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COMMITTEE ON FISHERIES

SUB-COMMITTEE ON FISH TRADE

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Agenda Item 6

SAFETY AND QUALITY, WITH PARTICULAR EMPHASIS ON FISHMEAL AND BSE

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INTRODUCTION

1. During its 8th session, the COFI Sub-Committee on Fish Trade¹ (COFI:FT) recommended further strengthening of FAO's work on fish safety and quality, in order to meet the increasing need for capacity-building, especially in developing countries, and to promote a more rapid harmonization of fish safety and quality standards and systems in accordance with the rules of the SPS and TBT agreements. FAO was requested to strengthen its support to improve safety and quality management in aquaculture, particularly through the implementation of Hazard Analysis Critical Control Point (HACCP) principles in the production chain. Equivalency of safety management systems was recognized as an area where progress was relatively slow and which required specific attention, including capacity-building. The work of Codex was highlighted and the importance of active participation in this work was emphasized.
2. The 25th Session of COFI² requested FAO to pursue further its work in this field, with particular mention of HACCP, dioxins, residues and fishmeal, capacity building and institutional strengthening in the field of WTO multilateral trade negotiations relating to fish trade. The Sub-Committee on Fish Trade was requested to avoid duplication and coordinate with the Sub-Committee on Aquaculture, especially with regard to safety and trade of aquaculture products. The latter was again stressed during the 2nd Session of the Sub-Committee on Aquaculture³.
3. During both the 8th Session of COFI: FT and the 25th Session of COFI, many Members expressed serious concern regarding the maintaining of restrictions on trade and use of fishmeal for animal feed, on the grounds of alleged link to the Bovine Spongiform Encephalopathy (BSE). The FAO report endorsed by the 8th Session of COFI: FT concluded that there were no epidemiological data linking fishmeal to BSE. It was foreseen that the said restrictions would be removed as of 1 May 2003 and COFI requested to include this item on the 9th Session of COFI: FT and called on FAO to prepare a report on this matter for the meeting.
4. The objectives of this paper are to i) highlight recent developments in fish safety and quality, including fishmeal, ii) describe FAO efforts in this area and iii) seek the guidance of the Sub-Committee on how to further shape FAO's work.

RECENT DEVELOPMENTS IN FISH SAFETY AND QUALITY

5. The last decades have seen major developments in the field of fish safety and quality with significant impact on international fish trade. Globalization of fish trade, coupled with technological developments in fish handling, preservation and distribution and the increasing awareness and demand of consumers for safe fish of high quality have contributed significantly to these developments and culminated in the adoption of HACCP-based systems and scientifically based risk assessment methods. The international regulatory framework that is shaping the present and future of fish safety and quality was enacted in the 1990's and is embodied in the two agreements (SPS and TBT) of WTO and the standards, guidelines and recommendations developed by the relevant committees of the *Codex Alimentarius*. These safety and quality concepts are also enshrined in the Code of Conduct for Responsible Fisheries, particularly Articles 6 and 11.

¹ FAO. 2002. Report of the 8th Session of the COFI Sub-Committee on Fish Trade. Rome. Italy.

² FAO. 2003. Report of the 25th Session of the Committee on Fisheries COFI. Rome. Italy

³ FAO. 2003. Report of the Second Session of the COFI Sub-Committee on Aquaculture. Rome. Italy

6. Practical implementation of this regulatory framework commenced in the early 1980s when many countries engaged in reforming their fish inspection systems to implement preventative HACCP-based safety and quality systems and the supporting hygiene and sanitary requirements. While there is growing and strong evidence that the implementation of HACCP-based systems has contributed to improve fish safety and quality significantly, there has been recently a growing awareness of the importance and need of an integrated, multidisciplinary approach to safety and quality, considering the entire fish food chain. FAO defines the food chain approach as recognition that the responsibility for the supply of food that is safe, healthy and nutritious is shared along the entire food chain - by all involved with the production, processing, trade and consumption of food. Stakeholders include farmers, fishermen, food processors, transport operators, distributors, consumers, as well as governments obliged to protect public health. This holistic approach to food safety along the food chain differs from previous models in which responsibility for food safety mainly concentrated on the food processing sector and government control services. The implementation of the food chain approach requires an enabling policy and regulatory environment at national and international levels with clearly defined rules and standards, establishment of appropriate food control systems and programmes at national and local levels, and provision of appropriate training and capacity building.

7. In fisheries, there are five broadly defined needs on which a strategy in support of a food chain approach to food safety should be based:

- Fish safety and quality from a food chain perspective should incorporate the three fundamental components of **risk analysis** - *assessment, management and communication* – and, within this analysis process, there should be an **institutional separation** of science-based risk assessment from risk management – which is the regulation and control of risk.
- **Tracing techniques** (*traceability*) must be improved from the primary producer (including animal feeds and therapeutants used in aquaculture), through post-harvest treatment, processing and distribution to the consumer.
- **Harmonization of fish quality and safety standards**, implying increased development and wider use of internationally agreed scientifically-based standards.
- **Equivalence in food safety systems** – achieving similar levels of protection against fish-borne hazards and quality defects whatever means of control are used – must be further developed as no such agreements have as yet been put in place.
- Increased emphasis on **risk avoidance or prevention at source** within the whole food chain – *from farm or sea to plate* –, including development and dissemination of good aquaculture practices, good manufacturing practices and safety and quality assurance systems (i.e HACCP). These are necessary to complement the traditional approach to fish safety and quality management based on regulation and control.

