary Science	www.nmbu.no		
Kimen	Kimen Seed Laboratory	www.kimen.no		
Hormon- laboratoriet	The Norwegian Doping Control Laboratory, Oslo University Hospital	www.oslo- universitetssykehus.no		
DTU	The Technical University of Denmark, National Food Institute	http://www.food.dtu.dk		
Official labo	ratories	Website		
Eurofins		www.eurofins.com		
AL control				
SenjaLab		www.senjalab.no		
Analysesente	eret	www.trondheim.kommune.no		
Mat og Miljø	laboratoriet	www.welcon.no		
VestfoldLab		www.vestfoldlab.no		
vestioluLab				
ØMM-Lab		www.ommlab.no		

National accreditation bodies

Norwegian Accreditation is the only Norwegian body for accreditation of laboratories. All the laboratories designated by NFSA are assessed and accredited in accordance with the Standard EN ISO 17025 by Norwegian Accreditation.

Norwegian Accreditation is the Norwegian signatory to the EA multilateral agreements on accreditation (MLA). Through this MLA, Norwegian Accreditation is also a signatory to the ILAC and IAF agreements.

The NFSA seeks external advice in certain areas:

- The Council for Animal Ethics can, on its own initiative or on assignment for the NFSA or the Ministry, submit opinions on ethical issues relating to animal husbandry and the use of animals.
- The Legal Advisory Council for Veterinary Medicine is, among other things, tasked with advising the veterinary authorities in disciplinary cases involving animal health personnel, cases concerning proper practice, cases relating to veterinary medicine and animal protection issues.
- The NFSA has appointed nine experts on different issues relating to experimental animals. These experts advise the NFSA in connection with our experimental animal administration.

1.2. Resources for the performance of controls

Legal basis for controls

The Food Act and the Animal Welfare Act give the NFSA's authority and decision-making powers in all matters that fall under Regulation (No) 1621of 22 December, which incorporates Regulation (EC) No 882/2004. In addition, the Act relating to Cosmetic Products and Body Care Products, the Animal Breeder Act and the Plant Breeder Act give the NFSA further authority and decision-making powers. The Public Administration Act and Freedom of Information Act constitute an important framework for the NFSA's exercise of authority.

Pursuant to Section 13 of the Food Act, the competent authority and its staff have full access to the premises and documentation of food business operators. The Food Act also requires the operators to undergo inspections and assist the competent authority in the process.

Overview of staff resources

The total number of full-time equivalents (FTEs) in the NFSA involved in controlling food and feed safety, animal and plant health and animal welfare in the relevant control bodies is 703.3 (at the end of 2015).

Staff qualification and training

Competence development in the NFSA is managed on the basis of a multi-annual functional strategy that identifies critical areas for development. Vital components of competence development are:

- Statutory training
- The NFSA's School of Supervision
- Vocational training
- 'Better Training for Safer Food'

Statutory training is required for border veterinarians and veterinarians involved in abattoir inspections, among others.

The NFSA's School of Supervision was established in order to ensure that supervisory personnel have a common platform for official controls. The School of Supervision consists of foundation courses in administrative law, control methodology and communication during inspections.

Subject-related vocational training is developed continuously based on the critical areas for development specified in the functional strategy.

A multi-annual training calendar has been elaborated on the basis of the functional strategy and ongoing competence development measures. Its purpose is to assist managers and employees to draw up multi-annual plans for competence building. All managers are responsible for having a general overview and for planning the necessary competence over time.

Better Training for Safer Food (BTSF), a European Commission (EC) initiative, is an important tool for calibrating official control activities. NFSA employees participate regularly in BTSF training sessions. These members of staff constitute a competence pool for, among other things, ensuring uniformity. They are available to the rest of the organisation when required.

All common course activities are documented in the digital learning platform ('Ransel').

1.3. Organisation and implementation of official controls

Official controls are carried out by the regional offices in accordance with delegation decisions adopted by NFSA head office.

The long-term plan for official control describes the activities of the NFSA plan for the following five years. These activities are described at a national level. At regional levels they may be described in more detail and include other priorities based on a risk evaluation. The long-term plan includes obligatory control activities for the NFSA. The plan is updated annually and forms the foundation for the discussion of the upcoming year's priorities for official control.

The annual budget disposal letter (BDL) to the regional level is based on the long-term plan for official control, other main priorities and a regional risk evaluation. It contains the annual budget, ongoing tasks, special assignments and prioritisations. Feedback from the regional offices during the year is given in the interim reports. Based on the annual budget disposal letter, the operational plans for appurtenant activities incorporate effectiveness targets and a risk-based approach that reflects where unacceptable conditions might arise, with the resulting consequences. When circumstances change, (e.g. a health situation or other occurrence), the annual budget disposal letter to the regions may be updated. Such updates generally occur twice a year (in June and in October); however the head office may update the annual budget disposal letter whenever it is considered necessary.

The objective of the annual budget disposal letters and the long-term plan for official control, as well as of the other tools mentioned above, is to control or supervise all segments of the food sector within a set period, covering all stages of production, processing and distribution.

Risk-based prioritisation of official controls

Risk-based planning

The individual departments in the regions plan their supervisory activities on the basis of a twofold risk philosophy: Firstly, the inherent risk that the industry represents. Secondly, the concrete risk that the individual establishment represents based on any history of non-compliance and ability/willingness to comply with regulations.

The NFSA operates on the basis of a combination of a block budgetary allocation, goal and performance management. Each entity is assigned a block allocation and goals for what it should



achieve. In addition, certain requirements are set for what is to be done. It is then up to the entity to manage the available resources in such a way that it fulfils the requirements and achieves its goals.

The management and prioritisations are based on an annual assessment of the status of the NFSA's social mission, the general risk map, development trends, the results of monitoring and other supervisory activities, and other factors that could have a bearing on the NFSA's social mission. The annual management activities are based on a three-year perspective and are governed by the internal budget allocation letter. The organisation is followed up every four months with respect to compliance with management signals. The head office then adjusts and/or specifies its management signals in a supplementary BDL.

Monitoring

Animal and fish diseases and certain threats to food safety are monitored. The basis for monitoring can be obligations to or recommendations from the European Union (EU) and/or our own risk assessments. Plant pests are monitored on the basis of our own risk assessments.

The monitoring programmes are carried out in accordance with instructions issued by the head office on the basis of advice from the knowledge support institutions.

Smiley inspections are not risk-based. Establishments in the food and beverage service industry that fall under this scheme must be inspected every eight months regardless of risk. In addition, they can request a new inspection after rectification of non-conformities that have resulted in a poor score.

Organisation of control

The regions are responsible for all activities governed by the Food Act, the Animal Welfare Act, the Act relating to Animal Health Personnel and the Act relating to Cosmetic Products and Body Care Products, etc.

Below, different ways of organising supervisory activities are described:

Control projects

Control projects can be organised as Nordic, national or regional projects. National control projects must comply with the applicable guidelines. The control projects provide:

- an overview of the current status in an area
- the possibility of standardising sanctions
- the possibility of attracting media attention, which could increase their impact
- opportunities for dialogue with the industry before and after the project

In addition, control projects provide for calibration of control activities and raise competence in relation to control projects.

Coordinated control/campaigns

Campaigns are a less formal way of coordinating control activities between several units and have many of the same advantages as control projects.

Control activities relating to chains

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In this type of controls, a group of companies, a chain or other type of organisation is targeted by implementing control activities in relation to the head office and other facilities/establishments around Norway. Supervisory activities relating to chains often take the form of audits, particularly of the head office.

Supervisory activities relating to chains ensure:

- help from the chain management to ensure compliance
- uniform control of all chain's activities
- competence development in the area within which the chain operates
- a more professional relationship with big chains

Control methodology

The NFSA has different control methods at its disposal to assess whether operators are in breach of any regulations. Most of these methods involve an inspector observing and communicating with the people in charge of the site where the activity takes place. Other control methods are also in place, including as documentary check and sampling.

Inspection

Inspections take place in the establishments, and they are the most common way of acquiring a factual basis for determining whether an establishment is complying with regulations or whether a consignment of goods is in accordance with regulations. The inspector observes the premises and equipment, and, if relevant, inspects the consignment of goods and pertaining documentation, talks to the staff and checks whether what is said corresponds to what is observed.

As a rule, all inspections are unannounced. In cases where it is needed to ensure that responsible personnel are present at the inspection site, notification is given shortly before the inspection. For the planning of an audit, the establishment is notified longer in advance.

Audits

Audits are in principle more extensive than inspections, and they primarily control an establishment's systems – whether they meet the regulatory requirements and whether they function in practice.

Document control

Documents and registers can also be sources of information about practices in establishments subject to supervision. Document control can be carried out without inspectors visiting the establishment, for example by documents being sent to the NFSA or by reviewing registers etc. that are accessible via the internet.

Sampling

Inspectors may collect samples in connection with inspections, audits and document control. The NFSA has agreements with laboratories that perform analyses of samples of food, water and feed.

Table 4. List of official laboratories used by the regions

Laboratory Northern Central	Southern and Western	Eastern	Greater Oslo
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Alcontrol		Х		X	Х
Analysesentert/PreBIO		Х			
Eurofins	Х	X	X	X	Х
Mat- og Miljølaboratoriet			X		
Senjalab	Х				
Vestfoldlab				X	
ØMM-lab					Х

Case processing tool and guidelines

MATS is the NFSA's case processing and decision support tool. All establishments subject to official controls by the NFSA are registered in MATS with all their activities subject to controls. Official control activities are planned, implemented and followed up using MATS. We retrieve data about completed supervisory activities from MATS.

The guidelines for supervisory activities are set out in the quality system and can also be accessed via MATS.

Smiley inspections are planned, carried out, handled and followed up with the support of a specific case handling system developed for this purpose, MARTA. Registered control data are communicated between MARTA and MATS.

1.4. Enforcement measures

Measures in cases of non-compliance

The NFSA's procedures and legal powers in connection with infringement are described in *Virkemiddelbruk ved tilsyn* (administrative rules concerning infringement procedures), 3rd Edition amended 28 October 2014.

In the event of non-compliance, the NFSA has under the Food Act the legal authority to make the necessary administrative decisions to ensure compliance.. This includes prohibiting imports, exports and marketing, and ordering withdrawal from the market, isolation, euthanasia, destruction, rejection, restrictions, labelling or special treatment. Furthermore, orders may be issued requiring the implementation of special cleansing and disinfection procedures or the closure of premises. The NFSA also has the authority to impose coercive fines until compliance is achieved.

The Animal Welfare Act also includes a number of specific measures that are mentioned in section 2.11 of this document.

Enforcement is based on the principle of proportionality and shall be effective and dissuasive. Based on this the sanctions used should be effective and necessary to ensure compliance.

