European Commission

DG Health and Food Safety

Overview report

Implementation of the Rules on Finfish Aquaculture

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OVERVIEW REPORT
OF A SERIES OF FACT-FINDING MISSIONS
CARRIED OUT IN 2014 AND 2015
ON THE IMPLEMENTATION
OF THE RULES ON FINFISH AQUACULTURE

Executive Summary

Aquaculture represents a growing contributor to the production of aquatic food worldwide. Most fisheries in the world are currently just below sustainable exploitation limits. In parallel, global consumption of fish as food has doubled in the last twenty years and is expected to continue to rise.

In the European Union (EU), aquaculture production is an important economic activity in many coastal and continental regions but has remained stable in recent years. The current reform of the Common Fisheries Policy aims, inter alia, to develop the full potential of EU aquaculture in line with the Europe 2020 objectives: sustainability, food security, growth and employment. In addition, the EU's high standards both facilitate intra-EU trade and create opportunities for European businesses to compete on the global market. High levels of safety are fundamental to stable markets and consumer confidence and also protect Europe from the economic and human costs of disease outbreaks.

This report describes the outcome of a series of fact finding missions to Member States and Norway carried out between September 2014 and November 2015, with the principal aim of providing an overview of how EU legislation on aquaculture is implemented. An analysis of the findings and conclusions is intended to provide a solid basis on which to identify what is working, or not working, in relation to the enforcement of controls and the interpretation of legislation and in addition will facilitate the identification of areas which could benefit from a simplification exercise and greater flexibility, particularly for small to medium sized enterprises.

This report concludes that official controls are in general implemented with a high level of expertise, and support the development of the sector as a whole. However, a number of issues were found in key areas, in particular:

- *Registration and authorisation procedures can be complex, suffer delays or be misinterpreted, affecting the development of the aquaculture sector and the overview of its health status by competent authorities.*
- *The legal framework for the movement of farmed fish is not yet robust enough due to a lack of clinical checks prior to certification, and the difficulties in reliably verifying the health status of dispatch and recipient farms.*
- *Variations in the degree of expertise of competent authorities affect their capability to detect health problems during official controls.*
- *Passive surveillance can be of limited effectiveness in terms of early detection of diseases in particular due to a lack of common approach to the concept of significant increase of mortality.*
- *The limited availability of veterinary medicinal products has led to suboptimal treatment of certain diseases and has potential to increase antimicrobial resistance.*
- *The new consumer information requirements have been poorly understood resulting in confusion or incomplete information at point of sale.*
- *The development of the organic sector is restricted by limited availability of suitable organic feed.*

This report also highlights a number of good practices with a view to sharing with all parties involved in the aquaculture sector.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AAH	Aquaculture Animal Health
APB	Aquaculture Production Business
AMR	Anti-Microbial Resistance
BTSF	Better Training for Safer Food
CA	Competent Authority
CB	Control Body
DG	Directorate General
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EN	European Norm
EU	European Union
EURL	European Union Reference Laboratory
FAO	Food and Agriculture Organisation of the United Nations
GM	Genetically modified
ISO	International Standards Organisation
MS	Member State/s
OIE	World Organisation for Animal Health
PAP	Processed Animal Protein
VMPs	Veterinary Medicinal Products

1 INTRODUCTION

This report describes the outcomes of a series of fact-finding missions which was undertaken between 2014 and 2015 as part of the published DG Health and Food safety audit programme. The series consisted of eight fact-finding missions to Member States and additionally DG Health and Food Safety participated as observers in a similar mission to Norway in June 2015 led by the European Free Trade Association (EFTA) Surveillance Authority as part of its planned series of audits.

This series was carried out in agreement with the Member States and EFTA competent authorities.

2 OBJECTIVES AND SCOPE

The primary objective of the fact-finding series was to gain a broad overview of the structure and variety of aquaculture finfish production in Europe both seawater and fresh water and the degree to which EU legislative requirements concerning food safety, food quality, animal health and animal welfare standards are being achieved in aquaculture.

The information gathered during the mission series also aims at identifying and disseminating to representative organisations good practice in this sector. In addition, by identifying issues which are affecting this important economic sector, a contribution can be made to EU 2020 on "Blue Growth" and to the EU Commission's Strategic Guidelines for the Sustainable Development of EU Aquaculture[1].

The conclusions which are detailed in this overview report of the series will assist in the identification of proposals for future EU policy covering animal health, public health and consumer information, and in the planning of future DG Health and Food Safety activities for this important sector.

In terms of scope the mission team focused on:

- Aquaculture finfish production businesses (APBs), i.e. own-checks and official controls on:
    - Public health requirements at farm level.
    - Input of roe, fry, fingerlings, fish source domestically through intra-EU trade and imports.
    - The use of veterinary medicinal products (including medicated feed).
    - Input and use of feed (including processed animal protein (PAP)).
    - Movement of live fish on / off the farm (to other farms and processors).

[1] COM (2013)229 final – Communication from the Commission to the European parliament, The Council, The European Economic and Social Committee and the Committee of the Regions - Strategic Guidelines for the sustainable development of EU aquaculture (29.4.2013).

  - Health status (checks, records, biosecurity, animal health programmes etc.).
  - Organic status of aquaculture products.
- Traceability and labelling from farms through establishments to retail level.
- Import of aquaculture products from non-EU countries and traceability and labelling of such products.

Full references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version.

3 BACKGROUND

Seven principal factors defined the rationale for this series:

- EU finfish aquaculture industry produces almost 700,000 tonnes of finfish and together with other EFTA countries produces over 2 million tonnes. Aquaculture production employs over 85,000 people throughout the EU and constitutes an important source of income for persons working in the sector.
- Previous audits included different elements of the scope of this mission series in a piecemeal approach, but no audits or missions took place which aimed at gathering information on the procedures for all aspects of finfish aquaculture within the scope of this mission series.
- Council Directive 2006/88/EC contains three primary pillars aimed at reducing severe economic losses caused by disease outbreaks including:
  - animal health requirements for placing on the market,
  - minimum preventive measures aimed at increasing the awareness and preparedness of the CAs, aquaculture business operators and others related to the industry, for diseases in aquaculture animals; and
  - minimum control measures to be applied in the event of a suspicion, or an outbreak, of certain diseases in aquatic animals.
- Regulation (EC) No 178/2002 of the European Parliament and of the Council requires MS to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.
- Failures at any stage in the feed chain can have important economic consequences and it is necessary to safeguard public health from any dangers arising from the use of medicated feedingstuffs for animals intended for human consumption.
- The EU legal framework governing the sector of organic production pursues the objective of ensuring fair competition and a proper functioning of the internal market in organic products, and of maintaining and justifying consumer confidence in products labelled as organic.

- Importantly EU legislation is intended to be flexible to take account of the continuing developments in and diversity of the aquaculture sector for all the areas covered by this mission series.

Production overview

Annex III provides an overview of current production data for the main finfish species farmed in each Member State. Salmonid species such as Atlantic salmon and rainbow trout make up almost 60% of total production and are in the case of salmon species farmed in cold water marine in northern Europe whereas trout production is more widely produced. The other main carnivorous farmed species included sea bream and sea bass which make up a further 25% with production centred in the Mediterranean waters. Carp production accounts for 10% of overall production and is extensively cultivated primarily in fresh water ponds in central Europe. Other important minor species include the production of turbot, European eel and sturgeon for caviar production. Norway is currently producing over 1.3 million tonnes of Atlantic salmon, and 75,000 tonnes of large rainbow trout, all of which is farmed in marine based production units offshore.

Better Training for Safer Food (BTSF) workshop

Following on from the series of fact-finding missions a workshop was held on 8-10 March 2016 in the framework of the training programme BTSF. The objective was to discuss the key findings of the series of visits with experts from 22 MS, including 14 countries which were not visited during the mission series. The main goal of the workshop was to encourage participants and their respective CAs to:

- take ownership of the findings and conclusions of this fact-finding mission series and to use them to improve their official control activities;
- gain an insight into good practices elsewhere in the EU and how such practices might be adopted in their own situation, possibly with modification to national structures and organisation of controls;
- discuss weaknesses and recurring problems with a view to identifying possible root causes and solutions to remedy or alleviate the problems.

Representative organisation feedback

For each of the countries visited a number of meetings were held with the sector representative organisations to gather information on issues which the members had encountered with the implementation of legislation.

