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Norwegian adaptation to seafood quality
legislation at the EU market
– a case of market integration

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About NILF

- Research and analyses on agricultural policy, food industry, commodity trade, economics, farm management and rural development.
- Documentation of economic results in the agricultural sector at national and farm level. This includes serving as secretariat for the Budget Committee for Agriculture and preparing the annual statistics for Account Results in Agriculture and Forestry.
- Develops tools for farm management and accountancy.
- Funded by the Ministry of Agriculture and Food, the Research Council of Norway and through projects for public and private institutions.
- Main office in Oslo; regional offices in Bergen, Trondheim and Bodø.

Foreword

This paper is the outcome of a project entitled “*Quality control of Norwegian seafood export – system and rules*”. The paper shows an example of a governmental system that aims to ensure and to document that exported seafood meets the legal requirements of the export market. The project was headed and completed by the Norwegian Agricultural Economics Research Institute (NILF) following an assignment by the Norwegian College of Fishery Science. The project was funded by Norad (Norwegian Agency for Development Cooperation). Stig S. Gezelius at NILF has been the project leader. The project has benefitted from information and comments from representatives of the Norwegian Food Safety Authority, the Ministry of Fisheries and Coastal Affairs, National Institute of Nutrition and Seafood Research (NIFES), and the Norwegian Seafood Federation (FHL). However, these individuals and institutions are not responsible for any errors or inaccuracies. The author is, naturally, responsible for the quality of the document.

Oslo, November 2009

Ivar Pettersen
Director general

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Extended Summary

Joint international rules for seafood quality

The EU constitutes the main market for Norwegian seafood. Seafood is one of Norway's main export products. Being a non-EU member, Norway is dependent on an efficient system for ensuring access to the EU market. When the EU developed its common market, differences in Norway's and the EU's legal requirements regarding food safety and animal health emerged as a significant obstacle to market access. The trade barrier represented by such different national production and quality requirements can in principle be overcome in three basic ways: *mutual recognition*, which means that states agree to simply accept each other's rules; *equivalence*, which means that the importing state accepts the exporting state's regulations because these fulfil the importing state's regulatory objectives; and *harmonisation*, which means that different states apply the same rules [2].

Norway's strategy for facilitating access to the EU's seafood market is a case of harmonisation through direct adoption of the importing state's rules. Harmonisation is based on the Agreement on the European Economic Area (EEA) between EFTA, consisting of Norway and two other non EU-members, and the EU. The EEA agreement includes Norway in the EU's common market in areas that are covered by the agreement. The EEA agreement ensures that EU rules concerning food safety and animal health are incorporated in Norwegian legislation. The EEA agreement thus entails that law-abiding Norwegian seafood exporters automatically qualify for access to the EU market. A major function of the EEA agreement is that *seafood quality is verified at a national system level*, hence freeing exporters from requirements for quality verification at product level. This means that exporters in EEA countries can ship their products to any other EEA country without food safety and animal health documentation *as if* they shipped these products within their own country. By contrast, exporters in countries outside the EEA will normally have to provide their products with such documentation in order to access the EEA/EU market. The EEA agreement thus entails that the markets of the importer and the exporter are treated as one. This market integration also means that Norway constitutes the EU's extreme border against third countries; Norway enforces the EU's regulations vis-à-vis third countries that export seafood to the EEA/EU market.

Common EEA rules concern food safety and animal health requirements, as well as national implementation of these requirements:

- Rules regarding suitability for human consumption, including
 - Rules regarding hygiene in the treatment of seafood, including
 - procedures for the handling and processing of seafood at all stages
 - equipment and facilities for handling seafood at all stages
 - packaging, canning, labelling and traceability of seafood products
 - Rules regarding inspection of seafood products, including
 - checks for parasites, toxins, and contaminants
 - checks of freshness
 - Rules regarding inspection of facilities for handling seafood, including,
 - fishing vessels

- landing sites, fish plants, food factories, and markets
- storage and transport.

Common EEA rules are also established for animal health matters, including:

- Rules regarding the health of aquaculture animals, including
 - Authorisation and registration rules for aquaculture businesses and processing establishments
 - Controls of aquaculture businesses and establishments
 - Requirements for traceability and records of e.g. animal mortality
 - A requirement for regulations regarding good hygiene, animal movement, treatment and vaccination systems, and marketing practices to avoid spread of diseases
 - A requirement for risk-based animal health surveillance schemes and surveillance plans
 - Animal health certification in relation to the movement of animals between states or specific areas
 - Notification requirements to ensure proper information flow regarding diseases
 - Designation and listing of competent authorities and laboratories, and facilitation of their work.

EU legislation to be adopted in EFTA countries enters the EEA agreement through a constant stream of updates. Updates to the EEA agreement are made through a set of procedures for unanimous decision-making among EEA member states. Ensuring that member states comply with the EEA agreement is an important task under the EEA framework. Consequently, the EEA agreement establishes a specialised body – the EFTA Surveillance Authority (ESA) – that is tasked with monitoring and assessing the EFTA states' compliance with the EEA agreement.

In Norway, the main areas subject to harmonisation with the EU's seafood regulations are governed by the Norwegian Food Act of 2003. This act aims to promote safe food for human consumption, as well as quality, and animal health in all parts of the food production, processing and marketing chains. The Food Act is an enabling act that authorises the government to decide most of the regulatory details. This means that most of the harmonisation is carried out by passing new or amended regulations at ministerial level.

The responsibility for passing Norwegian seafood regulations under the Food Act is split between three Ministries: The Ministry of Agriculture and Food is responsible for regulations that are relevant to farm animal health and regulations that apply specifically to the primary production of agricultural products; the Ministry of Fisheries and Coastal Affairs is responsible for regulations that are relevant to fish health and regulations that apply specifically to the primary production of seafood; the Ministry of Health and Care Services is responsible for food regulations that are relevant to human health after the primary production phase. A number of regulations relevant across ministerial domains are also passed as joint regulations by the three Ministries.