Pursuant to the Norwegian Public Administration Act, administrative decisions may be appealed to the next administrative level. In the NFSA, authority to make decisions is delegated to the regional level. Appeals are considered by the NFSA's head office.

Any person who, intentionally or through negligence, violates certain provisions of the Food Act or decisions made by the NFSA is liable to fines or imprisonment.



Sanctions, as described in Article 55 of Regulation (EC) No 882/2004, may be imposed by a national court. There are no limits set out in law regarding the amount of fines. Serious infringements may be reported to the police and eventually brought before the courts for prosecution under criminal law.

1.5. Verification and review of official control

Internal control activities

NFSA internal control activities consist of:

- First-line control (the day-to-day system that aims to ensure that work is done correctly)
- Second-line control (a more detailed investigation carried out by a line manager or the person responsible for a process to see whether work in a certain area is carried out as decided)
- Third-line control (internal audits)

The NFSA is developing the system for verification of the effectiveness of official control activities. The analysis method has been completed and needs to be tested. The management system and procedure for verification of official control activities has not yet been completed.

First-line control

First-line control is the individual manager's system for ensuring that his/her units tasks are carried out as decided. For instance, all managers are obliged to check every inspection report that the unit prepares to send to establishments.

Second-line control

Internal control is exercised by NFSA staff at various levels to ensure that:

- the NFSA's operations are targeted and efficient
- the NFSA's reports to superior authorities are reliable
- the NFSA complies with laws and regulations

Some second-line control activities are mentioned below.

Management dialogue (the management's review)

The Director General of the NFSA engages in dialogue with the directors of the regions and at the head office every year to follow up the units operations and deliveries. The topics are evaluation and follow-up of the past year and what bearing the evaluation will have on future plans. Topics can also include whether the governing documents are expedient and sufficient in relation to achieving the NFSA's goals, whether they are complied with and how nonconformities are dealt with. The basis for the management dialogue includes reporting, nonconformities identified in internal audits, ESA inspections, investigations by the Office of the Auditor General of Norway, the improvement portal, user surveys and evaluations.

Four-monthly reports



The departments of the regions report to the head office every four months on what they have done and what they have achieved in relation to the budget allocation letter. Scorecards are used as the reporting tool. The reports are followed up by supplementary internal budget allocation letters.

Production dialogue

Every second month, the head office has a dialogue with each region on how they are working to meet their target for the number of required control activities. The regional director follows the same procedure with the heads of department in the region.

Internal reviews

Within a limited discipline area, the head office can check that control activities are carried out in accordance with the applicable guidelines. This is often done in preparation for ESA audits.

Other reviews

Interregional expert forums review reports from national and regional control projects assess how uniform the control system is, and whether the guidelines are complied with. These reviews result in proposals for improvements in the improvement portal.

Third-line control – internal audits

Internal audits are conducted on behalf of the Director General of the NFSA, and the results are reported to him. Internal audits are conducted by teams of specialists, consisting of employees of the NFSA. All audits are carried out in accordance with documented procedures set out in the NFSA's quality management system. In addition to these central internal audits, the regional offices and head office can conduct local audits. Local audits can also be performed as part of the quality system process.

There is a three-year plan for internal audits that ensures that all areas are audited over time. The plan is regularly updated. It is prepared on the basis of previous audits, ESA inspections and national control projects. The plan shall cover all disciplines during the course of a five-year period. The choice of topic for each audit is also based on an assessment of the risk to society and the risk relating to the NFSA's activity.

Auditing of Debio

The NFSA audits Debio once a year to check whether it exercises its authority in an objective and efficient manner and meets the requirements of the Public Administration Act and the Freedom of Information Act.

The NFSA also has an observer role in Norwegian Accreditation's audits of Debio.

1.6. Multi-annual national control plan (MANCP) and annual reports

The MANCP is intended to ensure effective control of food safety and quality over the entire food chain, as well as the health and welfare of animals and fish, plant health and cosmetics safety.

The MANCP implements Regulation of 22 December 2008 No 1621 implementing Regulation (EC) No 882/2004 on official controls performed to ensure verification of compliance with feed



and food legislation, and animal health and animal welfare rules. The MANCP applies to all supervisory activities and other measures that the NFSA carries out in order to ensure regulatory compliance in its administrative area, including control activities and other activities not covered by the Regulation (EC) No 882/2004. It does not apply to control activities that the NFSA carries out on behalf of other agencies.

The MANCP is reviewed and updated in June every year, based on the result of changes to the regulations, an assessment of the previous year's activities and the status of the NFSA's responsibilities.

2 ORGANISATION OF CONTROL SYSTEMS

2.1. Control system for animal health

Terrestrial animals

The Animal Health section at the NFSA's head office is responsible for contingency plans, monitoring and preventive measures against animal diseases. The section seeks to eradicate endemic disease, control the transmission of infectious agents and improve the general health of terrestrial animals. Inspections are carried out by the local departments of the regions.

Holding registration, animal identification and movement controls

The domestic animal database 'Husdyrregisteret' contains a register of all bovine, ovine, caprine, porcine and poultry holdings. The database is part of MATS.

Livestock keepers are also responsible for recording identified diseases, medical treatments and preventive measures. When livestock is transported, a copy of their health cards must accompany them. Livestock keepers are responsible for keeping records of all animals in their herd in a herd book. The herd book and health card records must be retained for at least 10 years, even if production stops. If requested by the NFSA, keepers must provide information about the origin and destination of all animals in their ownership, animals produced and sold as live animals, and slaughtered animals.

Cattle:

Everyone keeping cattle is obliged to report births, deaths and movements of animals to the NFSA ('Husdyrregisteret'), which then records the origin, identity, movement and disposal of all cattle, using input from cattle birth and movement data, livestock markets, slaughterhouses and export points for live animals.

Updating and reporting to the 'Husdyrregisteret' database is done by direct input online from various stakeholders, such as animal keepers, slaughterhouses, 'Storfekjøttkontrollen' (a beef cattle control system administered by Animalia, the Norwegian Meat and Poultry Research Centre), 'Kukontrollen' (a dairy cattle control system administered by TINE SA, Norway's largest producer, distributor and exporter of dairy products), ear tag producers and NFSA personnel.

The maximum time limit for reporting deaths or movements is seven days after the event has occurred. The maximum time limit for reporting births is seven days after the animal has been identified (ear tagged).

A holding number is allocated to each holding.

The system for the identification and registration of cattle comprises the following elements:

- ear tagging;
- on-farm register;
- 'Husdyrregisteret';
- animal passports for animals to be exported to EEA countries.

All cattle must be tagged at birth with a unique identification number issued by the NFSA.

Sheep and goats:

Sheep and goat farmers are required to tag all animals born on their holdings, either before they are moved off the holding or within 30 days after birth. Farmers are required to keep a holding register to record the details of the animals on the farm and the details of all movements to and from the farm.

For each holding, the register contains:

- the identification code of the holding
- the postal address and geographical location of the holding
- the name, address and occupation of the animal keeper
- the species of animals (sheep/goat),
- the type of production, and
- the result of the inventory of animals and total number of sheep and goats as of 1 January each calendar year.

Pigs:

The main rule is that pigs must be identified on their holding of birth as soon as possible and in any case before they leave the holding of birth. The animals must be identified either with an ear tag or a readable tattoo showing the identification code of the holding of birth. The ear tag or tattoo may also show an individual number. Pigs moved from the holding of birth directly to the slaughterhouse may alternatively be identified with a tattoo ('slap mark') showing the keeper's supplier number at the slaughterhouse.

As an exception from the main rule, unidentified piglets may, on certain conditions, be moved from the holding of birth to another holding in Norway for fattening. However, the animals must be identified before they are moved from the fattening holding to a Norwegian slaughterhouse. The animals may not be exported to other EEA countries.

Every animal keeper must keep an updated holding register. The register must contain information about the identification code of the holding, the number of weaned pigs on the holding and any cases of pigs being identified with another identification code than the code they were assigned on the holding of origin. The holding register must also contain information about the movements of pigs to and from the holding, unless the movements are immediately registered with the NFSA (in 'Husdyrregisteret'). All movements of pigs between holdings must be registered with the NFSA (in 'Husdyrregisteret') within seven days of the movement taking place.

Poultry:

Establishments that keep hens, turkeys or ratites must be registered, including the name and address of the operations manager, the address of the holding, type of holding and capacity of the establishment. Recent additions to the register include information required by Directive 2002/4/EC, Annex 1, and definitions referred to under point 2.1 of the Annex. Changes in information about the establishment must be reported to the NFSA.

Farmed deer and South American camelids:

South American camelids (lama, alpaca, guanaco and vicuna) born in Norway shall be marked with a yellow ear tag before they are 14 days old, or before they are moved from the holding where they were born. The animals are considered to be moved from the holding when they are let out to graze.

Farmed deer (deer and fallow deer) born in Norway shall be marked with a yellow ear tag at the first gathering after birth, but before they are moved from the holding where they are born.

Ear tags shall be designed in such a way that they cannot be reused after removal. The information on the tags must be pre-marked with black lettering that cannot be changed. Farmers are required to keep a holding register to record the details of the animals on the farm and the details of all movements into and off the farm.

Reindeer

All domesticated reindeer shall be marked with a registered mark no later than 31 October in the year they are born. The registered mark is made by cutting the ears. Ear tags made of metal or plastic are used temporarily when buying and selling animals. The marking of reindeer and registration of reindeer marks is regulated by the Reindeer Husbandry Act Chapter 5.

Control of the identification and registration of animals

Checks concerning the requirements for the identification and registration of animals are included in the NFSA's inspection tasks. As regards bovine, ovine and caprine animals, the NFSA must perform checks in accordance with the minimum requirements laid down in Norwegian legislation implementing Regulation (EC) No 1082/2003 and Regulation (EC) No 1505/2006.

Animal health controls – terrestrial animals

Biosecurity measures and movement control

Norwegian animal health legislation contains minimum requirements for biosecurity measures on farms and in connection with the movement of animals. The NFSA supervises that the rules are followed and the local departments of the NFSA do on-the-spot checks and follow up reports about illegal movement of animals.

The rules for controlling live animals imported to Norway are laid down in the Regulations of 31 December 1998 No 1484. Animals can enter Norway from other EEA States in accordance with EEA legislation. Entry of animals in Norway from third countries is also permitted pursuant to EEA legislation. Norway has two border inspection posts for live animals, one at Gardermoen Oslo airport and one at Storskog (in the county of Finnmark, near the Russian border).