4 OVERVIEW OF MAIN FINDINGS AND CONCLUSIONS

4.1 ORGANISATION

EU legislation set out in Regulation (EC) No 882/2004 of the European Parliament and of the Council requires that official controls should meet a number of operational criteria so as to

ensure their impartiality and effectiveness, and that there should be sufficient number of suitably qualified and experienced staff, and possess adequate facilities and equipment to carry out their duties properly. In addition, official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality.

All countries visited have developed management structures and operational groups to implement aquaculture legislation. In general, in each country visited there was one or two primary CAs responsible for the area of finfish aquaculture. Within the CAs, specific units or Control Bodies (CBs) are responsible for dealing with controls on aquaculture animal health and welfare, veterinary medicines, feed production including controls on medicated feed, organic production and labelling and traceability.

Additional authorities (e.g. the Ministries of Health and Environment) are responsible for coordinating actions relating to labelling and traceability at retail level and for environmental impact assessments relating to the overall licensing of APBs.

The following point is considered of particular relevance

- With regard to the requirement that there be a sufficient number of suitably qualified and experienced staff in place it was noted in a number of instances that there was limited access to specific expertise on risk assessment and epidemiology of fish diseases due to a lack of specialised official staff which reduced the effectiveness of official controls.

Examples of good practice

- There was a significant reduction in the number of official visits to farms when inspections from several different authorities were combined in one on-site visit covering all aspects of aquaculture legislative requirements.
- The establishment of additional quality assurance mechanisms for official controls adds to the overall confidence in Aquaculture Animal Health (AAH) control and assisted in ensuring a harmonised and consistent approach to its official control responsibilities.

Conclusions on organisation

- In general the CAs designated for official control of the aquaculture production chain have clear areas of responsibility as well as structures, organisation, and legal powers that provide a solid basis for official controls and enforcement.

4.2 COOPERATION

Regulation (EC) No 882/2004 requires that MS should ensure that where different responsible authorities are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented, and that these procedures extend to cooperation of the CAs in and between the MS.

All countries visited had similar types of management structures comprising different levels (from central to local governmental level) and the cooperation between the CAs at all levels was a general legal requirement.

All but one of the countries visited had various plans/procedures in place describing cooperation within and partly also between different CAs. However, these individual plans did not always describe their interoperability with each other.

The majority of countries visited had high level agreements to promote coordination and information sharing between the responsible services. In practice these were implemented in a variety of ways, from ad-hoc and regular operational level meetings to annual stakeholder meetings, which provide a forum for discussion of major policy issues (including contingency planning) and liaison between the different CAs, industry and interested bodies.

<u>The following points are considered of particular relevance</u>

- The exchange of information following notifications for disease outbreaks did not always work as intended, particularly in regionalised MS, or between regions where there is a high level of autonomy with the consequence that disease outbreaks were not properly followed up.
- The application by regional services of centrally prepared information was poor in some instances, and additionally there was sometimes no mechanism in place to ensure the sharing of information on measures which had been adopted by individual regions to implement guidance from central level. In such cases this led to a duplication of work and to different approaches by the same CA.

Examples of good practice

- Regular communication about disease prevention between official control services, operators and private veterinary practitioners heightened awareness and reduced spread of diseases during outbreaks.
- CAs who facilitated annual stakeholder meetings ensured that the discussion of major policy issues (including contingency planning) took place and also encouraged better liaison between the different CAs, industry and interested bodies.

Conclusions on cooperation

- Generally cooperation was good but weaknesses were noted in some countries visited particularly those regionalised MS where additional efforts are still necessary to increase the levels of coordination of all relevant control activities in the context of this mission scope.

4.3 TRAINING

In most MS, staff performing official controls were trained for their area of competence, as required in Article 6 of the Regulation (EC) No 882/2004 and were actively involved in ongoing training.

The following points are considered of particular relevance

- While in some MS official inspectors worked only with fish health, it was generally the case that the main tasks for inspectors related to other farm animals and consequently they only carried out occasional visits to fish farms. The consequence of this was that many inspectors found it difficult to recognise signs of fish diseases or to carry out post mortem examinations on site to investigate health problems.
- Many inspectors had received training through BTSF or other specific courses on aquaculture but not all official inspectors performing official controls and animal health surveillance in fish farms had the necessary training, experience and expertise to carry out effective risk-based animal health surveillance. This reduces the effectiveness of passive surveillance for listed and emerging diseases.
- None of the countries visited set minimum qualifications and experience for inspectors responsible for risk-based animal health surveillance scheme required under Article 10 of Directive 2006/88/EC, with the consequence that some MS consider any qualified veterinary practitioner suitable. This reduced the effectiveness and value of official controls in some cases due to lack of specialisation.
- It was noted that while some official inspectors have participated in courses on AAH within the framework of BTSF, there is no system in place to ensure that the learning from the BTSF is disseminated within their organisation.
- In some countries, gaps were observed with regard to training on specific issues such as on how to certify the correct fish health status for Intra-Union trade.
- The availability of post-graduate courses on fish diseases was the exception in most MS visited, which contributed to the lack of specialised staff in some MS.

Examples of good practice

- The compulsory induction and continuous training of fish health inspectors helps ensure that inspectors are properly trained and kept up to date on all aspects of their work.

Conclusions on training

- While many of the responsible officials interviewed during the visits showed a high level of competence and familiarity with the legislation for Aquaculture Animal Health (AAH), there was in some instances a lack of experience and expertise which undermined the effectiveness of official control visits by some inspectors.
- There is a lack of minimum qualifications and level of experience for inspectors responsible either for official controls under Article 7 or for the health surveillance scheme required under Article 10 of Directive 2006/88/EC, to ensure a more harmonised and effective official controls.

4.4 REGISTRATION/AUTHORISATION PROCEDURES OF AQUACULTURE PRODUCTION BUSINESSES

4.4.1 Aquaculture licensing

Aquaculture takes place in coastal and inland waters throughout the EU. Typically, public authorities own these waters and allocate concessions or licences to aquaculture operators, but there is no harmonised approach to EU aquaculture licencing, and no provision for such in EU law.

In common with the findings of the European Court of Auditors report on the effectiveness of the European fisheries Fund support for aquaculture[2], it was also found overall that the licensing systems developed at MS level could be lengthy and costly; that legislation and administration are complex and overlapping and outcomes uncertain; and that the period of validity of licences was in many cases too short thus limiting long term planning and investment.

It was also noted that on environmental matters there was very little guidance at national level to assist operators navigate the main policy areas set out in the EU's water framework directive[3], marine strategy framework directive[4], environmental impact assessment directive[5]

[2] Special Report n° 10/2014: The effectiveness of European Fisheries Fund support for aquaculture

[3] Directive 2000/60/EC establishing a framework for Community action in the field of water policy

[4] Directive 2008/56/EC of establishing a framework for Community action in the field of marine environmental policy

[5] Council Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment

and habitats ('Natura 2000') directive[6], which again led to uncertainty for operators in the MS visited.

The following points are considered of particular relevance

- The procedure for granting maritime concessions and other authorisations for aquaculture took several years in practice for a number of the projects reviewed during the course of visits to MS.
- In some countries the length of time offered for concessions for fresh water production can be as little as 5 years, which created uncertainty for APBs in particular given that each new concession must be tendered for.
- While Directive 2006/88/EC provides that authorisation should, where possible, be combined with or included in an authorisation regime which the MS may already have established for other purposes, for example under environmental legislation, this in practice was rarely the case in most MS visited.

4.4.2 Fish health authorisation

In order to enable the CAs to establish a complete overview of the aquaculture industry, which would assist in the prevention, control and eradication of aquatic animal diseases, a system of authorisation is required in each MS.

EU legislation also recognises the need for flexibility in the application of Article 4 of Directive 2006/88 taking into account the nature, characteristics and location of the APB, and the risk of spreading aquatic animal diseases to other populations of aquatic animals as a result of its operation. In such cases MS may, in accordance with Article 4(4) of the said Directive, require only the registration by the CA where aquatic animals are kept without the intention of being placed on the market; for put and take fisheries[7]; and APBs which place aquaculture animals on the market solely for human consumption through the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer as defined in Article 1(3)(c) of Regulation (EC) No 853/2004 of the European Parliament and of the Council.