Coordination of regulation and implementation efforts in Norway has been facilitated by the establishment of a joint administrative body responsible for food safety – the Norwegian Food Safety Authority – that serves all three ministries. The Norwegian Food Safety Authority has management responsibility in relation to all Norwegian acts that concern the production and trade of food, including food safety and animal health. It is also responsible for the implementation of harmonised regulations in the seafood sector, including knowledge generation, guidance to the industry, and inspection. The competences of the Food Safety Authority encompass the entire value chain, including

primary production such as fisheries and aquaculture, processing industry, importers, food shops, restaurants, and the practices of veterinary personnel. The Norwegian Food Safety Authority is responsible for preparing regulations to be passed by the ministries, and is also authorised to pass its own regulations in certain cases.

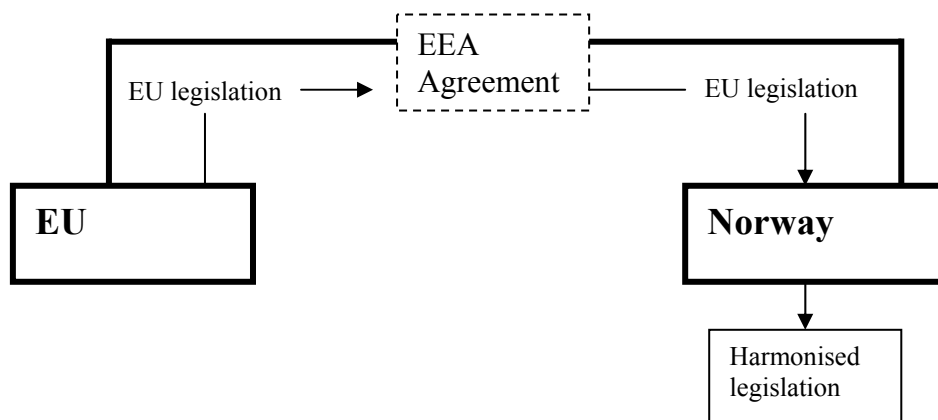


Fig. 1 Establishment of joint international rules

Uniform implementation of uniform legislation

The inclusion of Norway in the EU's common market is based on a system to ensure not only the harmonisation of food safety and animal health requirements, but also harmonised implementation of these quality requirements. In line with the EEA-agreement, the system for Norwegian access to the EU market includes surveillance and control on two levels. First is control performed by Norwegian authorities to ensure that Norwegian businesses comply with the harmonised rules. These control activities are designed and organised according to EU-legislation included in the EEA-agreement. Second are the controls performed by the European Free Trade Association (EFTA) to ensure that Norway's implementation complies with EEA rules.

Norway's system for national control is outlined in EU regulations that are part of the EEA agreement. These regulations establish common rules for EEA countries regarding organisation of national controls, such as inspections, laboratory analyses, and report procedures. EU/EEA regulations state that official controls shall be performed in relation to all parts of the value chain, and require each member state to appoint a *competent authority* that is responsible for these controls. EU regulations require that controls cover all aspects necessary to ensure that the objectives of the legislation are achieved.

Actors at all levels in the seafood industry are subject to control, including, among other things:

- Producers of feed for aquaculture animals.
- Primary seafood producers such as factory- or freezer vessels and fish plants, including their surroundings, premises, offices, equipment, installations, production input products, and their machinery
- Fish buyers
- Storages and transporters.

These controls include checks on:

- Hygiene conditions
- Freshness criteria
- Testing for histamines, residues, contaminants, parasites and micro-organisms.

Controls include the entire processing and marketing chain:

- Raw materials and ingredients used in food and feed production
- Equipment and products that are used in preparation of food products
- Manufacturing procedures
- Labelling, presentation and advertising.

Sampling and analysis are key tasks in relation to many of these control activities. EU regulations establish common rules also in relation to these tasks within the EEA, including:

- Procedures for sampling during official controls and analyses of samples
- Authorisation of laboratories.

Effective controls require reliable registers and procedures for approving food business. EU legislation thus contains joint rules regarding:

- Rules for approval of food production establishments, including factory and freezer vessels
- Registers of approved establishments.

Organising and performing harmonised implementation also requires common standards for planning and enforcement. The EEA-agreement thus contains joint rules for this, including:

- Rules for multi-annual national control plans
- International controls of national controls
- National sanctions against transgressors.

The Norwegian Food Safety Authority is Norway's competent authority in relation to food safety and animal health requirements under the EEA agreement. The tasks of the Norwegian Food Safety Authority thus include rules harmonisation work, planning of control activities, performance of inspections, and approval of and collaboration with laboratories.

According to EEA rules, the Norwegian Food Safety Authority performs risk assessment and inspections throughout the entire food production and marketing chains. The surveillance activities of the Food Safety Authority can be divided into two basic types with regard to both food safety and fish health. First are *surveillance programmes*, the purpose of which is to constantly monitor and to register the state of affairs regarding specific hazards, such as specific toxins or diseases. The surveillance programmes organise the routine-based taking and laboratory analyses of test samples from food production sites. Second are *inspections*, the purpose of which is to monitor regulatory compliance among seafood producers. The Food Safety Authority perform inspections that are required by EEA regulations, including audits, inspections at production sites, and sampling for laboratory analysis. Inspections are performed with and, as required by EEA legislation, without prior warning and are directed at all stages in the food production and distribution chain. Test samples are analysed by laboratories that are

approved and accredited according to EU/EEA standards. In line with requirements of the EEA agreement, the Norwegian Food Safety Authority develops multi-annual risk assessment-based control plans for the organisation of control activities, and also develops emergency plans aimed at handling serious risks to human or animal health.

Norwegian regulations require, in line with EEA rules, that everyone who produces, processes or transports food register by the Food Safety Authority. Agencies that process food, including the freezing of fish catches, are also under license requirements, as are transporters of perishable foodstuffs.

Detected violations of public regulations may result in several different types of sanctions depending on the nature of the offense. The basic and initial reactions are typically administrative compliance measures in the form of a requirement that irregularities are corrected within a given deadline. In cases of immediate threats to human or animal health, the Food Safety Authority applies the measures that are seen as necessary to restore acceptable levels of safety – for example destructing or withdrawing hazardous products from the market, or closing the part of the business that represents the health threat. In cases where food producers do not comply with the Food Safety Authority's requirements, stricter measures, such as coercive periodical payments or closing of business, are applied. In cases where administrative compliance measures do not lead to compliance or the detected violation is especially severe, the Food Safety Authority may report the violation to the police, who may take the offender to court. In that case, the offender may face penalty in the form of fines or, in severe cases, imprisonment.