Norway has national surveillance programmes for the following diseases:

- paratuberculosis in cattle, lama and alpaca;
- BVD/MD in cattle;
- tuberculosis in farmed deer;
- scrapie in sheep and goat;



- maedi in sheep;
- PRRS, Swine Influenza and TGE in swine;
- ILT in poultry, turkey, partridges, pheasants, guinea hens and quail;
- ART in turkey, pheasants, ostriches and guinea hens.

Animals from herds or flocks not included in the national surveillance programmes may not be moved to herds or flocks that are included in the programmes until their health status has been examined and found satisfactory. As a consequence, imported animals must normally be kept isolated in approved isolation facilities for the first weeks or months after arrival, even though quarantine is not required. The period of time the animals are isolated differs between species and depends on the nature of the disease in question. During the period of isolation, the animals are tested for several diseases. The NFSA is responsible for approval of the isolation facilities and testing during the isolation period.

Passive and active surveillance

Passive and active surveillance systems for animal diseases are an important part of animal health controls. The NFSA will take action if a disease listed on either List A or List B is notified (see the table below). The response depends on the disease in question. The topic is described more thoroughly under the heading 'Animal disease: combating/eradication'. The passive surveillance system is based on a notification and reporting system.

Lis	st A	Lis	st B	Lis	st C
	African horse sickness		Echinococcosis/hydatidosis		Equine coital exanthema
	(AHS)		Leptospirosis		Equine influenza
	African swine fever (ASF)		Transmissible spongiform		Contagious equine metritis
	Avian influenza (AI)		encephalopathy (TSE), including		(CEM)
	Bluetongue		Chronic wasting disease (CWD)		Equine rhinopneumonitis
	Brucellosis		Paratuberculosis, Johne's disease		Equine viral arteritis (EVA)
	Ebola hemorrhagic fever		Salmonellosis		Bovine cysticercosis
	and Marburg hemorrhagic		Trichinellosis		Winter dysentery in cattle
	fever		Tuberculosis		Caseous lymphadenitis in
	Epizootic hemorrhagic		Equine infectious anemia (EIA)		sheep and goats
	disease of deer (EHD)		Strangles		Contagious ecthyma (orf)
	Avian infectious		Equine encephalomyelitis		Infectious keratoconjunctivitis
	laryngotracheitis (ILT)		Bovine genital		Porcine circovirus diseases
	Classical swine fever		campylobacteriosis		(PCVD)
	(CSF)		Bovine spongiform		Porcine cysticercosis
	Rinderpest		encephalopathy		Benign enzootic paresis
	Lumpy skin disease (LSD)		Tritrichomoniasis		(Talfan disease)
	Anthrax		Bovine viral diarrhoea (BVD)		Swine dysentery
	Foot and mouth disease		Enzootic bovine leukosis (EBL)		Proliferative enteropathy
	(FMD)		Infectious bovine rhinotracheitis		Avian encephalomyelitis
	Newcastle disease (ND)		Infectious pustular vulvovaginitis		(AE)
	Dourine		(IBR/IPV)		Chicken infectious anemia
	Contagious bovine		Ringworm		(CIA)
	pleuropneumonia (CBPP)		Caprine arthritis-encephalitis		Infectious bursal disease
	Teschovirus		(CAE)		(IBD) Gumboro disease
	encephalomyelitis		Border disease (BD)		Mycoplasma infections
	Aujeszky's disease (AD)		Enzootic abortion of ewes (ovine		Marek's disease (MD)

Table 3 List of diseases (2016) that must be either immediately notified to the competent authority (A and B list) or reported (C list) within a week if suspected or diagnosed.

EFTA SURVEILLANCE
AUTHORITY

	Rabies		chlamydiosis)	Nosemosis of honey bees
	Rift Valley Fever (RVF)		Infectious foot rot	Varroosis of honey bees
	Sheep and goat pox		Contagious agalactia	Acarapiosis of honey bees
	Scabies psoroptica ovium		Ovine pulmonary	Chlamydia infections
	(sheep scab)		adenocarsinoma	Clostridial infections
	Transmissible		Maedi-visna virus infection	Cow pox
	gastroenteritis of swine		Scrapie	Swine pox
	(TGE)		Contagious caprine	Fox encephalitis/hepatitis
	Swine vesicular disease		pleuropneumonia (CCPP)	contagiosa canis (HCC)
	(SVD)		Porcine respiratory coronavirus	Listeriosis
	Peste des petits ruminants		infection	Louping ill
	(PPR)		Swine influenza	Contagious respiratory
	Glanders		Clostridium perfringens type C	diseases bovine and swine
	Vesicular stomatitis (VS)		infection	(Nysesyke)
			Porcine epidemic diarrhoea	Malignant catarrhal fever
			(PED)	(MCF)
			Porcine respiratory and	Parafilariosis
			reproductive syndrome (PRRS)	Pasteurellosis
			Avian rhinotracheitis (ART)	Babesiose
			Turkey rhinotracheitis (TRT)	Q-fever
			Egg drop syndrome (EDS-76)	Ringworm
			Fowl cholera	Tick-borne fever
			Avian infectious bronchitis (IB)	Toxoplasmosis
			Avian mycoplasmosis	Tuberculosis
			Avian paramyxovirus infection	Tularemia
		_	(except Newcastle disease)	
			Avian tuberculosis	
			Duck virus enteritis (DVE)	
			Duck virus hepatitis (DVH)	
			Small Hive Beetle	
			American foulbrood of honey	
1			bees Stonebrood	
1			Tropilaelapsinfestation of honey bees	
1			European foulbrood	
1			Monkey pox	
1			European brown hare syndrome	
1		_	Leishmaniosis	
1			Myxomatosis	
1			Ringworm	
1			Sarcopic mange in foxes	
1			Distemper	
1			Rabbit hemorrhagic disease	
			(RHD)	
1			Parvovirus enteritis	

The animal disease reporting procedures

National reporting procedures

Pursuant to the Norwegian Food Act, any one who suspects an animal disease that may have considerable social and economic consequences shall immediately notify the NFSA.

Veterinarians and laboratories are obliged to report terrestrial animal diseases under (NO) Regulation 19 December 2014 No 1841 concerning warning and notification of diseases in

animals. The regulation require veterinarians and laboratories to immediately notify the NFSA if A and B diseases are suspected. Reporting procedures between the two administrative levels of the NFSA are described in contingency plans/instructions for A and B diseases for terrestrial animals and List 1 and 2 diseases for aquatic animals. If an A or B disease is suspected, the region must notify the head office and internally within the region. The region is required to notify local and regional organisations. The regions are responsible for updating the national animal disease database. The head office shall notify central organisations and inform the public. The head office must also consider whether to report to the Office International des Epizooties (OIE), ESA and the European Commission, but this is not required if it is only a preliminary finding.

If an A or B disease is confirmed, the region shall notify the head office, internally within the region, and local and regional organisations. The region is responsible for updating the national animal disease database. The head office shall notify the OIE, ESA and European Commission within 24 hours of the outbreak being confirmed.

The regions in the NFSA are responsible for the controls and for reporting at slaughterhouses.

The National Veterinary Institute (VI) immediately reports laboratory findings that indicate occurrences of A and B diseases and rare agents not previously detected in Norway to the NFSA. Negative test results on samples taken if A or B diseases are suspected are reported in the same way.

International reporting procedures

Pursuant to international agreements, Norway is obliged to report outbreaks of various animal diseases to the other EEA States. Reporting pursuant to these agreements is the responsibility of the NFSA's head office.

Under the EEA Agreement, Norway is obliged to report primary outbreaks of the diseases listed in Council Directive 92/894/EEC to the EFTA Surveillance Authority and the European Commission, within 24 hours of the outbreak being confirmed. Secondary outbreaks must be reported at weekly intervals. The lifting of restrictions must also be reported. Reporting is done in the Animal Diseases Notification System (ADNS) or by e-mail in accordance with Council Directive 82/894/EEC.

As member of the OIE, Norway also reports outbreaks of animal diseases to the OIE in accordance with the requirements laid down in the Terrestrial Animal Health Code, Article 1.1.2.3. This includes giving notification of listed diseases within 24 hours, weekly reports, six-monthly reports and annual reports.

Active surveillance

Norway has ongoing surveillance programmes for several animal diseases. Detailed information about the programmes and the results is available in the annual report, which can be downloaded from the National Veterinary Institute's website:

http://www.vetinst.no/eng/Research/Publications/Surveillance-and-Control-Programmesannual-reports Other national surveillance and control programmes:

Bee diseases: European foulbrood (2011). Information about the results of this programme is available on the NFSA's website:

http://www.mattilsynet.no/dyr_og_dyrehold/dyrehelse/dyresykdommer/apen_yngelrate/maan edlige_rapporter_fra_provetaking_av_bier.2488

The programmes are part of Norwegian legislation relating to terrestrial animal health and food in Norway. The NFSA is responsible for the implementation of measures under this legislation. The National Veterinary Institute ensures the scientific quality of the programmes with regard to epidemiological design, testing and analysis using approved methods, and by presenting and interpreting the results in accordance with accepted standards. Sampling is performed by or under the supervision of official inspectors from the NFSA.

Eradication of animal diseases

The Norwegian Food Act provides the legal basis for the (NO) Regulation of 27 June 2002 No 732 concerning measures against contagious animal diseases (including aquatic animal diseases). The regulation establishes the general principles for the eradication of animal diseases in Norway. The regulation implements the EEA legislation on animal diseases.

General measures taken where a List A disease is suspected or confirmed are in accordance with the EEA legislation:

- (a) All animals on the holding must be kept isolated. Animals shall not be taken from or brought into the holding.
- (b) Meat, milk, eggs, other animal products, cadavers, feed, waste, manure, utensils etc. likely to transmit the disease shall not leave the holding.
- (c) No unauthorised persons or vehicles shall be admitted to or leave the holding. Entrances to buildings, access roads and holding boundaries must be marked with warning signs.
- (d) Appropriate means of disinfection must be used at the entrances and exits of buildings housing animals of susceptible species and of the holding itself.

If a List A disease is confirmed, the NFSA may take any measure necessary to prevent its spreading or to eradicate the disease. This may include restrictions as described above in other holdings that have had contact with the holding where the disease is suspected or confirmed. Animals from the affected/suspected/contact holdings may be ordered to be slaughtered and/or destroyed. Animal products from the affected/suspected/contact holdings may be ordered to be traced and destroyed. Slaughterhouses, dairies, semen collection centres, animal transporters etc. may be ordered to implement control measures. Depending on the disease that is confirmed, protection and surveillance zones shall be established around the outbreak.

If a List B disease is suspected or confirmed, the following general measures must be taken:

- (a) Susceptible animals shall not leave the holding.
- (b) The person responsible for the holding must implement measures to prevent further spreading and to control/eradicate the disease.