In order to improve the prevention of the occurrence and spread of the diseases listed in Directive 2006/88/EC, MS should establish, keep up to date and make publicly available a register of aquaculture production businesses and authorised processing establishments containing at least the information set out in Annex II of the said Directive, but especially on species kept and their health status. In addition, to facilitate the interoperability of these information systems, the Annex to Commission Decision 2008/392/EC describes a model layout for an internet-based information page.

In general it was found that AAH authorisation of APBs is site-specific, follows transparent

[6] Council Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora

[7] 'put and take fisheries' means ponds or other installations where the population is maintained only for recreational fishing by restocking with aquaculture animals.

procedures, and covers most types of aquaculture businesses.

All MS visited inspected new farms but the requirements sometimes varied within the MS due to a lack of national standards or guidelines concerning biosecurity, what are epidemiological units, and requirements relating to record keeping.

In most MS the online registers of aquaculture farms were neither kept up to date by the CAs, nor user-friendly due to language barriers and a lack of search functions.

<u>The following points are considered of particular relevance</u>

- In some MS the authorisation procedure and categorisation of APBs was significantly delayed with the result that the CA did not have a complete overview of the health and risk profiles of APBs.
- Some MS considered existing farms which had been operating prior to the adoption of current aquatic health legislation as being authorised, without any further inspections/checks.
- A number of MS had not yet a coordinated country-wide approach to the authorisation process, as no harmonised guidance or instructions have been agreed. As a consequence, different approaches were found within the MS visited in relation to the evaluation and need for biosecurity standards, contingency plans and policies on prevention of animal health risks.
- Many MS have used blanket derogations for 'put and take fisheries' without necessarily taking the risks associated with each operation into account. In addition, three MS applied the option for derogation laid down in Article 4(4) of Directive 2006/88/EC for small/medium sized APBs producing 'small' amounts of fish for the local market. However, these derogations did not take into account the limitations defined in Article 1(3) (c) of Regulation (EC) No 853/2004 ("direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer"). It was noted that in all three cases limitations or guidance had not been defined and it was left to local services to interpret the rules.
- In most cases where a derogation was granted, this meant that the site was neither subject to scheduled visits and sampling nor were the APBs required to apply biosecurity measures, or be under the care of a private veterinary practitioner.
- In one MS the authorisation was not site specific but could include farms on several different sites under the same authorisation number.
- In some MS there were unknown numbers of small family farms, which were producing for their own needs, and which were not subject to registration or any form of risk assessment. Such farms sourced their fish from authorised farms without being registered as recipients of fish in the records on the authorised farm.

Examples of good practice

- Comprehensive and user-friendly information on AAH rules, authorisation procedures, biosecurity and aquatic animal diseases publicly available on a dedicated website.
- One-stop-shop for licensing applications, thus avoiding the bureaucracy of dealing with multiple administrations. This approach involves a simplification of the process where applicants for aquaculture licences send one application form to a defined responsible administration. This service then sends the application to relevant sector authorities, and after receiving the invited comments, makes the final decision on the application. Each sector authority has a time limit for submitting its comments on the application and for granting or refusing in accordance with the legislation under its responsibility.

Conclusions on registration/ authorisation procedures

- The overall licensing procedures, (which include planning permission, environmental impact assessment and appropriate assessment for Natura 2000 sites[8]) are in general very complicated, unpredictable, and lengthy. The involvement of multiple authorities in licensing and supervision, especially with respect to site licensing, is also hindering the development of this sector.
- In general AAH authorisation of APBs is site specific, follows transparent procedures, covers all types of aquaculture businesses and is carried out in line with requirements in EU legislation. However, delays in some MS mean that official services do not have a complete overview of the health status of the sector.
- The online national register of farms which was intended to provide up to date information for official services and APBs trading animals and products is not achieving its intended objective, and consequently is seldom used as was intended.
- The rules laid down in Article 4(4) of Directive 2006/88/EC, which allows simple registration rather than full authorisation of aquaculture farms under certain conditions, have not been properly understood in some MS with the result that some operators are exempt from certain controls and requirements without the potential risks having been properly assessed.

4.5 PRIMARY PRODUCTION (HATCHERIES AND FARMS)

4.5.1 Movements and intra-EU trade

Directive 2006/88/EC provides that the placing on the market of aquaculture animals is subject to animal health certification set out in Regulation (EC) No 1251/2008 when the animals are introduced into a country, zone or compartment declared disease-free or subject

[8] Natura 2000 is a network of core breeding and resting sites for rare and threatened species, and some rare natural habitat types which are protected in their own right. It stretches across all 28 EU countries, both on land and at sea. The aim of the network is to ensure the long-term survival of Europe's most valuable and threatened species and habitats, listed under both the Birds and Habitats Directive 92/43/EEC.

to a surveillance or eradication programme.

In order not to jeopardise the health status of the place of destination or sites during transport, operators must ensure that the necessary disease prevention measures are applied at all stages including any water exchange points.

Placing of fish in intra-EU trade was found to be subject to the general requirements laid down in Chapter III of Directive 2006/88/EC and animal health certification requirements for placing on the market of aquaculture animals laid down in Chapter III of Regulation (EC) No 1251/2008. In addition, all MS had set up an effective import control system in order to ensure compliance. In MS visited, imported consignments of live fish were relatively few and compliance with international certification procedures had been high.

A lack of clinical checks prior to certification for intra-EU trade (found in some MS) was compounded by the difficulties in reliably verifying the health status of the dispatch farm. Information about the health status of the recipient farm was sometimes obtained from the owner and sometimes from veterinary authorities at destination. The publicly available registers were not always considered reliable or fit for purpose by the certifying officials. In some countries, health declarations on intra-EU trade certificates were rarely verified by official controls or supervised/audited by the central CAs.

Movements as well as vehicles used for live fish were generally recorded on the farm and controls on such records were mainly included in official controls. Most movement records checked on the farms visited included all relevant information, and inspection reports covered all requirements.

<u>The following points are considered of particular relevance</u>

- In one MS all movements of aquaculture fish/fish eggs within the country, as well as any introduction from outside, must be pre-approved, and in the case of dispatches the APB must also provide a report from a clinical inspection carried out by a veterinarian not more than six weeks prior to the movement.
- In some instances it was found that checks on the health declarations in intra-EU trade AAH certificates were not included in official controls.
- In one MS certain paperwork to authorise movements between APBs within the MS was completed and signed by the same operators who had a direct commercial interest in fish being moved.

Examples of good practice

- TRACES notifications for all movements of live fish are verified to ensure that the movement has been pre-approved in line with national requirements thus ensuring that health status of the recipient and dispatch farm is correctly assessed.

Conclusions on movements and intra-EU trade

- The legal framework for safe movements is in place but the system is not yet robust and reliable. In particular, a lack of clinical checks prior to certification, and difficulties in reliably verifying the health status of the dispatch farm, as well as finding information about the health status of recipient farms weakened the animal health measures related to movements of fish in many MS visited.

4.5.2 Official controls and fish health surveillance

Directive 2006/88/EC envisages two types of inspection of APBs which include official control inspections (Article 7), and inspections under animal health surveillance schemes (Article 10) carried out by officials or by qualified aquatic animal health services. The objective of both of these types of inspection is to detect any increased mortality at farm level appropriate for the type of production, as well as to detect listed diseases on farms where species susceptible to those diseases are present. In addition, the animal health surveillance inspections should aim at advising the aquaculture production business operators on animal health issues, and where needed, at undertaking the necessary veterinary measures. The net result should be for official services to have a complete overview of the aquatic animal health situation and to achieve early detection of emerging and listed fish diseases.

The Annex to Decision 2008/896/EC provides guidelines for MS for risk-based animal health surveillance schemes referred to in Article 10 of Directive 2006/88/EC. These guidelines cover the records which should be analysed during inspections by qualified aquatic animal health services with particular attention being paid to the mortality records, in order to enable an assessment to be made of the health status track-record of the farm. This decision also provides guidance on the determination of the risk level of farms and the frequency of inspection. Furthermore, in line with Point 2.2 (3) of the Annex to Decision 2008/896/EC MS should determine whether the inspections which are part of the risk-based animal health surveillance schemes (Article 10) are to be carried out by the CA or whether private veterinarians or other qualified AAH services should also be permitted to carry them out.

In general, AAH is subject to official controls according to Article 7 of Directive 2006/88/EC, with a planned frequency often higher than the minimum recommended in Part B of Annex III to Directive 2006/88/EC. Official services often indicated that it was difficult to provide timely advice if visiting a site every four years which is the recommended minimum for low risk farms.