The market integration system created by the EEA agreement requires that the EU verifies that Norway implements the EU's legislation in a similar fashion as EU countries. This system level quality verification replaces the product quality verification that exporters normally have to go through in the form of food safety and animal health documentation when entering the EU market. The EFTA Surveillance Authority (ESA) is responsible for verifying that Norway's adoption and implementation of the EU's food safety and animal health legislation complies with the EEA agreement. ESA thus controls the implementation activities of Norway's competent authority – the Norwegian Food Safety Authority – on a routine basis. EFTA states are required to notify ESA of their adaptation of national law to EEA rules, and ESA intervenes in cases where EEA rules are not properly adopted by a member state. Cases that are not solved following ESA intervention may be brought before the EFTA court by ESA. ESA also has special responsibilities regarding the national implementation of rules regarding public, animal and plant health, which entails that it performs inspections of implementation practices in member states. ESA collaborates closely with the EU Commission to ensure uniform implementation throughout the EEA, but functions as a separate authority that is formally independent of the EU and the members of EFTA. ESA regularly meets with the Norwegian Food Safety Authority to control that EEA rules are properly incorporated in Norwegian legislation. ESA also inspects the Norwegian Food Safety Authority's control activities to ensure that the practical implementation of EEA rules comply with requirements of the EEA agreement. ESA functions as Norway's final guarantor vis-à-vis the EU that Norway faithfully adopts and implements relevant EU law and, consequently, that Norwegian seafood meets all requirements for marketing in the EU. As a result, Norwegian seafood products are only met with food safety and animal health documentation requirements when these products are processed in the EU for export outside the EEA. The basic features of the system for implementing seafood safety and aquatic animal health requirements are outlined in simplified form in Fig. 2.

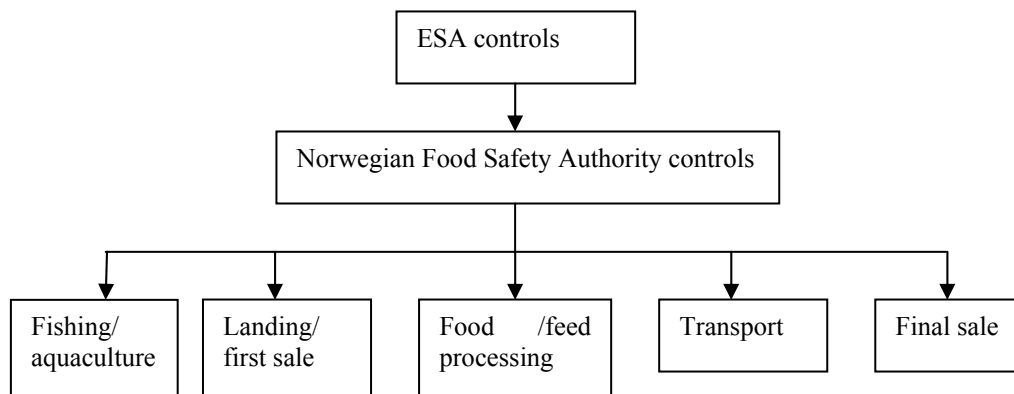


Fig. 2 The system for implementing seafood safety and aquatic animal health requirements

1 Paths to market access

Norway is one of the world's largest exporters of seafood, exporting seafood for 6.2 billion USD in 2008. The EU constitutes approximately 60% of Norway's seafood export market, making it vitally important to the Norwegian seafood industry [1]. Being a non EU-member, Norway is dependent on an efficient system for ensuring access to this market. Norway signed a free trade agreement with the EU in 1972 to reduce import duties. However, when the EU developed its common market, differences in Norway's and the EU's legal requirements regarding food safety and animal health emerged as a significant obstacle to market access. Consequently, Norway needed a way of overcoming this trade barrier. Trade barriers represented by different national production and quality requirements can be overcome in three basic ways: mutual recognition, equivalence, and harmonisation [2].

- *Mutual recognition* means that two states simply agree to accept each other's rules. A mutual recognition agreement thus entails that producers who comply with the regulations of the exporting country, automatically qualifies for access to the importing country.
- The principle of *equivalence* entails somewhat stronger integration between national legislations than mutual recognition. Equivalence entails that the importing state accepts the exporting state's regulations because these fulfil the importing state's regulatory objectives.
- *Harmonisation* represents the highest level of integration between national rules because it entails that different states apply the same rules. There are two main paths towards harmonisation. First are international standards, such as those of the Codex Alimentarius Commission (Codex), upon which states can base their legislations to ensure that they fulfil WTO-accepted requirements [2]. Second is direct adoption by the exporting state of the importing state's rules, which entails the highest level of integration between national legislations.

Norway's strategy for facilitating access to the EU's seafood market is a case of harmonisation through direct adoption of the importing state's rules. This strategy reflects a very high level of interstate integration that is based on the Agreement on the European Economic Area (EEA) of 1994 between the EU, Norway and two other non EU-member states. Norway's access to the EU's seafood market is thus based on the dynamics of a system for current interstate integration rather than a fixed set of unilateral rules and procedures. The EEA agreement entails that the markets of the importer and the exporter are treated as one, meaning that law-abiding Norwegian seafood exporters automatically qualify for access to the EU. A major function of the EEA agreement is that *food safety and animal health are verified at a national system level*, hence freeing exporters from requirements for quality verification at product level. This means that exporters in EEA countries can ship their products to any other EEA country without food safety and animal health documentation *as if* they shipped these products within their own country. By contrast, exporters in countries outside the EEA will normally have to provide their products with such documentation in order to access the EEA/EU market. As a result of the EEA agreement, Norway constitutes the EU's extreme border against third countries in matters of food safety and animal health,

meaning that Norway enforces the EU's regulations vis-à-vis third countries that export seafood to the EEA/EU market. Proper enforcement of rules concerning such third countries is an important element of the EEA agreement because seafood products that are imported to Norway can subsequently be traded freely within EEA. In the following, we will describe the institutions that integrate Norway in the EU's common market, and the specific procedures for food safety and animal health control that pertains to seafood within this common market.