(c) Unauthorised persons must not be admitted to rooms where animals of susceptible species are kept. The entrances to buildings must be marked with warning signs.

The NFSA may impose further restrictions on the affected/suspected holding. It may also trace and establish restrictions on contact holdings. Animals in the affected holding may be ordered to be slaughtered and destroyed, animal products from the holdings may be ordered to be traced and destroyed, and environments/persons may be ordered to be cleaned and disinfected. The NFSA may also decide that suspected cases must be handled in the same way as if the disease had been confirmed and that control measures must be taken in holdings that have had direct or indirect contact with the holding where a List B disease has been confirmed. Slaughterhouses, dairies, semen collection centres, animal transporters etc. may be ordered to implement control measures.

Official controls of semen collection/storage centres, embryo collection teams and breeding organisations.

Norwegian semen collection/storage centres and embryo collection/production teams are approved by the regional offices of the NFSA. Approved establishments are assigned a registration number. Official controls of these establishments are carried out by the Regional Offices.

The authorisation and inspection of breeding organisations approved to maintain herd books is done by the Southern and Western Regional Office, national assignments department. The same office is also responsible for the approval of breeding programmes.

The NSFA head office is the appeal body for decisions made by the regional offices and it is also responsible for issuing guidelines.

Semen collection centres and semen storage centres are regularly inspected by an official veterinarian at least twice a year, as laid down in point 1(c) and 2(b) of Chapter II of Annex A of Directive 88/407/EEC.

Aquaculture animals

The national legislation in place fulfills the relevant EEA requirements in the field of fish health. In some instances Norway has established and implemented stricter requirements than are required by EEA legislation regarding fish health.

NFSA, Department of control, Section for Fish Health and Fish Welfare, is the competent authority in the control and monitoring of fish health and fish welfare. The NFSA cooperates with the Directorate of Fisheries on authorisations and controls by joint inspection- and audit teams. The NFSA also cooperates with private fish health services in the control and monitoring of fish diseases at fish farm level.

Site registration and identification

No person may engage in aquaculture activities without registration as the holder of an aquaculture license in the aquaculture register. The aquaculture license permits the production

of specific species in limited geographic areas (sites) subject to the prescribed restrictions on the scope of the license that apply at any given time.

The establishment of aquaculture establishments and mollusc farming areas, expansion of production and any other significant change of previously approved aquaculture establishments or mollusc farming areas shall be approved by the NFSA.

For approval to be granted, the establishment of the aquaculture sites must not involve any unacceptable risk of spreading disease, including to the aquaculture establishment or mollusc farming area and the surrounding environment.

When considering the risk of spreading disease, particular emphasis shall be given to the distance to watercourses, other aquaculture related activities and groups of aquaculture establishments. There must also be emphasis on the species to be produced, the form of operation and the scope of production.

For marine aquaculture establishments the distance to other aquaculture related undertakings and watercourses shall primarily be considered on the basis of where the production units are placed. For land-based aquaculture establishments, the distance to other aquaculture related undertakings and watercourses shall primarily be considered on the basis of water inlet(s) and outlet(s).

An internal control system shall be in place substantiating that requirements for reasonable operations in terms of biosecurity and animal welfare, including requirements for a contingency plan, risk based medical examinations, maintaining good water quality and log-keeping, can be complied with;

The aquaculture establishment must be able to ensure the requirements of the species for a good aquatic habitat. There must be a reliable and sufficient supply of water of appropriate quality. The establishment shall be located and designed so that there is a low risk of harming or exposing the aquaculture animals to unnecessary stress. When considering the welfare aspect, information about the establishment's design and equipment, and where it is placed at the location shall be considered in relation to the form of production and water data.

Approval may be subject to conditions. A register of Norwegian aquaculture establishments is available in MATS, the NFSA's operating system for official control.

The NFSA regulations and control cover the whole production chain. There are i.a. regulations relating to the approval and use of disinfectants in aquaculture establishments and transport units, and regulations relating to disinfection of inlet water to and waste water from aquaculture-related activities.

Movement controls

In order to be authorised for transporting aquaculture animals, the vessels must comply with the national Regulation (NO) 17 June 2008 No. 820 containing requirements related to fish health and fish welfare during transport. The district office has the competence to authorise and withdraw authorisation of the means of transport. In general, the authorisations are valid for five years. The NFSA has made the list of authorised means of transport available on its website.

Movements into disease free zones or compartment and movements between infected and non-infected farms are regulated by procedures to reduce the probability for spreading disease. *E.g.* according to the contingency plan for control of Infectious Salmon Anaemia (ISA) in Norway, the transport route shall be authorised by the NFSA when transporting fish from farms with confirmed ISA. Furthermore, the NFSA and the operators pay special attention to the epidemiological status of the areas sailed through when transporting fish on well boats.

Transport routes of infected live fish have to be authorised by the NFSA. Strict rules apply for the disinfection of transport water. The operators are obliged to keep records on movements. The NFSA has issued guidelines for the inspection of means of transport.

An overview of areas declared free from Infectious salmon anaemia (ISA) in Norway can be found here:

http://www.mattilsynet.no/language/english/fish_and_aqaculture/fish_health/areas_declared_f_ ree_from_infectious_salmon_anaemia_isa.8754

Health controls

Own supervision

According to the Norwegian regulation relating to operation of aquaculture farms the person responsible for daily operations shall ensure that risk based supervision be carried out of factors of significance for the environment, health and welfare of aquaculture animals. Supervision of fish farms shall be done at least once daily insofar as weather conditions permit.

Health checks

Risk-based health checks shall be made of aquaculture animals to prevent and treat disease and injury. The health check shall be performed by authorised veterinarians or fish health biologists. The operating log shall be reviewed during each health check. On the basis of a risk evaluation, a representative sample of the production units shall be inspected. A representative sample of newly dead animals or animals exhibiting abnormal behaviour shall be examined and relevant tests shall be performed. Revealing any cases of diseases on lists 1, 2 and 3 shall be particularly stressed. In the event of increased mortality, apart from when such mortality is obviously not caused by disease, or when there is no reason to suspect contagious/non-contagious disease, the health status of the entire aquaculture establishment shall be assessed. Specimens shall be taken and tests performed to establish the cause.

Notification

The Norwegian Food Safety Authority shall be notified immediately if there is:

a) unexplained increased mortality,

b) reason to suspect diseases on lists 1,2 or 3, or

c) other factors which have led to significant repercussions in terms of fish welfare, including disease, injury or failure.

Requirements for weekly reporting of mortality, from aquaculture production businesses during an outbreak of list 1 or list 2 diseases, are also laid down in the Norwegian legislation. Sea lice levels have to be reported weekly.

2.2. Control system for food of animal origin

Competent Authorities

The Hygiene and Drinking Water section at the NFSA's head office is responsible for food safety controls covering official control of slaughterhouses, meat-cutting plants, meat processing plants, dairy plants, egg packing centres, egg-processing plants.

The Seafood section is responsible for food safety controls covering official control of fish processing plants and vessels, and control of live bivalve molluscs.

The Animal Health section is responsible for controlling primary production of terrestrial animals.

The Export and Import section is responsible for controlling food imports and exports. The NFSA's head office is responsible for interpreting legislation relating to the relevant field, for risk assessment and for issuing instructions on control and surveillance to the regions. The regions decide which topics should be prioritised in their surveillance and control work, within the framework set by the head office. The regions are responsible for carrying out the controls.

Registration and approval of establishments

All establishments controlled by the NFSA (for food of animal origin) have to be approved in accordance with the relevant legislation. The evaluation of establishments is based on their applications and audits/inspections of the premises performed by the local departments. A certificate of full or conditional approval is issued.

Standardised procedures for approval are in place through MATS. Only those establishments that fall under the scope of Regulation (EC) No 853/2004 are approved and given an approval number in accordance with Regulation (EC) No 854/2004. All approval numbers for FBOs are issued by the NFSA.

Other establishments producing food of animal origin are registered if the production and distribution are on a small scale according to national regulations. The list of approved establishments for Norway is available at:

http://www.mattilsynet.no/language/english/food_and_water/approved_products_and_establis hments/?kategori=1011#godkjenninger

Live bivalve molluscs

The NFSA is responsible for the approval of production areas for live bivalve molluscs. It is also the Competent Authority for the classification of harvesting areas, monitoring of toxic algae and marine bio-toxins and the approval of dispatch centres pursuant to Regulation (EC) No 853/2004 and 854/2004.

Organisation and implementation of official controls

The NFSA head office is responsible for interpreting legislation, developing control plans, surveillance programmes, guidelines and instructions for the regions. The regions are responsible for carrying out official inspections and audits. These controls are based on



instructions and guidelines for the specific areas to be controlled. The inspections and audits carried out at regional level are documented through MATS. See the description of risk-based prioritisation in section 1.3.

The mandatory official controls at slaughterhouses are mostly carried out by official veterinarians. Routine meat control tasks alone take up a third of the local departments' staff and resources.

Official controls of identification marks placed on products and tagging of live animals are carried out on animals sent for slaughter. Traceability is covered during controls that are carried out as part of the official controls of the establishments.

The animal food surveillance and monitoring programmes are the responsibility of the NFSA. These programmes are risk-based, based on both local knowledge of the production and foodstuff in question, and on the outcomes of national monitoring programmes.

Monitoring of zoonosis and zoonotic agents

In Norway, *Salmonella* control plans are compulsory for breeding flocks of Gallus gallus, laying hens, broilers, turkeys, swine and cattle. The Norwegian Veterinary Institute (VI) is responsible for editing the Norwegian annual report on trends and sources of zoonosis and zoonotic agents in humans, foodstuffs, animals and feeding stuffs. The institutions and laboratories involved in the reporting are the NFSA, the VI, NIFES and the Norwegian Institute of Public Health (NIPH).

See the report on the VIs website http://www.vetinst.no/eng/Publications/Zoonosis-Reports

Norwegian legislation includes some national measures that are stricter as regards monitoring and control of *Salmonella* and *Campylobacter* than those laid down in EEA legislation, e.g.:

- Norway has a national action plan against *Campylobacter* spp. in broilers that ensures that all broiler flocks slaughtered before 51 days of age are tested prior to slaughter. The testing is only done in the high season for *Campylobacter* contamination risk, which is between May and October. Carcasses of positive flocks are either heat-treated or frozen for a minimum of three weeks before marketing.
- in breeding turkey holdings, the food business operator collects samples for Salmonella testing every two weeks instead of every three weeks;
- all broiler holdings are subject to official controls each year (which is beyond the EEA requirement of at least one flock of broilers on 10% of the holdings with more than 5,000 birds);
- the application of sanitary restrictive measures is considered mandatory for all *Salmonella* serovars (not just for *Salmonella Enteritidis* and *Salmonella Typhimurium*), and these measures are applied immediately upon suspicion of a positive result;
- the use of vaccines is forbidden at all levels.