APBs visited largely operated in accordance with authorisation requirements laid down in Directive 2006/88/EC concerning recording obligations, traceability, hygiene practice, and the requirement to have a risk based animal health surveillance scheme in place to detect increased mortality. The exception to this was found in smaller APBs and for registered operators which are not obliged to have such schemes in place.

Fish health surveillance (Article 10) is mostly carried out by official inspectors and in some MS by specialised aquaculture animal health inspectors, with the main objective to

investigate either the presence of diseased fish or evidence of increased mortality. In many MS the surveillance inspection is combined with an official control under Article 7 but in some MS local officials carry out the health surveillance inspections whilst the official controls are carried out by officials from regional level. The interpretation of the recommended visit frequencies when surveillance and control inspections are combined varied among countries, which led to variable frequencies of animal health inspections for the same farm category.

It was noted that in most MS visited, operators are not required to have their animal health surveillance schemes in writing. There were often no official guidelines on the frequency and scope of surveillance visits carried out by private veterinarians (as described in Part B of Annex III to Directive 2006/88/EC) and no information provided to the operator or private veterinarians as to which risk classification the farm had been given by the authority. It was also noted these visits were seldom recorded or evaluated as part of official controls.

The fish diseases of concern for most operators were predominantly diseases other than the exotic and non-exotic diseases listed in the Directive 2006/88/EC, e.g. "production diseases" caused by parasites, virus and bacteria, which were not the targets for official controls or animal health surveillance inspections carried out by official veterinarians.

There was limited verification/audit by central level of the official measures implemented at local level, and correction of the on-line register was very slow in a number of observed cases.

<u>The following points are considered of particular relevance</u>

- Official control staff are not always competent or experienced enough to "check the health status of the animals, to advise the APB operator on AAH issues, and where necessary, undertake the necessary veterinary measures", and rarely evaluate the records from fish health surveillance visits required under Article 10 of Directive 2006/88/EC, when such visits were carried out by other official staff or private veterinarians.
- The procedures for the determination of the risk level of farms were not always clear to regional/local staff responsible for such classification, particularly with regard to the range of factors to be considered when determining the risk level of a farm.
- Operators of farms with a lower health category are not usually motivated to upgrade the health category of their farms as it is their perception that this generally adds no significant benefit for the APB. On the contrary, some operators stated that a higher health status would restrict the movements of fish/roe to the farm.
- In general, awareness among the personnel employed in APBs was high in respect of the importance of addressing unusual mortality quickly, but in some MS the approach to investigate those events rarely included the participation of the CA or official diagnostic laboratories to find a solution, due to a perceived lack of expertise in the official services.
- On a limited number of sites visited, particularly smaller APBs the results of official controls were not fully documented and did not indicate findings concerning:

- the maintenance of mortality records for each epidemiological unit;
- whether threshold values for increased mortality had been set, and in cases where mortality above this threshold had been investigated/what were the results;
- whether movement records ensured full traceability from egg to processing;
- whether hygiene practices were implemented as planned and if the plan was fit for purpose;
- whether a risk based animal heath surveillance scheme was in place, by whom it is implemented and whether at an appropriate frequency;
- the conclusions of the official control, for example areas where improvement was required/identified, and what recommendations are given to the APB to ensure continuous improvement.
- follow-up of previous non-compliances indicating if deficiencies had been addressed.

- Without exception it was found that official controls did not take account of the results of inspections for privately adopted quality control schemes even though such schemes shared many of the objectives of AAH legislation such as biosecurity, feed and veterinary medicine controls, animal welfare and traceability.

Examples of good practice

- The use by veterinary inspectors of checklists and tools for official controls through an electronic management system demonstrated a better overview of the health status of farms and allowed for better targeted controls.

Conclusions on fish health surveillance

- AAH is subject to official controls with a planned frequency often higher than the minimum recommended. However, the capability to detect health problems during official controls and the degree of expertise available/provided to farmers was variable among and within MS due to lack of specialisation in this area.
- With some exceptions APBs mainly operated in accordance with authorisation requirements laid down in Directive 2006/88/EC.

4.5.3 Disease suspicion and investigation of increased mortality

In order to ensure early detection of possible outbreaks of listed or emerging aquatic animal diseases, it is necessary to oblige those in contact with aquaculture animals to notify any unexplained mortality or suspect case of disease to the CA.

To maintain a high level of disease awareness and preparedness and to ensure environmental protection, each MS is required to draw up a contingency plan specifying the national measures to be implemented in the event of an outbreak of emerging diseases and of exotic diseases listed in Part II of Annex IV to Directive 2006/88/EC.

MS visited had established a legal framework to provide for notification of a disease suspicion or confirmation as well as investigation of increased mortality in aquaculture animals, as required by Article 26 of Directive 2006/88/EC.

Once a notifiable disease had been confirmed, MS generally took appropriate measures, declared the APBs infected, issued orders to destroy diseased fish and clean and disinfect epidemiological units, issued restrictions on movements from the farm, and carried out epidemiological investigations with the aim of identifying the potential source of infection and other farms the infection may have spread to. However, in none of the cases studied had the source of infection been identified.

The cut-off percentage which would indicate significant increase of mortality above the level of what is considered to be normal for APBs under the prevailing conditions has not been developed by most MS official services in cooperation with APBs as envisaged in Annex I to Directive 2006/88/EC. In addition, there is generally no minimum required frequency for recording mortality by the APBs. The legal requirement to report increased mortality to the official control service or their private veterinarian varied among APBs and private practitioners.

Directive 2006/88 lays down provisions to ensure the necessary level of preparedness to effectively tackle emergency situations related to one or more outbreaks of serious exotic or emerging diseases affecting aquaculture, in particular by drawing up contingency plans to combat them. However, contingency plans are not legally required for the listed non-exotic diseases and very few contingency plans for aquaculture diseases were evident in MS visited.

In many cases listed diseases had been detected through routine sampling of apparently healthy fish, rather than through notification of increased mortality or clinical symptoms by APBs or by aquatic animal health services. In this regard APB operators highlighted the current lack of incentive to notify official services, unless efforts to treat the sick fish with the help of private veterinarians or health services had failed.

<u>The following points are considered of particular relevance</u>

- With regard to disease outbreaks it was noted that these are sometimes handled by local authorities only, and sometimes only limited information was forwarded to other districts/regions. In addition, official measures were sometimes limited to certain ponds in a farm even though the whole farm should have been considered as one epidemiological unit.
- The epidemiological investigations carried out on farms in different regions were not always coordinated in that official services did not verify if all relevant measures had been taken to investigate and limit the spread of disease.

Examples of good practice

- In the case of biannual approval, each aquaculture business operator submits a management plan for both years to the responsible control authority, and has a contingency plan in place for the species farmed. This allows the industry, in cooperation with the CAs, to plan the production cycles and controls in a given area at the same time as well as being prepared for the unexpected. In addition, close cooperation between aquaculture business operators, e.g. management plans being coordinated in defined zones in order to achieve an "all-in/all-out" approach in larger areas, and synchronisation of disease controls including fallowing periods, treatments and stocking with the same generation of fish. This has been shown to optimise disease control and reduce mortality levels.
- Integrated support service in collaboration with APBs and veterinary practitioners to provide diagnostic services, training and advice on prevention and control of diseases.
- Clear written biosecurity and contingency plans, which describe how the farmer will ensure biosecurity and welfare, including stronger biosecurity measures to be taken in case of a suspected or confirmed disease outbreak.

Conclusions on surveillance and disease suspicion

- While MS visited had established a legal framework to provide for notification of a disease suspicion or confirmation, the definitions of "increased unexplained mortality" vary considerably or were missing, which has obvious effects on the effectiveness of passive surveillance and early detection of disease outbreaks.
- The reliability of passive surveillance is questionable given that most notifiable diseases are discovered only through routine sampling.
- It is doubtful if the current system will detect emerging health threats to EU aquaculture due to the emphasis on listed diseases during clinical inspections, sampling and official testing.

4.5.4 Control of Veterinary Medicinal Products

There is a specific obligation for EU countries to implement residue monitoring plans to detect the illegal use or misuse of authorised veterinary medicines in food producing animals and investigate the reasons for residue violations. There is also an obligation for APBs to ensure that such treatments are recorded.

Common/different elements

All authorised/licensed products for aquaculture, which contain pharmacologically active substances, were in line with Commission Regulation (EU) 37/2010. Almost all MS visited had recorded no results above maximum residue levels for aquaculture samples in the last several years.