2 Supra national institutions for harmonisation

As the EU developed its single market in the late 1980s and early 1990s, it became evident that the traditional free trade agreement from 1972 no longer constituted an adequate framework for ensuring smooth access to the EU market, especially in terms of ensuring and verifying that Norwegian seafood satisfies EU food safety and animal health requirements. This is one of the main reasons why Norway and two other members of the European Free Trade Association (EFTA) entered into the Agreement on the European Economic Area (EEA) with the EU in 1994. The objective of the EEA Agreement is to strengthen trade relations between EU and the EFTA states by creating a “homogenous European Economic Area” (EEA Agreement: Article 1). The EEA agreement subjects the EFTA states to the ‘four freedoms’ of the EU’s common market: free movement of goods, services, people, and capital among member states. These freedoms entail that quantitative restrictions and customs duties are removed, and that the non-EU members have agreed to adopt EU rules in a number of relevant areas [3,4]. The EEA-agreement thus includes the EFTA states in the EU’s common market in areas covered by the agreement. Although the EU’s Common Fisheries Policy (CFP) is not part of the EEA agreement, food safety and animal health are part of the agreement, meaning that Norway is effectively part of the EU’s common market in these fields [4,5].¹ Norway’s adaptation to quality requirements at the EU market is thus a case of market access through the political construction of common markets. Harmonisation of national legislations is a key element in this common market construction. The harmonised legislation include food safety and animal health requirements, as well as national implementation of these requirements:

- Rules regarding suitability for human consumption [6], including:
 - Rules regarding hygiene in the treatment of seafood, including:
 - procedures for the handling and processing of seafood at all stages
 - equipment and facilities for catch handling and personnel onboard fishing vessels
 - equipment for unloading and landing of catches
 - equipment and facilities for seafood processing and personnel at seafood factories
 - cleaning of facilities for seafood treatment
 - staff hygiene at seafood factories
 - packaging and canning of seafood products
 - storage of seafood products
 - transport of seafood products
 - Rules regarding inspection of seafood products, including:
 - checks for parasites
 - checks for toxins and contaminants

¹ The exclusion of the CFP from the EEA agreement is about to have certain trade implications for Norway: Norway must currently take unilateral steps to adapt to upcoming EU certification requirements that aims to verify that imported fish has been legally caught [25, 26].

- checks of taste, looks, and smell
 - microbiological checks
- Rules regarding inspection of facilities for handling seafood, including:
 - fishing vessels
 - conditions for landing and first sale
 - establishments for seafood processing and treatment
 - wholesale and auction markets
 - storage and transport conditions
- Rules regarding identification, including labelling/documents and traceability of seafood products.
- Rules regarding the health of aquaculture animals, including:
 - Authorisation of aquaculture businesses and processing establishments, including:
 - conditions for authorisation
 - registers of aquaculture businesses and establishments
 - Controls of aquaculture businesses and establishments
 - Recording obligations, including:
 - traceability of movements of aquaculture and aquaculture products
 - animal mortality during production and transport
 - water exchange during transport
 - A requirement for regulations regarding good hygiene practice to avoid spread of diseases
 - A requirement for risk-based animal health surveillance schemes
 - A requirement for marketing aquaculture animals and products in such a way that the health of aquatic animals are not jeopardised
 - A requirement for ensuring that aquaculture animals are healthy when marketed or released into the wild
 - Disease prevention requirements in relation to movement of aquaculture animals, including:
 - rules regarding transport operations
 - requirements regarding place of origin and quarantine
 - Animal health certification in relation to the movement of animals between states or specific areas
 - Disease prevention measures regarding movement of aquaculture products between zones and states
 - Notification requirements, including:
 - notification by sea farmers of relevant national authorities upon mortality increase or suspicions of disease
 - notification among member states upon confirmation of specific diseases
 - Surveillance and control measures to be taken upon suspicions of disease
 - Measures to prevent that detected diseases spread, including:
 - movement of animals
 - protection zones
 - declarations of infected areas
 - treatment systems for inactivation of pathogens
 - removal and disposal of animals and products in infected areas
 - fallowing of emptied infected farming areas
 - Requirements for plans regarding surveillance of the health status of aquatic animals in a given area
 - Requirements for sampling, diagnostic and listing of surveillance areas

- Rules regarding vaccination of aquatic animals
- Designation and listing of competent authorities and laboratories, and facilitation of their work [7].

EU legislation to be adopted in EFTA countries are listed in a series of annexes to the EEA agreement, which means that the EEA agreement remains in function through a constant stream of updates to these annexes. The process of updating the agreement is thus the key element of rules harmonisation among EU and EFTA countries. Updates to the EEA agreement must be done through a set of procedures for unanimous decision-making because the EFTA countries have not transferred formal legislative authority to the EU or the EEA institutions. The EEA Joint Committee – which consists of representatives from the EFTA member states, the EU member states, and the European Commission – is a key agency in this ongoing process of ensuring harmonised legislation. Upon publication of an EEA-relevant act in the EU, the act is sent to the EFTA secretariat which drafts a Joint Committee Decision based on consultations with legal expertise in the EFTA member states and the European Commission. The EEA Joint Commission agrees to include the new act in the EEA agreement following a consensus decision. However, this decision is legally binding on member states only after having been approved by national parliaments. Consultations with parliaments at an early stage are thus an important part of the procedures for ensuring smooth harmonisation [8,9]. The harmonisation process is also facilitated by EFTA members' ability to meet, speak and present relevant documentation, although without voting rights, in EU committees that prepare EEA-relevant legislation [28]. Once harmonised national regulations are established, ensuring that member states comply with the EEA agreement is an important task under the EEA agreement. Consequently, the EEA agreement establishes a specialised body – the EFTA Surveillance Authority (ESA) – that is tasked with monitoring and assessing the EFTA states' compliance with the EEA agreement [8].