2.3. Control system for imports of animals and food of animal origin

Competent authorities

The Export and Import section at the NFSA's head office is responsible for coordinating veterinary import control of products of animal origin (POAO) and live animals from third countries by the border inspection posts (BIP).

The section is the national contact point for TRACES and RASFF, not only for the European Commission (EC), but also within the NFSA. All the BIPs have access to the RASFF database and they all use TRACES.

BIP, TRACES and RASFF manuals are produced by the section. Circulars concerning border control are also issued when the need arises. They provide information on procedures, legislation etc. Relevant information from the European Commission or competent authorities of other countries is sent to the BIPs by email as it becomes available.

Annual seminars for BIP personnel are organised by the Export and Import section in order to discuss and inform about relevant issues and problems.

Import controls

Information about approved BIPs is available on the EFTA Surveillance Authority's website:

 $\underline{http://www.eftasurv.int/internal-market-affairs/fields-of-work/food-safety/decisions-taken-by-the-authority/}$

The BIPs are organised as part of the regional level's local departments, where they are based. It is only in the Greater Oslo region that all BIPs belong to a border control and import department. Administrative responsibility for the BIPs as regards their budget, personnel administration and day-to-day management rests with the local department. Eleven of the BIPs are run by an official veterinarian (OV), while the other four, which are only approved for fishery products for human consumption, are run by an official fish inspector (OFI). The number of people working on border control can vary depending on the season and workload. All personnel at Norwegian BIPs must be approved by the Export and Import section and subsequently entered on the national list of approved signatories, in order to issue CVEDs. Prior to approval, the section must receive confirmation from the OV/OFI in charge of the BIP that the personnel have completed local training as prescribed in the national procedure.

Checks of incoming consignments are based on pre-notification via the CVED. This information is cross-checked with information from other authorities, for example Customs, port authorities, the pilot service and the coastal surveillance authorities. In addition, TVINN, the Customs Service's electronic database, will, at the time of customs clearance, intercept goods that are subject to border control, but that have not been correctly pre-notified. The NFSA also cooperates with Customs when it comes to checking for illegal products of animal origin (POAO) in personal luggage. Joint actions are implemented at airports and border crossings to check for illegal products and inform travellers.

To ensure correct and professional handling of illegal imports, the procedures to be followed were regulated in the Instruction of 10 January 2003 No 28. Illegal imports of POAO to Norway are handled by the local departments and the BIPs. Illegal imports are seized and transported to the nearest BIP approved for the relevant product category. The transport must be agreed with the BIP, and the local department must ensure that no contamination is possible during transport. The further handling of the goods is decided by the BIP.

Catering waste

The handling of catering waste from ships in international traffic at ports with BIPs is dealt with in guidelines issued to the BIPs by the head office, which were revised in February 2009.

The guidelines also state that responsibility for handling the waste may be outsourced to the local harbour services. However, the border veterinarian is still responsible for keeping copies of receipts of waste destruction and checking that legal requirements are fulfilled. So far, the guidelines are only accessible for the BIPs in the NFSA's intranet.

Approved laboratories are available for testing samples taken at the BIPs. This includes samples taken for surveillance programmes, as part of the physical control of consignments and samples taken on grounds of suspicion. The samples taken for surveillance programmes are sent to laboratories that have agreements with the NFSA at national level (NIFES or NVI), while other samples are sent to laboratories that have agreements with the NFSA at regional level.

Veterinary checks on food of animal origin

Import controls of products of animal origin and live animals from third countries are in accordance with EU legislation. For imports of food of animal origin, pre-notifications are received through the TRACES system. The NFSA has direct access to or receives cargo manifests from freight companies for cross-checking purposes.

Import and export goods must be declared in the electronic customs clearance system TVINN. All import declarations containing animal products from third countries listed in Council Decision 2007/275/EC, which is implemented in (NO) Regulation of 26 June 2008 No 726 concerning veterinary border control, are subject to manual processing. The Directorate of Customs updates the TVINN system with control data received from the NFSA. The customs regions perform the controls. The goods are not released before the original CVED has been controlled. The declarations received by TVINN are managed using various control filters, which select objects for document control and/or physical control. The Directorate of Customs has instructed customs officers to alert the NFSA immediately every time they detect products of animal origin that have not been checked at a BIP, if they come from a third country.

Approved laboratories are available for testing samples taken at the BIPs. This includes samples taken for surveillance programmes, as part of the physical control of consignments and samples taken on suspicion. The samples taken for surveillance programmes for fishery products and residue samples from other animal products are sent to laboratories that have agreements with the NFSA at national level (NIFES for fishery products and FERA Ltd for residues). Microbiological samples taken for the surveillance programme from POAO other

than fishery products are sent together with other samples to laboratories that have agreements with the NFSA at regional level.

2.4. Control system for feeding stuffs and animal nutrition

Competent Authorities and official controls

The NFSA's Seafood section is responsible for the implementation and enforcement of EEA feeding stuff legislation, as well as having overall responsibility for the implementation of controls. Official control of feed business operators is carried out by the regions of the NFSA using a risk-based approach. Every year, the head office issues instructions to the regional departments regarding surveillance programmes and the frequency of and national priorities for official controls. All parts of the feed chain are controlled periodically, based on inspections, audits and sampling. The Seafood section is also responsible for preparing guidelines and instruction documents that describe procedures, how to conduct controls, how to assess findings and which action to take in cases of non-compliance. These documents are part of the NFSA Quality Manual.

An interactive national Animal By-Products (ABP) and Feed Forum enables communication between the regional offices and the head office. This is described further in section 2.6 Control System for Animal By-Products (ABP).

Approval or registration of feed business operators

Feed business operators are approved or registered in accordance with Regulation (EC) No 183/2005 (Annex II operators) and, if relevant, Regulation (EC) No 999/2001. Using the NFSA's quality manual available in MATS, feed business operators have a web-based application for approval or registration. The evaluation of feed business operators is based on their applications and is performed by the regional departments. Lists of registered and approved operators are generated automatically from MATS and updated daily. The lists are available on the NFSA website. The operators are classified into four risk categories depending on their activities in the feed sector. The frequency of inspections depends on the risk classification.

FBOs that fall under Annexes I and III of Regulation (EC) 183/2005 are registered either as primary producers in a register administered by the Norwegian Agriculture Agency, as feed users in the domestic animal database (Husdyrregisteret) or in a register of Norwegian aquaculture establishments (Directorate of Fisheries).

Samples are taken and analysed as part of the NFSA basis surveillance programme for contaminants in feed, results communicated yearly. Additional samples can be taken /analysed for verification or upon suspicion..

Samples taken as a part of the surveillance programmes are distributed among the designated central laboratories. The NFSA has approved the use of these laboratories for surveillance programmes and has also signed agreements on advisory support with these central laboratories.

For samples taken as a part of the on-site inspections certain official laboratories are to be used, provided that the analytical method in question is a part of the agreement between the NFSA and the laboratory. Otherwise, the designated central laboratory is to be used.

Medicated feed

The production of medicated feeding stuffs is controlled by the Norwegian Medicines Agency (NoMA), and the production of medicated feed is subject to approval by NoMA. Veterinary medicines must be incorporated into feed in the form of a pre-mixture.

Enforcement

The legal basis for sanctions in cases of infringement is set out in legislation relating to feed and described in NFSA's procedure *Virkemiddelbruk ved tilsyn* (administrative rules concerning infringement procedures). Documented procedures are in place in the NFSA Quality Manual for actions to be taken in cases of infringements.

2.5. Control system for Transmissible Spongiform Encephalopathy (TSE)

Competent authorities

The NSFA's Animal Health section is the competent authority for epidemiological surveillance and national control programmes for TSE, and for maintenance of these programmes and their implementation. The NSFA's regional departments are responsible for implementing TSE controls in accordance with instructions, standard operating procedures (SOPs), sampling plans and supervisory procedures. Private veterinary practitioners carry out activities on behalf of the NSFA, such as notification of animals with suspected TSE and occasional sampling.

The NSFA's regions are the competent authority responsible for the enforcement of official controls of the removal of specified risk material (SRM) in food establishments.

Epidemio-surveillance

The (NO) Regulation of 27 June 2002 No 732 on control of animal diseases require veterinary practitioners to give notification of any clinically suspect animal they come across in their practice. It also establishes the same obligation for the keeper, transporter or others responsible for the animal. TSE in small ruminants has been a notifiable disease since 1965, in cattle since 1991, and in cervidae since 2004.

SOPs are in place for guidelines and other information about handling TSE clinical suspects and confirmed cases. When an animal is declared an official TSE suspect, it is euthanised on the spot. The carcass is brought to an incineration plant by a dead animal collection service or by other means, and the head is sent to one of the VI's regional laboratories.

In the active surveillance context, the following subpopulations are monitored (as of 1 January 2016):

Bovine animals:

• all bovine animals over 48 months of age subject to special emergency slaughter;



- all bovine animals over 48 months of age subject to special slaughter after antemortem inspection;
- all bovine animals over 48 months of age that have died or been killed (fallen stock), except those killed in the framework of an epidemic;
- all imported bovine animals irrespective of age.

On a yearly basis until January 2014, Norway also tested a random selection of 10,000 bovine animals over 30 months of age subject to normal slaughter for human consumption.

Ovine and caprine animals:

- all ovine and caprine animals over 18 months of age, or that have more than two permanent incisors erupted through the gum, that have died or been killed for other purposes than being slaughtered for human consumption (fallen stock);
- a random selection of 10,000 ovine animals over 18 months of age, or that have more than two permanent incisors erupted through the gum, that have been slaughtered for human consumption;
- all ovine and caprine animals over 18 months, or that have more than two permanent incisors erupted through the gum, that have been slaughtered for human consumption, died or been killed from holdings placed under an official movement restrictions;
- all imported ovine and caprine animals irrespective of age;
- animals over 12 months of age that are killed for destruction in accordance with official guidelines on the eradication of TSE.

With regard to scrapie in sheep and goat and BSE in cattle, the competent authority has taken several initiatives to raise awareness among farmers, private veterinary practitioners and others who handle such animals.

Deer (Cervus elaphus atlanticus), captive and free-ranging:

- all deer animals over 12 months of age that have died or been killed for other purposes than being slaughtered for human consumption (fallen stock);
- all imported deer animals irrespective of age.

Other animals:

Other captive and free-ranging cervidae (hunted, fallen stock, clinically sick, animals injured or killed by vehicles).