All of the feed mills which were preparing medicated feed for aquaculture used dedicated lines for production, had detailed standard operating procedures and had comprehensive production records allowing for full traceability of the production process, in addition to regular homogeneity tests and carry-over (cleaning/flushing effectiveness) checks.

Most MS had issued standardised treatment record books, which were compulsory. These templates were in use on most of the farms visited and withdrawal times were clearly indicated when veterinary medicinal products (VMPs) or medicated feed had been prescribed thus fulfilling the requirements of Article 10 of Council Directive 96/23/EC. Separate defined storage areas for VMPs/medicated feed were available on those farms where such products had been used. It was found that both these requirements were a normal part of routine aquatic animal health inspection controls carried out a farm level.

Generally the level of antibiotic use in aquaculture animals is very low, particularly for salmonid species which is attributable to the vaccination programmes which are in place.

<u>The following points are considered of particular relevance</u>

- The interpretation of ‘cascade’ system varied in MS visited which resulted in uncertainty for some APBs and in some cases sub-optimal treatment of certain diseases. In particular the lack of commonality on how the ‘cascade’ system is applied in each MS and the difficulty in determining what products are licensed in each MS is creating some issues in relation to the availability of medicines for the aquaculture sector.
- The lack of VMPs with market authorisation for fish, in particular the absence of medicated premixes, led in some instances to medication intended for other species to be mixed in fish feed on farm, which increases the risk for suboptimal treatments and may increase the risk for development of anti-microbial resistance (AMR).
- In a limited number of cases antibiotic treatments were administered apparently without a full investigation aimed at excluding other (non-bacterial) causes of the mortality.
- MS CAs do not collect accurate information on which VMPs veterinarians use for fish, or data on the quantities prescribed to fish farms. This was particularly the case in one MS where prescriptions were mostly made under the ’cascade‘ system due to the fact that only one antibiotic was authorised for use in aquaculture finfish.
- In a number of MS visited medication under the ‘cascade system’ often took place through on-farm dissolving of VMPs in water and then mixing the solution with fish feed, which is less than optimal.
- With regard to the targeted collection of samples, some MS did not implement the targeting criteria set out in Chapter 3(1) of Annex IV to Directive 96/23/EC, particularly with regard to the breakdown between different stages of production, and samples taken at establishments.

Examples of good practice

- Larger APBs operated electronic systems to track administered VMPs and withdrawal periods which allowed for a better overview of the effectiveness of treatments.
- The submission by the veterinarian (or the operator) of samples from sick fish for bacterial culture and testing of sensitivity to the available antimicrobials before selecting the VMP to prescribe promoted the prudent use of antimicrobials in treatment of disease.

Conclusions on controls of veterinary medicinal products

- Official controls on the use of VMPs at farm level were routinely carried out as a normal part of aquatic animal health inspections, with very few non-compliances found.
- The application of the 'cascade' system for veterinary medicines is not applied in a harmonised way which has resulted in difficulties for operators and animal health specialists in determining what products are licensed in each country.
- The sub-optimal use of antibiotic VMPs, either because of lack of availability, lack of testing for antimicrobial sensitivity, and/or poor on-farm mixing due to economics of producing medicated feed commercially, could lead to the development of antibiotic microbial resistance.

4.5.5 Aquaculture feed production

The primary objective of feed legislation, in particular Regulation (EC) No 183/2005 of the European Parliament and of the Council, is to ensure that feed hazards present at the level of primary production are identified and adequately controlled.

All of the country feed manufacturers visited had identified the main hazards derived from ingredients and production processes and controlled these through process controls supported by monitoring plans for sampling and testing, both for incoming ingredients and final products. All of the establishments were officially controlled in accordance with planned schedules and the main points concerning feed safety were covered during inspections.

In the farms visited, it was noted that storage conditions of feed were a normal part of official controls and were generally correct, cross-contamination of feed with veterinary medicines or other chemicals was avoided and measures were always in place to ensure the right feed went to the right destination. In addition, feed was labelled correctly on all sites visited.

The following points are considered of particular relevance

- The majority of retailers continue to apply an exclusion policy on the use of authorised Genetically Modified (GM) ingredients such as GM soya, and authorised non-ruminant PAP particularly for salmonid feed, with the consequence that feed prices are higher for such operators.

- The warning sentence with regard to the presence of fishmeal or non-ruminant PAP on the labels was almost unreadable in a number of instances due to requirements to have several languages listed on the label, which resulted in a very small font size.

Conclusions on aquaculture feed production controls

- There is a system for official controls both for aqua feed producers, and at farm level to verify that feed hazards are adequately controlled.
- Farmers are not benefiting from lower feed costs due to a continued resistance to incorporate ingredients such as non-ruminant PAP from terrestrial animals.

4.5.6 Traceability and labelling

MS are required to ensure that APBs have in place systems and procedures to identify any operator from whom they have been supplied with aquaculture products, and to whom these products have been sold.

EU legislation establishes specific information that must accompany fishery and aquaculture products sold to consumers and mass caterers. These requirements outlined in Council Regulation No (EU) 1379/2013 complement the general EU rules on the provision of food information to consumers set out in Regulation (EU) No 1169/2011 of the European Parliament and of the Council, and contribute to more transparency on the market as they enable consumers to make informed choices on the products they buy. The new rules, which have been applicable from December 2014, require retailers to ensure that aquaculture products identify whether a product is farmed or wild and its country of origin.

With regard to official checks, it was found that traceability is a normal part of inspections carried out by inspectors at primary production level, and was based on the movement requirements set out in Directive 2006/88/EC.

Almost all of the approved fish processing establishments visited had implemented sophisticated electronic product identification systems using bar coding and imprinting tools that use tracking numbers to link finished products back to specific data relating to their production history. Official control by the CAs typically included an assessment of the food chain information one step backward and one step forward through the food chain. This began with an assessment of raw materials including origin and date of receipt, followed by a check on internal traceability of products within the company. Official controls normally concluded with an evaluation of forward traceability procedures for products supplied by the company, which also included procedures for product withdrawal.

With regard to consumer information requirements there was significant confusion among retailers in most of the MS visited concerning new labelling rules for aquaculture products, in particular the provision of consumer information relating to species, production method and production dates. Specifically it was found that wild and farmed labelling was mixed, production dates were often not available, and/or the country of origin was not always listed.

The following point is considered of particular relevance

- In three MS it was noted that it was standard practice for operators to include information on the production location i.e. the Food and Agricultural Organisation of the United Nations (FAO) catch area, even on aquaculture products which could be misleading for consumers.

Conclusions on labelling and traceability requirements

- The compliance with requirements relating to traceability and labelling were in general very good at primary level and processing, but at the final step in the chain, correct consumer information was often lacking or incorrectly presented.

4.5.7 Organic production

Organic production is an overall system of farm management and food production that is in line with the preference of certain consumers for products produced using natural substances and processes. Council Regulation (EC) No 834/2007 and Commission Regulation (EC) 889/2008/EC lay down rules on how such production systems should operate for aquaculture, and provide instructions relating to control and supervisory activities to ensure that these rules are adhered to by registered APBs.

In line with the general requirement that production be as close to natural conditions as possible, certain practices are prohibited or restricted in organic aquaculture production. These include a prohibition on use of recirculation systems, the use of artificial heating or cooling, and a restriction on the use of artificial light, with exceptions for hatcheries and nurseries.

It is also the intention of the Regulation that ultimately there should be a closed production loop with all lifecycle stages following organic production rules. This includes sourcing of fish for breeding or for improving genetic stock, or the sourcing of juveniles for on-growing purposes. However, legislation does recognise that this is not currently achievable and so limits have been set on the maximum percentage of non-organic aquaculture juveniles introduced to the farm with progressive reductions over a period to reach 0% by the 31 December 2016. For on-growing purposes the collection of wild aquaculture juveniles is also specifically restricted.

There are also specific rules on feed production with ingredients sourced according to set priorities, which include *inter alia* fish meal and fish oil from organic aquaculture trimmings and fish meal and fish oil and ingredients of fish origin derived from trimmings of fish already caught for human consumption in sustainable fisheries.

On veterinary treatments the use of hormones for reproduction purposes is prohibited and allopathic and parasite treatments are limited to two courses of treatment per year, with the exception of vaccinations and compulsory eradication schemes. On slaughter techniques there is also a general requirement that the process render the fish immediately unconscious and insensible to pain.