3 National institutions for harmonisation

In Norway, the main areas subject to harmonisation with the EU's seafood regulations are governed by the Norwegian Act on Food Production and Food Safety (Food Act) from 2003. This act aims to promote safe food for human consumption, as well as quality, animal health, and environmentally friendly food production. It regulates all parts of the value chain that relate to food safety. The Food Act is an enabling act – typical of the Norwegian legislative tradition – that authorises the government to decide most of the regulatory details. This means that most of the rules harmonisation is carried out by passing new or amended regulations. Consequently, the government's regulatory authority consists of two components: 1) passing regulations that are required to fulfil the intentions of the Food Act, and 2) passing regulations that are required to fulfil Norway's responsibilities according to the EEA agreement [10]. The parliament's delegation of regulatory competences to the government thus entails that most decisions regarding rules harmonisation are taken at ministerial level in Norway. However, decisions with significant consequences regarding national budgets, agreements with other states, or national autonomy must be made by the parliament. The parliament has its own board for European matters which is kept updated on harmonisation issues by the Ministry of Foreign Affairs [11].

The responsibility for passing regulations under the Food Act is split between three Ministries: The Ministry of Agriculture and Food is responsible for regulations that are relevant to farm animal health and regulations that apply specifically to the primary production of agricultural products; the Ministry of Fisheries and Coastal Affairs is responsible for regulations that are relevant to fish health and regulations that apply specifically to the primary production of seafood; the Ministry of Health and Care Services is responsible for food regulations that are relevant to human health after the primary production phase. The legislative competence regarding seafood is thus split between the Ministry of Fisheries and Coastal Affairs and the Ministry of Health and Care Services. This division of legislative competence requires current dialogue in terms of responsibility distribution. A coordination group headed by the Ministry of Food and Agriculture has been established for that task. A number of regulations relevant across ministerial domains are also passed as joint regulations by the three Ministries [12].

Coordination of regulation and implementation efforts has also been facilitated by the establishment of a joint administrative body responsible for food safety – the Norwegian Food Safety Authority – that serves all three ministries. The Norwegian Food Safety Authority has management responsibility in relation to all Norwegian acts that concern the production and trade of food, including food safety and animal health. This includes gathering and analysing relevant knowledge on food safety issues, guiding food producers, and monitoring compliance in the food industry. It also manages a number of registers and certification measures for the food industry: everyone who produces or handles food products is required to report their activity to the Norwegian Food Safety Authority [13]. The competences of the Food Safety Authority encompass the entire value chain, including primary production such as fisheries and aquaculture, processing industry, importers, food shops, restaurants, and the practices of veterinary personnel. The Norwegian Food Safety Authority is responsible for preparing regulations to be passed by the ministries, and is also authorised to pass its own regulations in certain cases [14].

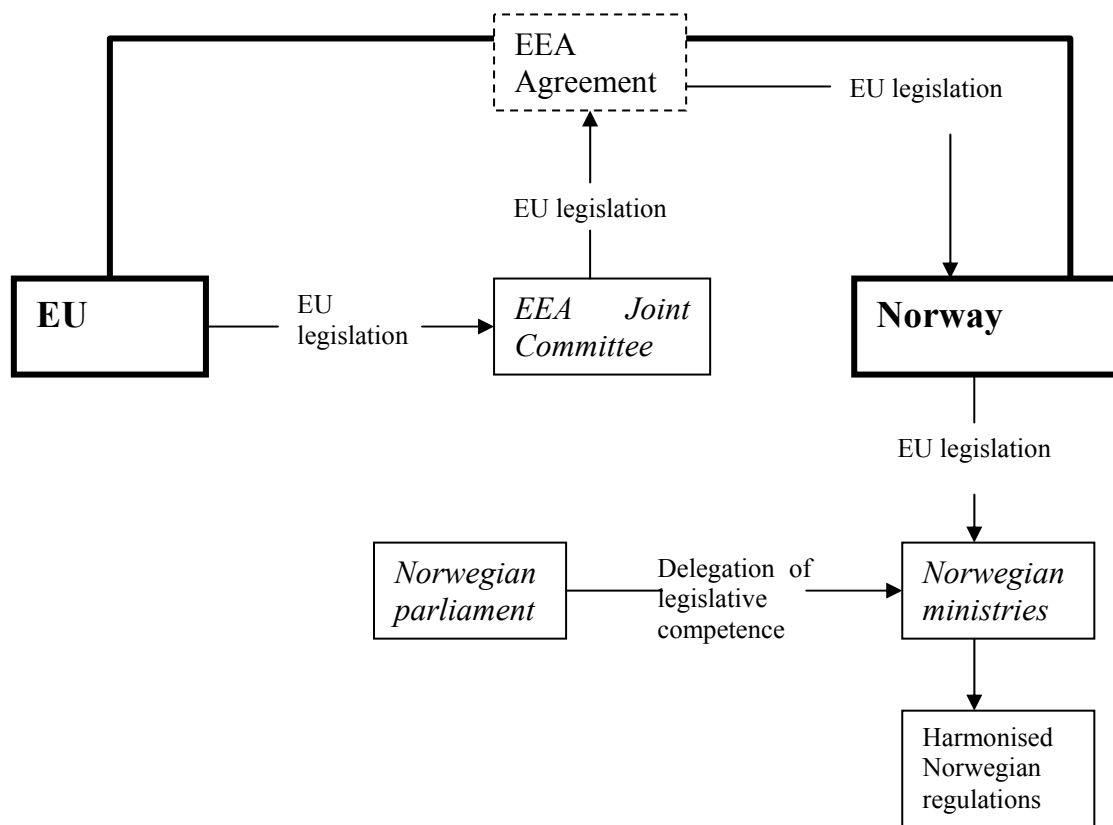


Fig. 3.1 The harmonisation process

The Norwegian Food Safety Authority fulfils key tasks in the process of incorporating updates to the EEA agreement in Norwegian seafood legislation. When the EEA Joint Commission has decided to include a relevant piece of EU legislation in the EEA agreement, the decision is transmitted to the relevant Norwegian ministries which delegate the preparation of harmonised regulations to the Norwegian Food Safety Authority. The Food Safety Authority also manages hearings for all legislation to be included in the EEA agreement to ensure industry influence [15]. The Directorate of Fisheries – which is a separate unit under the Ministry of Fisheries and Coastal Affairs responsible for harvest regulation and practical implementation of fisheries legislation – participates in the Norwegian Food Authority’s preparation of seafood regulations where the two agencies have overlapping implementation responsibilities. The Food Safety Authority prepares seafood regulations that are to be harmonised with EU legislation, and send them to the Ministry of Fisheries and Coastal Affairs – and to other Ministries if appropriate – for final approval. The institutional setup for legal harmonisation is illustrated in simplified form in Fig. 3.1.