Specified Risk Material (SRM)

Removal of SRM from food is verified as part of the official control of food establishments. In order to ensure the correct application of the regulation an official guideline on SRM controls has been issued.

Total Feed Ban

Since 1 January 2001 and in accordance with Council Decision 2000/766/EC, imports of meat and bone meal (MBM) are prohibited unless destined for pet food or for animal feed.



The ban on ruminant MBM in ruminant feed was adopted on 26 November 1990. Since there is no separation of ruminant waste material and waste from other species at slaughterhouses and rendering plants, this was also a *de facto* ban on the use of mammalian MBM. The mammalian MBM ban was formally adopted on 15 October 1999.

The risk of contamination of ruminant feed by protein-contaminated fat has been negligible during this period, since the main producers (Felleskjøpet) agreed in June 1996 to remove rendering fat from ruminant concentrates. According to the producers, they all removed it in 1999. In addition, rendering fat quality was monitored and non-lipid fractions above 0.5% triggered a price reduction or refusal of the fat.

MBM content in ruminant feed has been monitored by microscopy since 1995, except for in 1999 when there was no monitoring because of changes in personnel and the establishment of a new method. Since 2001, MBM has been monitored in all samples of feed destined for ruminants, pigs or poultry, as well as all samples of fish meal. When MBM is found, action is taken to identify the cause and remedy the situation.

The monitoring of animal feed production is performed through inspections carried out in accordance with Regulation (EC) No 882/2004 and Regulation (EC) No 183/2005.

Laboratories

NVI performs all tasks for the diagnosis of cases of TSE. NVI is the NRL for TSE. BSE samples are analyzed in two VI laboratories and both laboratories are accredited, and checked by the Norwegian body for accreditation annually. They also participate in annual ring trials for the tests used, organized by the respective European Union Reference Laboratories (EURLs). An ELISA test, TeSeE from Bio-Rad, is used for detection of PrPSc in cattle. Positive samples are analyzed further by Western-blotting in one of the NVI laboratories. The NRL reports monthly to NFSA concerning the progress in sampling and will also report to the relevant NFSA district office if samples received are unsuitable for analysis.

2.6. Control system for Animal By-Products (ABP)

Competent Authorities

The Seafood section at the NFSA's head office is the CA for policy and enforcement of ABP legislation, as well as having overall responsibility for the implementation of controls.

The NFSA enforces ABP regulations directly on the premises that it supervises. Official control of ABP at food, feed and other APB processing establishments is generally carried out as an extension of official controls by the regions/local departments.

These offices are responsible for all food, feed and ABP processing establishments. However, incinerators, and food waste collection and management establishments also fall under the responsibility of the Norwegian Environment Agency (Miljødirektoratet).

National ABP and Feed Forum

The Forum enables optimal communication at national level. Representatives of all the regions

and representatives of the head office are permanent members of the Forum's working group. The ABP and Feed Forum discusses, decides and disseminates information about best practices and controls. In parallel with the National Forum, each region has established a Feed and By-products working group with representatives from all departments in the region. The Forum and working group hold a minimum of two meetings per year and ensure a two-way flow of information, so that the implementation of regulations, practice and experience is coordinated and uniform across all levels in the NFSA, and thereby nationally.

Approval of ABP plants and other premises

Approval of all types of plants controlled and found to be in compliance with the ABP regulations (processing, storage, intermediate plants, and pet animals feed and collecting centres) is done using an electronic form available in MATS. The NFSA disseminates information about approval requirements under the ABP regulations on the NFSA's website, as well as at meetings between the NFSA and the industry, and by direct communication. Plants requiring approval must submit an application, which is followed by an approval inspection.

A list of ABP plants, as well as other types of special users approved or registered in compliance with ABP regulations, is compiled and publically available on the NFSA's website. <u>www.mattilsynet.no</u>

Official controls

MATS is in use for official controls of ABP at food, feed and all other types of ABP establishments. The system includes inspections as well as providing the industry with information about requirements, advice and approval guidelines. Application forms for recording movements of ABP are also included in the system. The system ensures the traceability of ABP, by including commercial documents and templates for health certificates. ABP plants are inspected regularly.

The NFSA selects, on a yearly basis, prioritised ABP areas for coordinated controls. This is planned and managed by the responsible section at the head office.

2.7. Control system for veterinary medicinal products (VMP) and residues

Veterinary Medicinal Products (VMP)

Competent Authorities

Controls of the production, distribution and use of VMPs are divided between the Norwegian Medicines Agency (NoMA) and the NFSA. The NoMA is responsible for licensing, and for official controls of the manufacture and distribution of VMP to the pharmacy level, while the NFSA is responsible for the control of VMP use by veterinary practitioners and on farms, and the national residue monitoring programme.

Authorisation of VMP

The legal basis for the registration of veterinary products depends on the type of product:


- VMPs: the Medicines Act of 4 December 1992, No 132, amended 1 July 2011, and the (NO) Regulation on medical products of 18 December 2009 No 1839, amended 18 December 2015. Registration requirements and procedures are similar to the requirements in the EU.
- Feed additives: the Food Act, (NO) Regulation of 14 January 2010 concerning feed hygiene, and (NO) Regulation of 7 November 2002 concerning feeding stuffs.

Registration and authorisation of VMPs

NoMA is responsible for the registration of veterinary products. The NFSA is responsible for issuing permits for the use of immunological VMPs pursuant to animal disease control legislation. The NFSA is also responsible for feed additives.

The EU forms 'Application form for VMPs and 'Application form for a variation to a Marketing Authorization' are required for applications to NoMA for marketing authorisations. Approval time depends on the type of product, and for medicinal products, it also depends on the procedure. Applications sent via the European Mutual Recognition Procedure: 120 days, and the Decentralised Procedure 240 days (+ clock-stop period). National applications:

- VMPs: 210 days (+ clock-stop period)
- Feed Additives: 2 to 3 months. Also subject to requirements essentially similar to those of the EU (EEA Agreement).
- Criteria for refusal of registration are equivalent to the EU criteria.

Foreign studies are accepted if relevant to Norwegian conditions, but all data must be signed or published. Clinical trials may be required to be carried out in Norway for immunologicals for Atlantic salmon.

With respect to VMPs, only products based on radioactive isotopes, magistral and officinal products and autogenous vaccines are exempt from registration. However, licensed veterinarians can prescribe VMPs that have not been licensed in Norway. The NoMA considers applications for such use.

Adverse reactions reported

The reporting of adverse reactions depends on the type of product:

- VMPs: veterinarians are requested to report adverse reactions to NoMA.
- Feed Additives: no formal requirements

Post-registration reporting

Manufacturers are obliged to notify the NoMA immediately about all new information relating to clinical effects and adverse reactions, toxicological and qualitative conditions, or defects and deficiencies in a product. Periodic Safety Update Reports must be submitted by Marketing Authorisation Holders in accordance with the EU/EEA requirements.

Manufacturing inspections and official controls of marketing/use

The NoMA carries out inspections on a routine basis, and it is responsible for control of the manufacturing and distribution of VMPs. The NFSA supervises veterinary practitioners and controls the use of VMPs.

Control of VMPs at wholesale and retail level

According to NoMA's internal procedures, large wholesalers should be inspected every three years and smaller ones every three to five years. There is a checklist for use during inspections of wholesalers. It includes checks of the VMPs and purchases by private veterinary practitioners (PVPs).

VMPs are mainly distributed via practising veterinarians who purchase VMPs from wholesalers for use in their own practice. Small quantities of VMPs are also distributed through other pharmacies. Retailers are subject to inspection every four to ten years. Checklists are used during the inspection of retailers and veterinary practitioners operating veterinary pharmacies.

Medicated feed controls

The production and distribution of medicated feed is permitted in Norway. Surveillance of medicated feeding stuffs is the responsibility of the NoMA. The medicines shall be incorporated into the feed in the form of a pre-mixture. The preparation of medicated feeding stuffs shall only be performed by feed business operators approved for the production of medicated feed.

As regards pesticide residues in feed, the EEA legislation is implemented in Norway. Annual sampling plans for the surveillance programme are drawn up by the NFSA's Seafood section. Inspectors at the NFSA's regional offices are responsible for the sampling.

Enforcement

The legal basis for sanctions in cases of infringement is incorporated in feed legislation and in 'Guide to the use of policy instruments' (virkemiddelveilederen). Documented procedures are in place in the NFSA Quality Manual on actions to be taken in cases of infringements.

Private veterinary practitioners (PVPs) and farms

The region in the NFSA is responsible for official control of the proper use and storage of medicines on farms. Animal keepers are obliged to keep records of the health status of animals and their medical treatment for at least ten years.

All VMPs are prescription medicines only, and must be prescribed by a veterinarian and used under the responsibility of the veterinarian (medicines for fish may also be prescribed by fish health biologists). It is also accepted that farmers can administer drugs for certain diseases that are common in their own holding for short periods on a contract with a PVP. The veterinarian is still responsible for the use of the medicines, and for training the farmer.

The NFSA is responsible for controlling the use of VMPs by veterinarians.

The Veterinary Medicines Register (VetReg) is part of MATS. The objective of the register is to ensure safe food, promote public health, animal health, animal welfare and consumer



interests, and to promote sustainable production. All prescriptions of medicines for animals must be registered by pharmacies and all treatment carried out by veterinarians on livestock and horses must be registered within seven days.

In cases where veterinarians do not fulfil the requirements concerning registration in the database, the NFSA can take appropriate measures against the veterinarian. In the worst case, the veterinarian could lose his licence to practise as a veterinarian.

Residues

Competent authorities

Responsibility for monitoring residues is divided between the sections for Chemical Safety and EEA (terrestrial animals and products) and Seafood (aquaculture), both under the head office of the NFSA. NoMA contributes to the National Residue Monitoring Plan (NRMP) based on its data on VMP use.

Implementation of the National Residue Monitoring Plan (NRMP)

The NRMP is based on total national production and the requirements of Council Directive 96/23/EC. The NRMP and the results of its implementation are submitted annually to the Authority. The NFSA is responsible for supervision of the NRMP. The sampling plan is reviewed and evaluated annually. Account is taken of the level of risk of residues in certain areas and animals.

Follow up of non-compliant results from official samples

All the results for terrestrial animals and animal products are reported to the local department that has taken the samples. In the case of non-compliant results, the local NFSA department will follow up in accordance with the instructions from the head office in the Quality System. The head office receives a copy of all the results and monitors that the results are followed up. For Aquaculture, the NRMP coordinator contacts the relevant region/local department for follow-up.

A detailed report on the results and the plan for residue control is sent to the Authority by 31 March every year.

Dairy plants operate self-control programmes for antibacterial substances (every delivery is tested). Non-compliant results can be traced back to each farm, and documentation of follow-up investigations by the dairy plants must be reported to the local veterinary officer.