In order to maintain and justify consumer confidence in products labelled as organic, the regulation sets out the frequency of physical inspection for all registered operators and the supervisory activities by CAs delegating control tasks to CBs.

Since this mission series has been completed, many of the production issues highlighted by the Expert Group for Technical Advice on Organic Production[9], have been addressed through ad hoc legislative amendments to Regulation (EC) No 889/2008. These include issues such as the amino acid profile in certain feeds, the use of whole fish in feed, and the sourcing of non-juveniles for on growing.

The legislation also requires registered operators to have in place a sustainable management plan proportionate to the production unit for aquaculture, and to carry out an environmental risk assessment in accordance with Annex IV to Council Directive 85/337/EEC. For operational reasons neither of these two requirements were covered within the scope of this particular mission series.

All MS visited had a system in place for the registration of APBs who apply to be approved as organic producers. In addition, all MS had opted to delegate the control tasks described in Regulation (EC) No 889/2008 to CBs, which had been authorised for this certification procedure, and for ongoing annual controls on aquaculture organic production. All CBs had been accredited according to EN 45011, or were in transition to the new accreditation standard ISO/IEC 17065:2012.

It was found that the implementation of specific aspects of the Regulation (EC) No 889/2008 concerning the rules on the production of organic feed, veterinary treatments, stocking density, and transport were part of normal inspections carried out by CBs. All certified farms visited were controlled at least annually in accordance with the provisions laid down in Article 63 of Regulation (EC) No 889/2008. In general the registered organic producers visited in each MS complied with the requirements of Regulation concerning husbandry practices and the rules on veterinary treatments.

A key issue for many operators visited during the series was the availability of organically grown juveniles for onward growing. Those operators who were producing juveniles for this market cited the lack of suitable organic feed to ensure optimum growth at the different growth stages. Feed manufacturers in turn referred to the current small market for organic feed, especially for non-salmonid species, and the economics for producing and researching the needs for this market.

<u>The following points are considered of particular relevance</u>

- Due to economics of production and the relatively small market for organic aquaculture, many authorised APBs avail of the derogation under Article 25c of Regulation (EC) No 889/2008 for simultaneous production of conventional and organic production. This

9 http://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents/final-reports/final_report_egtop_on_organic_food_en.pdf

requires complete separation of organic and conventional products at all stages (separate water systems and differentiation of fish at all stages of production), but this was not evident on some of the farms visited.

- Similarly, owing to the relatively small number of authorised APBs in each country, the CB responsible for certification did not always have suitably qualified technical experts dealing with organic aquaculture.
- CBs also inspect and certify fish feed manufacturers who have a major input into aquaculture production. Within the scope of such inspections, feed specifications are approved, and ingredients and suppliers verified during controls. In one MS the CBs now insist on third party verification of any sustainable fish products used, such as by the Marine Stewardship Council.

Examples of good practice

- The requirement that CB inspectors are trained and certified for specific production areas (including aquaculture) before carrying out inspections on organic production systems.

Conclusions on organic aquaculture production

- The system of controls is largely adequate for certifying organic aquaculture production, and the registered organic APBs visited generally complied with the rules laid down in Regulation (EC) 889/2009.
- The lack of suitable organic feed is one of a number of factors hampering the development of the sector.

4.5.8 Welfare and slaughter

Fish present substantial physiological differences from terrestrial animals and farmed fish are slaughtered and killed in a very different context, in particular as regards the ante-mortem inspection process. Therefore, provisions relating to Council Regulation (EC) No 1099/2009 on the protection of fish at the time of killing are currently limited to the key principle that animals should be spared any avoidable pain, distress or suffering during their killing and related operations.

There have been a number of communications from the Commission to the Council and the European Parliament COM(2002)0511[10], COM(2009) 0162[11], and COM(2013) 0229[12] which set out a strategy for the sustainable development of European aquaculture including promoting high animal health and welfare standards, and environmental actions to ensure a sound industry. Since then the European Food Safety Authority (EFSA) has published several

[10] http://www.europarl.europa.eu/RegistreWeb/search/simple.htm?reference=COM_COM%282002%290511

[11] http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52009DC0162

[12] http://www.europarl.europa.eu/RegistreWeb/search/simple.htm?reference=COM_COM%282013%290229

opinions on the welfare at killing of farmed Atlantic salmon[13] , turbot[14], carp[15], eel[16], sea bass[17], trout[18] and tuna[19]. EFSA has also published opinions on the general approach to fish welfare and the concept of sentience in fish[20] and on the knowledge gaps and research needs for the welfare of farmed fish[21].

In addition, the OIE Aquatic Animal Health Code[22] also makes recommendations that cover: the introduction to recommendations for the welfare of farmed fish; the welfare of farmed fish during transport; the welfare aspects of stunning and killing of farmed fish for human consumption; and killing of farmed fish for disease control purposes. This guidance is a baseline for farmed fish production on a global basis.

Chapter 3 of Regulation (EC) No 889/2008 on the rules for organic production lays down specific animal welfare rules covering all stages of production, including feed, stocking densities transport and slaughter methods.

With the exception of those farms which are operating under organic legislation, the MS visited did not have specific legislation in place concerning the welfare and slaughter of animals. There was also a general lack of awareness of EFSA's species-specific scientific opinions on fish farming, pre-slaughter and slaughter processes or the animal welfare guidance in OIE animal health code. However, the main salmonid farming countries were active in the preparation of guidance in relation to Article 3 of Regulation (EC) No 1099/2009, specifically for salmonid species. This guidance encompasses aspects of fish welfare identified as being important in the above OIE Code; the 2009 EFSA Scientific Opinion on slaughter in farmed salmon, as well as taking account of the welfare standards laid down by private animal welfare organisations in their assurance schemes.

Regulation (EC) No 889/2008 on organic production also encompasses animal welfare husbandry practices, including feeding, design of installations, stocking densities, water quality, handling and transport. The most important hazards in the pre-slaughter phase particularly for salmonid species were associated with crowding and transfer by pumping where e.g. adequate levels of dissolved oxygen are critical. It was found that these elements are assessed by CBs as part of ongoing approval of APBs registered for this type of

13 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1011.pdf

14 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1073.pdf

15 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1073.pdf

16 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1014.pdf

17 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1010.pdf

18 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1012.pdf

19 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1072.pdf

20 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/ahaw_op_ej954_generalfishwelfare_en.pdf

21 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1145.pdf

22 http://www.oie.int/en/international-standard-setting/aquatic-code/access-online/

production system.

In all MS visited the main slaughter methods used for salmon species were percussive and electrical stunning, both of which are followed by exsanguination, which closely follows the 2009 EFSA Scientific Opinion on stunning and killing of farmed salmon. In relation to the trout industry, the main slaughter method used was electrical stunning, which involves using an electric current to stun fish in water/ on ice until they are beyond the point of recovery. Chilling fish on ice without prior stunning was used on a small number of trout farms which produce limited tonnage. In contrast it was found that turbot, sea bass and sea bream were not stunned prior to slaughter under normal commercial farming conditions but were asphyxiated by chilling on ice. There were a number of methods used for the slaughter of tuna, including stunning by spinal rodding and surface shooting.

Slaughter and processing of aquaculture animals which are subject to disease control measures may spread the disease, *inter alia*, as a result of the discharge of effluents containing pathogens from processing plants. It is therefore necessary for the MS to have access to processing establishments that have been duly authorised to undertake such slaughter and processing without jeopardising the health status of farmed and wild aquatic animals, including in respect of the discharge of effluents. In general, most MS had designated facilities which could process diseased fish, or had facilities available which could be quickly adapted for this purpose.

<u>The following points are considered of particular relevance</u>

- In some MS there was no specific facility authorised to slaughter fish for disease control purposes
- In response to consumer concerns and retail requirements many larger APBs have adopted welfare assurance schemes such as Freedom Food assurance scheme for salmon, and standards produced by the Royal Society for the Prevention of Cruelty to Animals (RSPCA) for farmed trout.

Examples of good practice

- APBs signing up to a joint industry/government Code of Practice and implementing best practice in relation to AAH and welfare.
- One MS visited had, together with the main retail chains, recently developed guidelines and public information charts for live transport and killing of carp in retail shops, with the ultimate aim of reducing the number of fish sold live to consumers.