4 Harmonised implementation of harmonised rules

4.1 A uniform EEA implementation system

The inclusion of Norway in the EU's common market is based on a system to ensure not only the harmonisation of relevant food safety and animal health requirements, but also the harmonisation of national implementation systems to ensure that these quality requirements are met. In line with the EEA-agreement, the system for Norwegian access to the EU market is based on surveillance and control on two levels. First is control performed by Norwegian authorities to ensure that Norwegian businesses comply with the harmonised legislation. These control activities are designed and organised according to EU-legislation included in the EEA-agreement. Second are the controls performed by the European Free Trade Association (EFTA) to ensure that Norway's implementation activities comply with EEA legislation. In the next section, we will look at the control responsibilities of Norwegian authorities. We will subsequently describe EFTA's control of Norway's implementation.

4.2 Control at national level

Norway's system for national control of seafood safety and aquatic animal health requirements are outlined in EU regulations that are part of the EEA agreement [16-19]. These regulations establish common rules for EEA countries regarding organisation of national controls, such as inspections, laboratory analyses, and report procedures.

EU/EEA regulations state that official controls shall be performed in relation to all parts of the value chain: production of feed and animals, production of food, handling and processing of food, and transport. These regulations require each member state to appoint a competent authority that is generally responsible for national control activities. This competent authority may delegate specific control tasks to other national agencies provided that these satisfy requirements outlined in EU control legislation. The competent authority is also responsible for formulating control instructions in line with EU requirements, developing emergency plans, and documenting official control activities. EU regulations require that controls cover all aspects necessary to ensure that the objectives of the legislation are achieved.

Actors at all levels in the seafood industry are subject to control, including, among other things:

- Producers of feed for aquaculture animals
- Primary seafood producers such as factory- or freezer vessels and fish plants, including their surroundings, premises, offices, equipment, installations, production input products, and their machinery
- Fish buyers and sites for fish landings
- Storages and transporters.

These controls include checks on:

- Hygiene conditions, including the cleanliness of vessels, fish plants, their facilities, equipment and staff
- Compliance with hygiene and temperature requirements
- Random organoleptic checks of fishery products at all stages of production, processing and distribution to verify compliance with freshness criteria
- Samples and laboratory testing of seafood products when organoleptic checks raise doubt about freshness
- Random testing for histamines, residues, contaminants, and parasites
- Microbiological checks.

Controls include the entire processing and marketing chain:

- Raw materials and ingredients used in food and feed production
- Equipment and products that are used in preparation of food products
- Semi-finished products
- Products and items that come into contact with food
- Assessment of procedures for good manufacturing practices
- Labelling, presentation and advertising
- Examination of documents that are relevant to the compliance assessment
- Interviews with feed and food business operators and their staff
- The reading of values recorded by feed or food business measuring instruments, in addition to measurement verification through controls performed with the competent authority's own instruments.

Sampling and analysis are key tasks in relation to many of these control activities. EU regulations establish common rules also in relation to these tasks within the EEA, including:

- Procedures for sampling during official controls and analyses of samples
- National competent authorities' responsibility for appointing laboratories authorised to analyse samples
- National authorities' responsibility for appointing national reference laboratories that shall collaborate with joint EU reference laboratories to ensure harmonised analysis procedures.

Effective controls require reliable registers and procedures for approving food business. EU legislation thus contains joint rules regarding:

- Approval of food production establishments, including factory and freezer vessels, by national competent authorities
- Conditions for renewal, withdrawal, or suspension of approvals
- Registers of approved establishments.

Organising and performing harmonised implementation also requires common standards for planning. The EEA-agreement thus sets joint rules for this, including:

- Mandatory preparation of multi-annual national control plans
- Requirements regarding the contents of national control plans
- Information to the EU Commission regarding national control plans

- Information to the EU Commission regarding implementation of national control plans
- EU controls of national controls
- Joint training of member states' control staffs to ensure harmonised control practices.

Finally, EU legislation establishes joint rules for actions to be taken in cases of non-compliance, including:

- Imposition of sanitation procedures
- Marketing prohibition
- Product recall or destruction
- Suspension or withdrawal of approvals.

The Norwegian Food Safety Authority is Norway's competent authority in relation to food safety and animal health requirements under the EEA agreement. The tasks of the Norwegian Food Safety Authority thus include rules harmonisation work, planning of control activities, performance of inspections, and approval of and collaboration with laboratories. The Norwegian Food Safety Authority thus constitutes the management link between political decisions, the scientific knowledge that is required to implement these decisions, and practical enforcement. The Food Safety Authority interacts with political authorities in developing regulations, is responsible for approving laboratories involved in relevant sample testing, collaborates with scientific communities that perform risk assessment, and perform inspections throughout the entire value chain, as is illustrated in Fig. 4.1.

The Norwegian Food Safety Authority consists of a head office, eight regional offices, and more than 50 district offices. The head office coordinates the regional offices, each of which heads several district offices at local level. District offices are spread all over the country and perform most of the day to day monitoring of compliance in the seafood industry. Inspections constitute the dominant work load for the Food Safety Authority.