2.8. Control system for foodstuffs and food hygiene

Competent Authorities

The Food department at the NFSA's head office is responsible for legislation on food safety, environmental protection and general hygiene, as well as control and monitoring of general foodstuffs, chemical safety, food hygiene, labelling and quality and water supply systems.

Official controls of food premises

All food establishments, including primary producers, are required to register. However, all establishments covered by Regulation (EC) No 853/2004 and (EC) No 210/2013 must first be approved by the NFSA pursuant to Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 882/2004. Lists of registered and approved establishments are kept and maintained as required by Regulation (EC) No 882/2004., and the lists are available on the NFSA website <u>www.mattilsynet.no</u>, for example by searching for the phrase 'Godkjente produkter og virksomheter'.

All establishments that carry out any activity involving the production, processing and distribution of food have to comply with the hygiene requirements. The regional level of the NFSA is responsible for official control of foodstuffs at all levels, including retail, service sector, manufacturers, producers and packers.

Good Hygiene Practice Guides (GHP)

The inspections/audits that establishments undergo depend on the type of establishment. The frequency and number of inspections are based on an evaluation of possible health risks. To ensure compliance with the regulations, the inspections/audits sometimes involve sampling and labelling, as well as the establishment's internal (self-check) system.

About 8,000 of the registered food operators are restaurants. From January 2016, a scheme involving a 'smiley' in the inspection report was launched for this category of food retailers. Experience from a pilot project in Central Norway shows that this leads to better compliance with the rules. It has also become highly popular among consumers as well as establishments. The short version of the inspection report must be displayed for consumers to read before entering the restaurant. Results for all food operators and all Smileys can be found on the NFSA website <u>www.mattilsynet.no</u>. The restaurants also receive inspection reports containing more formal details about findings and improvements.

Potable water

Licensing and registration of water supply systems

Water supply systems serving 50 persons or more must be approved by the NFSA. However, water supply systems only serving food premises shall be registered by the NFSA. The water supply systems are subject to official control by the NFSA. The controls are mainly carried out by the regions, through their local departments. Water quality, monitoring, the use of materials or chemicals and information must be in accordance with Directive 98/83/EC. Sampling in accordance with Directive 98/83/EC is carried out by the water supplier. Water sampling in food establishments is carried out by the establishment. Both clean seawater and clean water may be used throughout the production and processing of fishery products in accordance with Regulation (EC) No 853/2004. As for the rest, water supply based on seawater must also satisfy the Norwegian drinking water regulations.

Approval and official control of natural mineral waters under Directive 80/777/EEC are the responsibility of the regional level of the NFSA, and are carried out by its various local departments. Reporting is done to the head office.

Food contact materials (FCM)

Control of importers and producers of FCM, and of the use of FCM at food establishments, is done at regional level. Region East has been assigned responsibility for having in-depth knowledge and a coordinating role in the area of FCM.

Norway has implemented all the EU regulations concerning FCM. Norway also has some national provisions. They include a requirement for a Declaration of Compliance for all types of FCM and lower limits for Cd and Pb in ceramics. Establishments that produce, import or sell FCM wholesale are obliged to notify their activity to the NFSA.

Rapid Alert System for Food and Feed (RASFF)

The national contact point (NCP) for RASFF is the Export and Import section at the NSFA's head office. The NCP has a staff of three advisers who share responsibility for ensuring that emails concerning RASFF notifications are read and acted upon without unnecessary delay. All information relating to RASFF, both from the European Commission and from the local departments of the five NFSA regions, are sent to the same e-mail address. The RASFF email inbox is under constant surveillance during office hours, while the emergency phone of the NFSA can be contacted outside office hours. When the NCP receives information from the European Commission about food, feed or FCMs that may pose a health risk in Norway, the information is forwarded to the relevant regional offices of the NFSA. The NFSA department located where the product has been distributed or where the product originates will then contact the business operators involved. The NCP has developed internal guidelines for the local offices of the NFSA. They describe the appropriate response to RASFF notifications. These guidelines also describe how information about detection of noncompliance in the Norwegian market that may pose a potential health risk should be forwarded to the NCP. The NCP will thereafter validate the information in iRASFF before the notification is submitted to the European Commission.

Food fraud

Administrative assistance and cooperation in the areas of feed and food

The NFSA started to structure its food fraud activities in 2014. The NFSA has participated in the EU initiatives relating to food fraud. This includes the EU network and the coordinated control plans. Since November 2015, the NFSA has been connected to the EU AAC notification system for food fraud cases. The NFSA has also supported the Norwegian Customs Service in the international operations OPSON and Pangea. There is also ad hoc contact with the police.

A food fraud contact point pursuant to Regulation (EC) No 882/2004 Article 35 has been appointed. Furthermore a regional food fraud team has been established in cooperation between NFSA Region Greater Oslo and NFSA Region East.

A national training course for field inspectors was held for the first time in May 2016. Norwegian inspectors have also taken part in training activities organised by the Swedish Food Safety Board. Norway has had five participants at the EU BTSF training course for food fraud module A, and one participant in module B. A Norwegian national expert seconded to



the European Commission and dedicated to food fraud recently returned to the NFSA and is part of the planning team for food fraud activities.

2.9. Control system for imports of food of non-animal origin

The Export and Import section at the NFSA's head office is responsible for import controls of food of non-animal origin in cooperation with the Customs Service.

Import control is an integral part of the general inspection of establishments that is carried out by the regions. All importers of food must register with the NFSA. Registration is done by the establishment itself. The importer must register the name of the establishment, address, telephone number e-mail address and contact person. In addition, information must be provided about which commodities will be imported to Norway, including CN codes with four digits or more for each commodity group.

Imports of products of non-animal origin from third countries must be notified to the NFSA 24 hours prior to the physical arrival of the consignments. The notification must include information about the importer and the first consignee, the amount and time of arrival of the commodities, the name of the dispatcher and the dispatching country, the country of origin of the commodities and the eight-digit CN code for each commodity group. The requirement for prior notification does not apply to certain fresh fruits and vegetables specified in Norwegian import regulations. There is no requirement for prior notification of foods of non-animal origin from countries within the EEA.

The first consignee of foods of non-animal origin is obliged to keep an import register that contains information about all consignments that have been imported to the establishment. The register shall be available for control by the NFSA. Information about imported consignments must be kept for two years. The first consignee shall also check that the imported consignments comply with requirements in Norwegian food legislation. In the event that the first consignee discovers a non-compliance in an imported consignment, this should immediately be notified to the NFSA. In such case, the consignment shall not be released for free circulation without the NFSA's permission.

The NFSA has entered into a cooperation agreement with the Directorate of Norwegian Customs. The two authorities cooperate at both the central level and the local level. As regards imports of food of non-animal origin, the main cooperation concerns commodities that are subject to EU safeguard measures. Based on information from the NFSA, the Directorate of Norwegian Customs can add restrictions or information to its electronic customs clearance system (TVINN). This ensures correct border control of consignments. Consignments subject to safeguard measures are not released for free circulation until the results of the official control are available.

The Export and Import section implements and follows up the EU legislation for risk products of non-animal origin laid down in Commission Regulation (EC) No 882/2004, Article 15(5) and other regulations concerning safeguard measures.

Products regulated through EU safeguard measures, such as Regulation (EC) No 669/2009, Regulation (EC) No 884/2014 or other regulations, can only be imported through a Designated Point of Entry (DPE). In Norway there are four DPEs: Oslo Port, Borg Port,

Larvik Port and Oslo Airport. Food and Feed Business Operators (FBOs) are required to notify the correct DPE of the estimated date and time of physical arrival of the consignment at least one working day prior to the arrival of the consignment. All consignments are subject to a document check, while a certain percentage of the consignments are subject to an identity and physical check, including laboratory analysis. Depending on the control performed on the consignments, the business operators are charged the relevant fees.

In addition to implementing EU safeguard measures for the import of food of non-animal origin from certain third countries, the Export and Import section issues guidelines and instructions for the local departments.

2.10 Control system for plant protection products (PPP)

The NFSA is responsible for the authorisation and control of the marketing and use of plant protection products (PPPs). The head office is responsible for overall planning at the national level, such as an annual control plan, while the regional offices plan and perform controls of the marketing and use of PPPs.

PPPs on the Norwegian market are authorised by the NFSA. Prior to authorisation, the National Approvals Department of the NFSA carries out an evaluation, involving toxicologists, eco-toxicologists, chemists, agronomists, horticultural and legal experts in the procedure.

Some 253 PPPs, including 112 active substances (chemical and microbiological), are authorised in Norway. In addition, 25 macro-organisms are authorised. They are component parts of 120 authorised macrobiological PPPs. The list of authorised PPPs is published on the website of the NFSA and is updated regularly: http://www.mattilsynet.no/plantevernmidler/godk.asp

Official controls of marketing/use

The number of distributors selling PPPs (both PPPs for professional use and concentrated products for non-professional use) is about 560. The number of distributors selling PPPs to professional users is about 320. Anyone selling PPPs to professional users or concentrated products for non-professional use must be registered with the NFSA. The NFSA's database 'MATS' records the addresses of retailers and wholesalers, and details of all inspections carried out.

Official control of marketing and use is carried out by inspectors from the NFSA's regions. Controls are undertaken in all regions of the country. The controls are carried out according to a multi-annual control plan prepared by the head office. The focus areas vary between inspections at retailers of pesticides, supervision of the use of pesticides, supervision of illegal use of pesticides etc. Infringement procedures are initiated in the event of non-compliance with legislation. If use of illegal PPPs is detected, the certification of professional users will be revoked.

Inspection of application equipment

There is a system in place for the inspection of PPP application equipment based on the European standard EN 13790. Sprayers in use must carry a sticker proving that they have successfully passed the mandatory technical inspection. There are approximately 100 trained inspectors authorised by the NFSA.

Training and certification of professional users

Norway has approximately 30,700 trained sprayer operators, including both PPP users and those who give professional guidance. A compulsory training and certification system has existed for all professional PPP users since 1995. These courses include examinations. Every 10 years, the trained sprayers must take a follow-up course. The NFSA defines the topics to be addressed in both initial and follow-up training. They cover the requirements of Annex I of Directive 2009/128/EC.

Integrated Pest Management (IPM)

Norway has a long tradition of encouraging reduced use of PPPs. The Norwegian Institute of Bioeconomy Research (NIBIO) operates websites that are used by farmers, retailers and the agricultural advisory services alike to obtain advice and guidance on PPP related matters. In addition, NIBIO develops crop-specific IPM guidelines covering major crops. Finally, the agricultural advisory services publish bulletins during the growing season providing information about pest pressure and appropriate actions for major crops.