Conclusions of animal welfare and slaughter

- With the exception of guidance on slaughter methods for salmon in the main producing countries, there are very few standards on fish animal welfare in the MS visited with the result that it is seldom included within the scope of official controls.

5 OVERALL CONCLUSIONS

This report concludes that official controls are in general implemented with a high level of expertise, and support the development of the sector as a whole. However, a number of issues were found in key areas, in particular:

- Registration and authorisation procedures can be complex, suffer delays or be misinterpreted, affecting the development of the aquaculture sector and the overview of its health status by competent authorities.
- The legal framework for the movement of farmed fish is not yet robust enough due to a lack of clinical checks prior to certification, and the difficulties in reliably verifying the health status of dispatch and recipient farms.
- Variations in the degree of expertise of competent authorities affect their capability to detect health problems during official controls.
- Passive surveillance can be of limited effectiveness in terms of early detection of diseases in particular due to a lack of common approach to the concept of significant increase of mortality.
- The limited availability of veterinary medicinal products has led to suboptimal treatment of certain diseases and has potential to increase antimicrobial resistance.
- The new consumer information requirements have been poorly understood resulting in confusion or incomplete information at point of sale.
- The development of the organic sector is restricted by limited availability of suitable organic feed.

This report also highlights a number of good practices with a view to sharing with all parties involved in the aquaculture sector.

6 ACTIONS BY THE COMMISSION SERVICES

Several actions have already been taken by the Commission in a number of areas covered by the scope of this mission. These are not a direct result of this mission series, but nonetheless share the same objective of better equipping aquaculture production businesses to implement EU legislation.

In this regard the DG Health and Food Safety has been following a number of initiatives aimed at ensuring a more effective animal health regime and more efficient access to veterinary medicines.

Aquatic animal health

The European Parliament and the Council adopted the Regulation on transmissible animal diseases ("Animal Health Law") in March 2016[23]. The animal health law is part of a package of measures proposed by the Commission in May 2013 to strengthen the enforcement of health and safety standards for the whole agri-food chain on the basis that "Prevention is better than cure".

Several legislative delegated and implementing acts will be adopted by the Commission until April 2019 to make the new rules applicable. To ensure that such acts are fit for purpose the Commission will consult experts, MS, EFTA, EU representative organisations (e.g. in the Animal Health Advisory Committee) and other interested parties during the drafting of these delegated and implementing acts, in the spirit of better regulation.

With regard to these delegated and implementing acts, the intention is to simplify and clarify where appropriate, have added flexibility, in particular as regards movements and disease control, and to reduce administrative burden concerning for example registration, approval.

Licensing

Licencing practices differ widely in the EU and that this is an area where MS competence prevails. To assist MS formulate policy in this area the Commission is currently promoting exchanges of "know how" and best practices[24]. These exchanges will be facilitated by the publication of MS multi annual strategic plans for aquaculture[25] based on guidelines adopted by the Commission in April 2013 (COM (2013) 229)[26].

The Strategic Guidelines identified among others a lack of spatial planning and the need for administrative simplification amongst the hindering factors that prevent further development of aquaculture sector. However, as administrative simplification and spatial planning also remain the competence of MS, the Commission is addressing these issues in the context of the open method of coordination through best practice exchange seminars. Moreover, the new directive on maritime spatial planning and integrated coastal management provides for a framework for MS to apply a comprehensive and coordinated planning process across sectors and between MS[27]. The Commission is also supporting MS efforts in addressing administrative simplification with the help of the High Level Group for administrative simplification[28].

The Commission is also currently developing guidelines on environmental matters to address the main policy areas set out in the EU's water framework directive, marine strategy

[23] http://ec.europa.eu/food/animals/health/regulation/index_en.htm

[24] http://ec.europa.eu/fisheries/cfp/aquaculture/good-practises/index_en.htm

[25] http://ec.europa.eu/fisheries/cfp/aquaculture/multiannual-national-plans/index_en.htm

[26] http://ec.europa.eu/fisheries/cfp/aquaculture/official_documents/com_2013_229_en.pdf

[27] http://ec.europa.eu/maritimeaffairs/policy/maritime_spatial_planning/index_en.htm

[28] http://ec.europa.eu/fisheries/cfp/aquaculture/aquaculture-advisory-council/index_en.htm

framework directive, environmental impact assessment directive and habitats ('Natura 2000') directive[29].

Veterinary medicinal products

The private and public sectors have indicated the following areas for improvement in the current legislation: regulatory burden; the lack of availability of veterinary medicinal products, especially for small markets such as aquaculture; and the functioning of the internal market.

The current ongoing revision of Directive 2001/82/EC seeks to put in place, while safeguarding public health, animal health, food safety and the environment, an up-to-date, proportionate body of legislation tailored to the specificities of the veterinary sector, aiming in particular to:

- increase the availability of veterinary medicinal products;
- reduce administrative burdens;
- stimulate competitiveness and innovation;
- improve the functioning of the internal market; and
- address the public health risk of AMR.

The proposed Regulation builds upon existing EU rules for veterinary medicines which ensure that only medicines that have been granted a marketing authorisation can be placed on the market. However, the new rules have been simplified to ensure the development of suitable medicines for animals in the EU. This reduction in red tape will concern both the marketing authorisation procedure and the monitoring of adverse effects (pharmacovigilance).

The proposed rules are particularly timely for minor species such as for finfish aquaculture for which available medicines are currently lacking.

The proposed Regulation also foresees the establishment of a single product database for all authorised veterinary medicinal products in the Union. CAs will be obliged to upload data on national marketing authorisations. Having a readily accessible, up-to-date database of all authorised medicines will mean an improved application of the provisions on the use of veterinary medicinal products outside the terms of the marketing authorisation ('cascade' system), as veterinarians will be able to identify the products they need from other MS.

To combat AMR and to help keep antibiotics effective in humans and animals, the proposal provides a comprehensive set of relevant provisions. Among others it introduces a possibility to reserve certain antimicrobials for humans only, provides for compulsory collection of data on sales and use of antimicrobials[30], strengthens the prescription requirements, includes

[29] http://ec.europa.eu/fisheries/cfp/aquaculture/guidance-documents/index_en.htm

[30] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp

limitations for retailing of antimicrobials by veterinarians and requires careful scientific benefit-risk assessment in the marketing authorisation procedures for antimicrobials.

Medicated feed

In September 2014 the Commission adopted proposals on veterinary medicinal products and medicated feed, to improve the health and wellbeing of animals, to tackle AMR in the EU and to foster innovation. The proposed Regulation[31] will repeal and substitute Directive 90/167/EEC on the manufacture, placing on the market and use of medicated feed. Its primary aim is to harmonise the production standards and marketing of medicated feed in the EU at an appropriate safety level, and to reflect technical and scientific progress in this area.

The proposed rules will ensure that medicated feed can only be manufactured from specifically authorised veterinary medicines and by approved manufacturers. AMR will be tackled through measures such as a ban on medicated feed being used preventively or as a growth promoter. Additionally, EU wide residue limits for veterinary medicines in ordinary feed are established at a limit to avoid the development of AMR. Finally, the new Regulation will tighten the rules for prescribing and handling medicated feed with antimicrobials

More specifically, anticipated production, mobile mixers, on-farm manufacturing of medicated feed and specialised distributors will be allowed EU-wide. In addition, the Regulation will set state-of-the-art measures for the homogeneity of medicated feed and scientifically derived carry-over limits for veterinary medicines in ordinary compound feed.

Animal welfare

The EU strategy for the protection and welfare of animals 2012-2015[32] foresees a study both on the welfare of farmed fish during transport and at the time of killing. The aim of the study is to gather additional information on current animal welfare practices prevailing in European aquaculture as regards the transport and slaughter of farmed fish. Information will also be gathered on national rules and on the use of international standards, best practices or voluntary assurance schemes. The data collected will be analysed to illustrate to what extent fish welfare issues are addressed or remain unresolved. In addition, factors which may influence the use of animal welfare principles such as the economic situation of the aquaculture industry, trade issues and available knowledge among business operators will also be assessed. It is anticipated that this report will be published mid-2017.