The Food Safety Authority basically applies similar principles for surveillance in relation to food safety and fish health. These surveillance activities can be divided into two basic types:

- *Surveillance programmes.* The surveillance programmes are part of the food safety and fish health legislation and are essential to the implementation of EU legislation in the Norwegian seafood sector. The primary purpose of these programmes is to monitor and to register the state of affairs regarding specific regulatory areas. For example, there are surveillance programmes to monitor the presence of toxins in seafood and the presence of diseases among farmed fish. These programmes organise the routine-based taking and laboratory analyses of test samples from food production sites. The Supervision Department of the Norwegian Food Safety Authority is responsible for administrating the surveillance programmes, and has a separate Section for Fish and Seafood that manages the programmes for the seafood sector. Laboratory sample analyses are performed by national reference laboratories listed according to requirements of the EEA agreement. The National Veterinary Institute and the National Institute of Nutrition and Seafood Research (Nifes) are the main national reference laboratories in relation to seafood [20,21].
- *Inspections.* The primary purpose of inspections is to monitor regulatory compliance among seafood producers. The district offices of the Food Safety Authority perform most of the controls that are required by the EEA regulations outlined above, inclu-

ding audits, inspections at production sites, and the taking of samples for laboratory analysis. The seafood producers are legally responsible for complying with seafood regulations, and the inspections performed by the Food Safety Authority serve as the state's main means of enforcement. Inspections are performed with and, as required by EEA legislation, without prior warning and are directed at all stages in the value chain. This includes inspections on fishing vessels, at fish plants, of transport, at storage facilities and markets. Inspectors examine feed, food, premises, gear and machinery, materials in contact with food, hygiene procedures and cleaning materials, written documentation, labels, adverts and other things relevant to the fulfilment of regulatory goals. Inspections include tests regarding histamines, contaminants, parasites, toxins, and examinations of product freshness. Test samples are analysed by laboratories that are approved and accredited according to EU/EEA standards [16-18].

In line with requirements of the EEA agreement, the Norwegian Food Safety Authority develops multi-annual control plans for the organisation of control activities. Control priorities of these plans are based on risk assessment. These plans encompass regular inspections in addition to project-based inspection campaigns directed at specific prioritised topics. These campaigns involve the entire organisation and aim to contribute to the Food Safety Authority's internal coordination in relation to control practices or to respond to specific political priorities or public demands. In line with EEA requirements, the Food Safety Authority also develops emergency plans aimed at handling serious risks to human or animal health. The Food Safety Authority has a standing state of readiness for emergency events, and performs internal practices to prepare for such events [11,22].

In order to perform adequate control, the Food Safety Authority depends on having an overview of actors and locations subject to control requirements. Consequently, Norwegian regulations require, in line with EEA rules, that everyone who produces, processes or transports food register by the Food Safety Authority. Agencies that process food are also under license requirements to ensure that relevant production requirements are met. Fishing vessels that only gut and decapitate fish are only required to register, while processing beyond this point or freezing of catch requires a license from the Food Safety Authority. Transporters of perishable foodstuffs are also under license requirements.

The trend has been for regulations to set general requirements and to leave technical specifics to private standards that may be approved as fulfilling regulatory requirements following evaluation. In the Norwegian seafood sector, there are thus a number of private industry standards regarding food production and production facilities. Food producers who comply with approved standards, and verify this during official controls, are thus also accepted as fulfilling regulatory requirements. While developing and complying with private standards are voluntary, deviance from approved standards requires alternative ways of proving that regulatory requirements are met. Private standards thus relieve regulatory authorities of the responsibility for working out technical solutions, grant the industry a certain freedom regarding implementation strategy, and serve as a private, voluntary interlink between public regulation and private compliance. The role of private industry standards are currently formalised in the EEA agreement's hygiene regulations, requiring that relevant and acceptable industry standards are taken into consideration during the development of public regulations [11]. Dialogue with stakeholders in matters of regulation and implementation is otherwise ensured, among other things, through regular dialogue-meetings between the Food Safety Authority and relevant stakeholders [15].

Detected violations of public regulations may result in several different types of sanctions depending on the nature of the offense. There are two basic types of sanctions applied in Norway's enforcement of food law:

- First are penalties such as fines or imprisonment. Penalties are imposed by the court following prosecution by the police or, in the case of fines, by police decision provided that the offender consents. Norwegian public administration, including the Norwegian Food Safety Authority does not have prosecuting authority, so detected violations perceived as qualifying for legal penalty are reported to the police who investigates the case and may raise a court case.
- Second are administrative compliance measures. These measures do not have status as legal penalty and, consequently, can be employed by the state administration. The main difference between penalty and an administrative compliance measure is that the latter, as a general principle, do not impose costs on the offender that extends beyond that which is necessary to ensure that the law is complied with. An administrative compliance measure would, in most cases, end the very moment the rule is complied with. The Norwegian Food Safety Authority has a number of administrative compliance measures, some of which are required by the EEA. Norwegian administrative measures include: requirements for withdrawal of goods from the market, destruction or confiscation of illegal products, killing of infected animals, suspension or withdrawal of licences, closing of businesses in whole or in part, and coercive periodical payments to enforce deadlines.

The enforcement system outline above may be understood as a "sanction ladder", where the basic and initial reactions typically are administrative compliance measures in the form of a requirement that irregularities are corrected within a given deadline. In cases of immediate threats to human or animal health, the Food Safety Authority applies the measures that are seen as necessary to restore acceptable levels of safety – for example destructing or withdrawing hazardous products from the market, or closing the part of the business that represents the health threat. In cases where food producers do not comply with the Food Safety Authority's requirements, stricter measures, such as coercive periodical payments, or closing of business are applied. In cases where administrative compliance measures do not lead to compliance, or the detected violation is especially severe, the Food Safety Authority may report the violation to the police who may take the offender to court. In that case, the offender may face penalty in the form of fines or, in severe cases, imprisonment. Penalties may be imposed on individuals as well as businesses [10,23].

4.3 International monitoring of Norway's implementation

The market integration system created by the EEA agreement requires that the EU verifies that Norway implements the EU's food safety and animal health legislation in a similar fashion as EU countries. This system-level quality verification replaces the product quality verification that exporters normally have to go through in the form of food safety and animal health documentation when entering the EU market. Given that food safety and animal health is documented at system level within the EEA, exporters can ship their products within the EEA *as if* they shipped these products within their own country.