2.11. Control system for pesticide residues

The Chemical Safety and EEA section at the NFSA's head office is the Competent Authority for legislation and official control of pesticide residues in food.

Official control of residues

Sampling and monitoring plans

The Chemical Safety and EEA section is responsible for interpreting legislation and developing control plans. It coordinates the surveillance programme for pesticides in food, guidelines and instructions for the regions and reporting as laid down in Regulation (EC) No 396/2005 on maximum residue levels (MRL) for pesticides in or on food, and feed of plant and animal origin.

The NFSA participates in the coordinated multi-annual EU Community control programme to ensure compliance with maximum levels of, and to assess consumer exposure to, pesticide residues in and on food of plant and animal origin.

The sampling plans for the Multi-Annual National Control Plan for Pesticide Residues are drawn up by NFSA in cooperation with the Norwegian Institute of NIBIO. The number of samples and type of food products are based on the recommendations in the relevant EU/EEA legislation and guidelines, Art. 30.2 of Regulation (EC) No 396/2005. The plan specifies the food to be sampled, the number of samples to be taken, and the pesticides for which they are to be tested.



Samples shall be taken of commodities originating from organic farming in proportion to the market share of those commodities in each Member State. The samples are submitted throughout the year, taking account of the analysis capacity of the laboratory. The laboratory is also involved in training NFSA inspectors, taking samples for pesticide analyses and carrying out the surveillance programme.

The samples are taken at the wholesale level and cover both imported and domestic products. The inspectors send the samples to the laboratory. Procedures have been established for the distribution of results from the laboratory to the NFSA. There are also guidelines for inspection procedures and on how to follow up residues of pesticides that are detected. Where pesticide residues are detected in food and the level is found to be higher than the MRL ('Guidance document on analytical quality control and method validation procedures for pesticides residues analysis in food and feed', SANTE/11945/2015 30 November–1 December 2015 rev. 0), the NFSA follows the EFSA's model for chronic and acute risk assessment and considers whether the residue level is a risk to the consumer. If the residue level found is higher than the MRL and the residue is considered to be a risk to the consumer, the rapid alert process is triggered.

Enforcement

When a pesticide residue exceeds the MRL, a new sample must be analysed to confirm the result. Enforcement action is taken if the pesticide residues in the repeat sample exceed the MRL.

Laboratories

The NRL for pesticide residue analyses in food of non-animal origin is the (NIBIO. All samples are routinely analysed for 334 pesticides, including some metabolites. The vast majority of the analysis methods (more than 90%) used by the NRL are accredited. According to the annual contract between the NFSA and the NRL, the results of the analyses carried out as part of the pesticide monitoring programme must be provided within three weeks.

However, when requested by the NFSA, the results of official targeted samples can be provided within 24 hours. Since 2009, samples of food of animal origin have been included in the programme. These samples are analysed at the Norwegian University of Life Sciences (NMBU).

2.12. Control system for animal welfare

Control and monitoring of animal welfare of terrestrial animals is the responsibility of the Animal Welfare section at the NFSA's head office. Control and monitoring of fish health and welfare is the responsibility of the Fish Health and Welfare section at NFSA's head office. The regions are responsible for controls relating to animal welfare. In accordance with the Animal Welfare Act, animal welfare committees assist the local departments. These committees consist of laymen and act under the responsibility of the regions. The idea behind this is that lay opinions should be expressed when controlling animal welfare.

Official controls on farms

As a basis, all animal species and types of farming systems are supposed to be inspected during the year. There are no annual targets for inspections, but in recent years, approximately 10% of holdings keeping farm animals have been inspected, with some variation between the different species. The regions select the holdings for inspection. In some cases, in order to make the best of the available resources, the inspection may be carried out in conjunction with checks for other purposes. The local departments are instructed to select the farms and the numbers of farms, not just based on the total number of farms keeping each species, but also to ensure a risk-based selection. Relevant criteria will be previous animal welfare history, whether the farming is intensive or extensive, findings in connection with the slaughtering of animals from the specific farm etc. In addition, the head office is entitled to control the focus by making some of the points in the different checklists obligatory, when necessary.

The NFSA also carries out campaigns focusing on special areas, based on experience of special problem areas etc. Some campaigns are national campaigns initiated by the head office, while others are regional campaigns.

The reaction from the NFSA in infringement cases will vary, depending on the specific situation. In some cases, giving advice to the farmer or pointing out the requirements/the obligations of the farmer will be sufficient. In other cases, more formal sanctions are necessary, such as imposing measures to improve conditions. In these cases, the Norwegian regulations require that formal notice is given prior to the imposition of measures. If a prior notice results in sufficient changes, there will usually be no formal sanction. In some cases, the NFSA may impose an administrative fine to enforce necessary changes. The NFSA may also impose a fine on persons or firms for infringements that have already happened.

In severe cases, the NFSA reports the situation to the police for further investigation and possible prosecution. If necessary, the NFSA has the authority to take animals into custody and even to prohibit individual persons from keeping animals in future or for a specific period. The results of inspections, including infringements detected and actions taken, are recorded in MATS.

The instructions from the NFSA head office are to carry out as many inspections as possible without giving the farmer/animal keeper prior notice. Nevertheless, in some cases it is necessary to announce the inspection beforehand to make sure there is someone representing the farmer/animal keeper present at the inspection. If notice is given less than 30 minutes before arrival at the holding, we consider the inspection to be unannounced.

Official controls during transport

The inspections are mainly carried out by the regions at the destination, particularly at slaughterhouses. In addition to Regulation (EC) No 1/2005 on the protection of animals during transport and related operations, Norway has stricter measures in force for transport that takes place entirely within Norway. As an example, long journeys are not allowed for the transport of slaughter animals (with some exceptions in northern parts of Norway), and the means of transport used for horses must be approved even for short journeys (less than eight hours).

Official controls at slaughterhouses

The regions have special teams at slaughterhouses to carry out the inspections. The aim is to ensure that all animals are spared any avoidable/unnecessary stress, pain, or suffering during movement, lairage, restraint, stunning or slaughter.

2.13. Quality of labelling

Control system for organic production

The Norwegian Food Safety Authority (NFSA) is the competent authority for organic production in Norway. More precisely, the plant section at the NFSA's head office is responsible for the organic area. Norway implemented regulations (EC) No 834/2007, 889/2008 and 1235/2008 on March 18th 2017, see https://lovdata.no/dokument/SF/forskrift/2017-03-18-355?q=økologi

Since that date Norway has followed these regulations. Before March 2017, Norway followed regulation 2092/1991 and a national regulation for organic aquaculture production in Norway.

There is only one control body for organic production in Norway. The NFSA has delegated authority to carry out official control of organic operators and make individual decisions about the production and sale of organic products to this control body, called Debio (see also chapter 1.1). The delegation is described in this document: https://lovdata.no/dokument/DEL/forskrift/2017-03-18-356?q=økologi

Debio carries out a physical inspection of all organic operators at least once a year according to regulation (EC) No 889/2008, art. 65.1.

The Norwegian Food Safety Authority has further responsibility for supervisory activities for evaluation of Debio. The supervisory activities are based on the requirements in the Council Regulation 889/2008, especially article 92c-e. According to these provisions, the Norwegian Food Safety Authority shall ensure the following requirements:

- Ensure that the inspections carried out by the control body are objective.
- Ensure that the inspection procedures and measures are followed.
- Documentation on the risk analyses procedure.
- Verify the effectiveness of the inspections.
- Take cognizance of any irregularities and/or infringements found and penalties applied.
- Withdraw approval of the control body if it fails to satisfy the requirements or no longer fulfils the criteria indicated in the relevant provisions or fails to satisfy the requirements.

To fulfil the requirements for supervision of control bodies, the NFSA has initiated the following measures:

Audits of the control body once a year. The focus on these audits is to verify the objectivity of the control body and to follow up that the control body performs its certifications according to its own written procedures.



Participate on audits done by Norwegian Accreditation. The control body is accredited according to standard NS-EN ISO/IEC 17065:2012. This standard sets some of the same requirements as the organic legislation. It is therefore efficient to participate on these audits to avoid overlapped focus.

Regular meetings with the control body to discuss interpretation of the legislation and appropriate penalties when irregularities and infringements arise.

Participate on inspections performed by the control body to see that the practical certification is in accordance with the legislation and the quality system of the control body.

Routines for sufficient exchange of information with the control body, see <u>https://lovdata.no/dokument/INS/forskrift/2017-03-18-357?q=økologi</u>



Annex $\boldsymbol{I}-\boldsymbol{A}\boldsymbol{C}\boldsymbol{R}\boldsymbol{O}\boldsymbol{N}\boldsymbol{Y}\boldsymbol{M}\boldsymbol{S}$, abbreviations and special terms

ACRONYM/ ABBREVIATION	DESCRIPTION
ABP	Animal By-Products
ADNS	Animal Diseases Notification System
BIP	Border Inspection Post
BDS	Budget allocation Letter
ССА	Central Competent Authority
CVED	Common veterinary entry document for products of animal origin and for live animals
CVO	Chief Veterinary Officer
Debio	Norwegian organisation for organic certification
DPE	Designated Point of Entry
EC	European Community
EEA	European Economic Area
EFTA	European Free Trade Association
ESA	EFTA Surveillance Authority - the Authority
EU	European Union
FBO	Food Business Operator / Feed Business Operator
FCM	Food Contact Material
GMO	Genetically Modified Organism(s)
НАССР	Hazard Analysis and Critical Control Points
EN ISO	International Standards Organisation
IPM	Integrated Pest Management
LBM	Live Bivalve Molluscs
MANCP	Multi-Annual National Control Plan
MANIAP	Multi-Annual National Internal Audit Plan
MARTA	Electronic case handling system for Smiley Inspections
MATS	Electronic operating system for official control
MBM	Meat and Bone Meal
MSM	Mechanically separated meat
MRL	Maximum Residue Limit



ACRONYM/ ABBREVIATION	DESCRIPTION
MS	Member State
NCP	National Contact Point
NFSA	Norwegian Food Safety Authority
NRMP	National Residue Monitoring Plan
NRL	National Reference Laboratory
NMKL	Nordic Committee on Food Analysis
NoMA	Norwegian Medicines Agency
OIE	World organisation for animal health
OV	Official Veterinarian
PONAO	Products of non-animal origin
PPP	Plant Protection Product(s)
PVP	Private Veterinary Practitioner
RASFF	Rapid Alert System for Food and Feed
SOP	Standard operating procedure
SRM	Specified Risk Material
TRACES	TRACES Trade Control and Expert System
TVINN	Electronic customs clearance system
VMP	Veterinary Medicinal products
VKM	Norwegian Scientific Committee