[31] http://ec.europa.eu/food/safety/animal-feed/medicated-feed/index_en.htm

[32] COM(2012) 6 final/2

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Official control		
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Food law		
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Feed production		
Reg. 999/2001	OJ L 147, 31.5.2001, p. 1-40	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Reg. 183/2005	OJ L 35, 8.2.2005, p. 1-22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
Distribution and use of veterinary medicinal products		

Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dir. 2001/82/EC	OJ L 311, 28.11.2001, p. 1-66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
labelling		
Reg. 1169/2011	OJ L 304, 22.11.2011, p. 18-63	Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004
Reg. 1379/2013	OJ L 354, 28.12.2013, p. 121	Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000

Animal health		
Dir. 2006/88/EC	OJ L 328, 24.11.2006, p. 14-56	Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals
Reg. 1251/2008	OJ L 337, 16.12.2008, p. 41-75	Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species
Dec. 2008/392/EC	OJ L 138, 28.5.2008, p. 12-20	2008/392/EC: Commission Decision of 30 April 2008 implementing Council Directive 2006/88/EC as regards an Internet-based information page to make information on aquaculture production businesses and authorised processing establishments available by electronic means
Dec. 2008/896/EC	OJ L 322, 2.12.2008, p. 30-38	2008/896/EC: Commission Decision of 20 November 2008 on guidelines for the purpose of the risk-based animal health surveillance schemes provided for in Council Directive 2006/88/EC
Animal welfare		
Reg. 889/2008	OJ L 250, 18.9.2008, p. 1-84	Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control
Reg. 834/2007	OJ L 189, 20.7.2007, p. 1-23	Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91

ANNEX 2 - MISSION SERIES COUNTRY LIST

Country	Date of aquaculture fact finding visit	Ref. No.
Ireland	8-19 September 2014	DG(SANTE)/2014-7125
Croatia	13-24 October 2014	DG(SANTE)/2014-7339
United Kingdom	3-13 February 2015	DG(SANTE)/2015-7377
Spain	20-30 April 2015	DG(SANTE)/2015-7352
Norway	8-18 June 2015	DG(SANTE)/2015-7372
Greece	15-25 June 2015	DG(SANTE)/2015-7374
Italy	20 September – 2 October 2015	DG(SANTE)/2015-7380
Poland	11-20 November 2015	DG(SANTE)/2015-7381

ANNEX 3 - EU AQUACULTURE PRODUCTION DATA

Production Figures for main EU producing countries in 2014

2014 finfish production (000 tonnes)																	Total
Species	**UK**	**EL**	**ES**	**IT**	**FR**	**DK**	**Pl**	**CZ**	**DE**	**HU**	**FI**	**IE**	**SE**	**HR**	**NL**	**PT**	**CY**	
Atlantic salmon	163											10						**173**
Portion Trout	11	2	13	37	22	28	18	1	8									**140**
Large Trout	4		3	2	12	11			1		12	1	9			0.5		**56**
Sea Bream		71	16	8	1									4		2	3	**105**
Sea Bass		42	17	7	2									3			2	**73**
Common Carp					3		18	18	5	10				3				**57**
Other Carp								1		4					3			**8**
Turbot			8													3		**11**
European eel																		**0**
Sturgeon nei				1														**1**
Megre																		**0**
Eel				1		1									3			**5**
Other species			2	1	2		2						1	1				**9**
Total	**178**	**115**	**59**	**57**	**42**	**40**	**38**	**20**	**14**	**14**	**12**	**11**	**10**	**11**	**6**	**5.5**	**5**	**638**

Source: FEAP data from producers and national statistics.

ANNEX 4 - AQUACULTURE RESEARCH AND DEVELOPMENT

In 2011 the Commission adopted a Communication on Blue Growth[1] showing how Europe's coasts, seas and oceans have the potential to be a major source of new jobs and growth that can contribute to the Europe 2020 strategy and improve the way we manage resources. The Communication singled out particular emerging industries for special attention, which included aquaculture. This strategy acknowledged that innovation is crucial for realising its growth and jobs potential and so the Commission through the Directorate General for Research and Development has provided funding in a number of areas within the scope of this mission series to address the challenges which the sector faces, and to help operators diversify into new commercial species.

On animal disease, FP7 Targetfish[2] aims to develop a targeted vaccination strategy, and prevent important fish diseases in European aquaculture industry. The project estimated that due to the lack of authorised VMPs, the consequent disease outbreaks in farmed fish species costs the sector 20% of the annual production value. It is recognised that the most appropriate method for disease control, both on economical and ethical grounds, is disease prevention by vaccination. TargetFish intends to advance the development of existing and new prototype vaccines against socio-economically important viral and bacterial pathogens of Atlantic salmon, rainbow trout, common carp, sea bass, sea bream and turbot. The project also aims to develop targeted vaccination strategies for currently sub-optimal and for novel vaccines. Improved vaccines will be brought closer to industrial application by addressing practical issues such as efficacy, safety and delivery route.

On animal welfare, FP7 COPEWELL[3] aims to provide a better understanding of the underpinning mechanisms and basic knowledge about the physiology, biology, and behaviour of fish and to give a deeper understanding of the basic mechanisms involved in coping styles. The expected impact of the project is to deepen our knowledge on the development of the brain function, behaviour and stress response in relation to the different husbandry practices and rearing methods in aquaculture farming.

Under Horizon 2020, the project ParaFishControl[4] is evaluating controls on parasites, which cause severe disease outbreaks and high economic losses in finfish aquaculture. The overarching goal of ParaFishControl is to increase the sustainability and competitiveness of the sector by improving our understanding of fish-parasite interactions and by developing innovative solutions and tools for the prevention, control and mitigation of the major parasites affecting Atlantic salmon, rainbow trout, common carp, European sea bass, gilthead sea bream and turbot.

On fish breeding, FP7 FISHBOOST[5] project aims to improve the efficiency and profitability

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1 Blue Growth opportunities for marine and maritime sustainable growth COM(2012)494

2 http://www.targetfish.eu/; http://cordis.europa.eu/project/rcn/105088_en.html

3 http://www.copewell.eu/; http://cordis.europa.eu/project/rcn/99347_en.html

4 http://www.parafishcontrol.eu/ ; http://cordis.europa.eu/project/rcn/193286_en.html

5 http://www.fishboost.eu/; http://cordis.europa.eu/project/rcn/111583_en.html

of European aquaculture by advancing selective breeding for Atlantic salmon, common carp, European seabass, gilthead seabream, rainbow trout and turbot. This will be achieved through detailed phenotyping and advanced genomic technologies. As with all such projects, a dissemination program will deliver the results to SMEs and other end-users, thereby advancing existing and stimulating new aquaculture breeding programmes in Europe.

On organic aquaculture, FP7 OrAQUA[6] project aims to increase the economic growth of the organic aquaculture sector in Europe, through recommendations for the current EU regulatory framework for organic aquaculture based on i) a review of the relevant available scientific knowledge, ii) a review of organic aquaculture production and economics, as well as iii) consumer perceptions of organic aquaculture. The project will focus on organic aquaculture production of relevant European species of finfish.

Integrated Multi Trophic Aquaculture (IMTA) is a concept where different species are grown together in such a way that the invertebrates and/or plants can recycle the nutrients that are lost from the farming of the other species. FP7 EDREEM[7] project aims to create smarter greener growth through taking waste streams that are at present lost to the environment (as pollution) and converting them into secondary raw materials for the production of high value seaweed and shellfish. To do this the project will develop, demonstrate and benchmark (against existing production techniques) innovative production technology for the European aquaculture industry. A similar project to this concerning aquaponics (FP7 INAPRO8) also aims at the commercialisation of an aquaponic system which will allow an optimised reuse of water resources, a minimisation of waste effluents as well as the recovery of nutrients from waste water together with a minimisation of energy demands, of infrastructure requirements and operating costs.

A scientific report from one MS research facility has described the level of AMR among pathogenic bacteria isolated from salmonids with health problems. The study showed, inter alia, that around 50% of the Aeromonas isolates were resistant to oxytetracycline, which was the only pharmaceutically active substance authorised for fish in that MS. The study recommended the testing of antimicrobial sensitivity in bacteria from outbreaks in order to promote prudent use of antimicrobials.

Additionally several research projects are currently ongoing in many national research institutes , which also focus on genetic improvement of reared species, fish diseases and their aetiology, diagnosis, treatment, and prevention.

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6 http://www.oraqua.eu/; http://cordis.europa.eu/project/rcn/111330_en.html

7 http://www.idreem.eu/; http://cordis.europa.eu/project/rcn/104831_en.html

8 http://www.inapro-project.eu/; http://cordis.europa.eu/project/rcn/111413_en.html

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