The EFTA Surveillance Authority (ESA) is responsible for verifying that Norway's adoption and implementation of the EU's food safety and animal health legislation

complies with the EEA agreement. ESA thus controls the implementation activities of Norway's competent authority – the Norwegian Food Safety Authority – on a routine basis [15]. ESA is headed by a board consisting of one member from each EFTA member state, and has a staff of some 60 employees. ESA's main task is to ensure that EEA rules are properly adopted and implemented by the EFTA states. EFTA states are required to notify ESA of their adaptation of national law to EEA rules, and ESA intervenes in cases where EEA rules are not properly adopted by a member state. Cases that are not solved following ESA intervention may be brought before the EFTA court by ESA. ESA also has special responsibilities regarding the national implementation of rules regarding public, animal and plant health, which entails that it performs inspections of implementation practices in member states. ESA collaborates closely with the EU Commission to ensure uniform implementation throughout the EEA, but functions as a separate authority that is formally independent of the EU and the members of EFTA [24].

ESA performs two types of control in relation to the Norwegian Food Safety Authority:

- First are meetings between ESA and the Regulations Department of the Food Safety Authority in order to control that EEA rules are properly incorporated in Norwegian legislation.
- Second are inspections by ESA of the Food Safety Authority's control activities in order to ensure that the practical implementation of EEA rules comply with requirements of the EEA agreement. Every year, ESA selects certain topics subject to control and notifies the Norwegian Food Safety Authority on these topics. Subsequently, ESA performs physical inspections, checking that the Food Safety Authority has adequate control routines. A typical area for ESA inspection is Norway's border controls of food imports from 3rd countries, which is considered to be important because this food can subsequently be traded freely within the entire EEA area. ESA also inspects, for example, the Food Safety Authority's inspections at Norwegian food production sites.

The EEA agreement requires that national controls of products exported to the EU are equally strict as those concerning products for national consumption. Given the harmonisation of Norwegian and EU regulations concerning product quality and control, the implementation system in principle ensures that the Norwegian seafood industry keeps to EU rules. ESA functions as Norway's final guarantor vis-à-vis the EU that Norway faithfully adopts and implements relevant EU law and, consequently, that Norwegian seafood meets all requirements for marketing in the EU. As a result, Norwegian seafood products are only met with food safety/animal health documentation requirements when these products are processed in the EU for export outside the EEA [11,16,18,22].

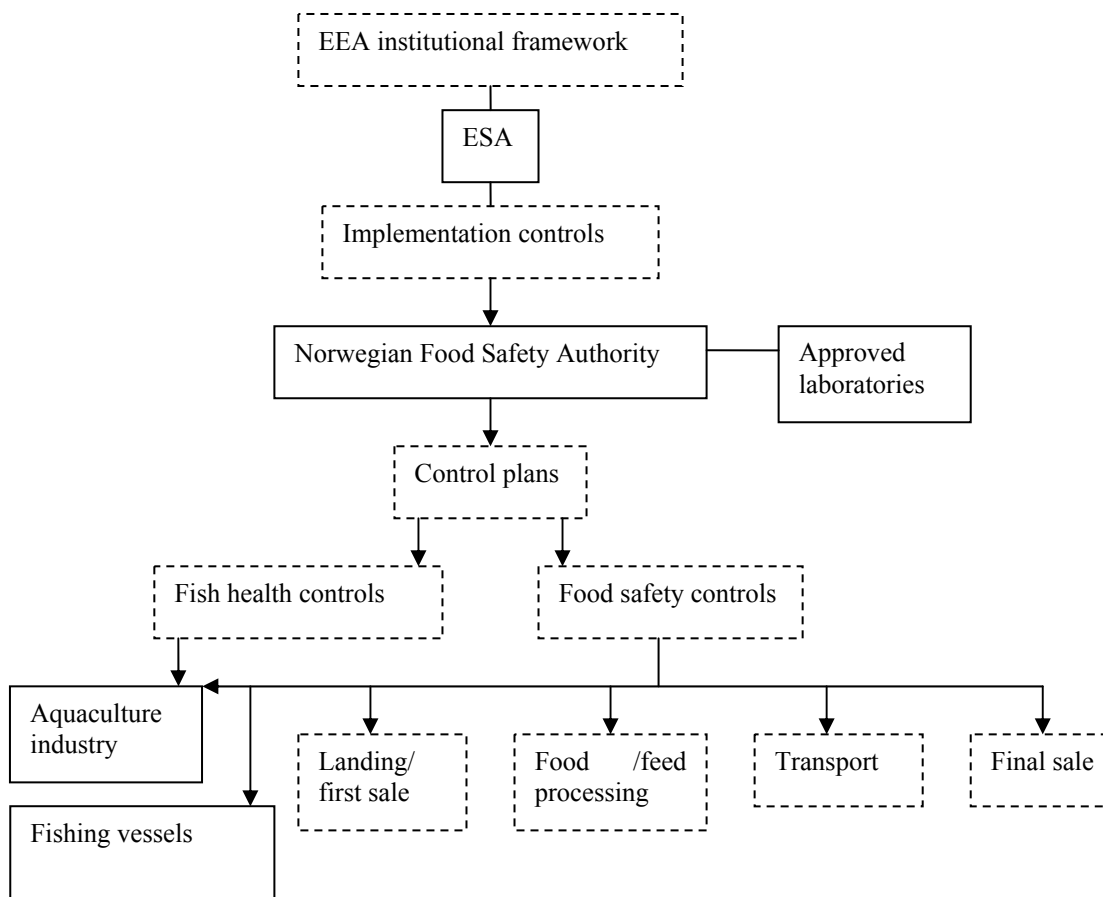


Fig. 4.1 The system for implementing seafood safety and aquatic animal health requirements

The basic features of the system for implementing seafood safety and aquatic animal health requirements are outlined in Fig. 4.1. Dotted boxes signify procedures and outcomes, while solid boxes signify organisations. Lines signify institutional ties, while arrows signify procedures.

The ability of the quality control system outlined above to ensure market access depends on the EEA-agreement. Hence, third countries that faithfully adopt a quality control system equal to Norway will still face food safety and animal health documentation requirements when trying to enter the EU market.² However, recalling the alternative paths to market access listed in the introduction to this paper, unilateral harmonisation of rules and implementation practices is a way of facilitating market access through either equivalence agreements or mutual recognition agreements.

² The EU has developed documents to guide importers who wish to import goods from third countries [27]. The European Commission Food and Veterinary Office, Programme of Audit and Inspection (FVO), sends inspection teams to third countries who wish to export food to the EU. FVO reports are publicly available [28, 29].

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