8. Efforts to integrate these developments into fish safety and quality policies are ongoing at national, regional (e.g., European Union EU) and international (e.g., *Codex Alimentarius* Commission) levels. Fish safety regulators have been applying a host of control measures, from mandating the use of HACCP to increasing testing, with varying degrees of success. However, the various scientific tools available to support the development of a food chain approach present limitations which need to be recognized and considered, including gaps in research data. Indeed, much of the data needed to develop science-based strategies are often incomplete, non-existent or require extensive resources to generate. In addition, the link between the food safety criteria and public health objectives is not always present in current safety regulations. Consequently, improved scientific tools must be adopted and novel approaches must be sought so that the need for regulatory control can be balanced with the need for regulatory flexibility and with the expectation that a regulatory agency's actions reflect the most current and effective scientific methods available to protect the public health.

9. In the major world fish markets (i.e. The European Union (EU), USA and Japan whose imports amount to 75 to 80% in value), regulatory agencies have initiated food safety reforms to incorporate these recent developments. In the European Union^{4,5} the established health rules affecting the production and placing on the market of food products have been contained in a large number of Directives which contain common principles such as those related to the responsibilities of manufacturers, the obligations of the Competent Authorities, the technical requirements for the structure and operation of establishments handling food products, the hygiene requirements which must be complied with in these establishments, the procedures for the approval of establishments, the conditions for storage and transport, the health marking of products, etc. These hygiene rules have recently been subjected to a complete recasting with the view to simplify them and eliminate specific inconsistencies which have arisen during their implementation, while securing a high level of consumer protection and taking into account the international obligations laid down in the WTO-Sanitary and Phytosanitary Agreement and in the *Codex Alimentarius*.

10. The EU has instituted the European Food Safety Authority to be consulted wherever necessary in order to ensure that scientific advice underpins the new food hygiene rules. The implementation of these hygiene rules are to be guided by the setting of objectives such as pathogen reductions targets or performance standards with the necessity to foresee the procedures for that purpose. The traceability of food and food ingredients along the food chain is an essential element in ensuring food safety. The EU Alert System for Food and Feed, initiated in 1999, is now operating fully and its regular reports are posted on the Web. These reports indicate that chemical and veterinary drugs residues, which were the most important cause for detentions/rejections in 2001 and 2002, may be presently on the decline, possibly because concerned exporting countries have adopted sampling and control regimes prior to shipments. Further preventative approaches at the production level such as improved good aquaculture practices, especially in fish and shrimp farming, are required to eradicate the problem which has disrupted trade flows during 2001 and 2002.

11. In the USA, implementation of the Federally Mandated Seafood Rule⁶, along with the Good manufacturing Practices GMP (21 CFR part 110) and Sanitation Control Procedures (21 CFR part 123) were continued. Likewise, application of the updated *Fish and Fishery Products Hazards and Controls Guide* issued by Food and Drug Administration, FDA to assist the fish industry was broadened. The Seafood HACCP Alliance, a national education program designed to complement the Guide, was strengthened. This programme involved academic and regulatory expertise in every state plus numerous international training efforts⁷. Risk assessment work for specific pathogens of concern for seafood was carried out. Of particular interest is the 2003 FDA Interim Final Regulation (21 CFR Parts 1 and 20) promulgated under the *Public Health Security and Bio-terrorism Preparedness and Response Act*. This regulation requires that domestic and foreign facilities that manufacture/process, pack or hold food for human or animal consumption in the USA register with FDA and submit electronically prior notice to FDA before the shipment is due to arrive into the USA. It is feared by several fish exporting countries, that the implementation of these requirements, at least in the beginning, may disrupt fish trade flows from exporting countries into the USA.

⁴ European Parliament legislative resolution on the proposal for a European Parliament and Council regulation on the hygiene of foodstuffs. Official Journal of The European Union. 2003. C180 E/267- 277

⁵ European Parliament legislative resolution on the proposal for a European Parliament and Council regulation laying down specific hygiene rules for food of animal origin. Official Journal of The European Union. 2003. C180 E/288- 298

⁶ FDA, 1995. Procedures for the safe and sanitary processing and importing of fish and fishery products, Final Rule. Federal Register. Vol. 60, No. 242. 65096-65202.

⁷ Seafood HACCP Alliance, 2001. HACCP: Hazard Analysis Critical Control Point Training Curriculum, 4th ed. Florida Sea Grant Report No 120, Gainesville, FL: University of Florida.

12. Furthermore, a recent review⁸ of the use of scientific criteria and performance standards for safe foods in the USA recommended that, for seafood, FDA takes the following specific measures i) include a process validation protocol in the *fish and fisheries products hazards and controls Guide* and appoint an appropriate advisory committee to periodically update this guide, ii) develop strategies to ensure the safety of imported seafood by focusing on pathogen intervention strategies prior to shipment and international harmonization of standards.

13. In Japan, application of HACCP- based food control regulations is pursued, including sanitary and hygienic requirements for fish handling and processing establishments and conditions for storage and transport. Risk analysis principles are being incorporated, along with spot checks at the entry border and quality control schemes of the Japanese fish industry, which controls imports at the source.

14. In addition to developments in these major fish markets, significant changes are taking place within the *Codex Alimentarius* Commission (CAC) deliberative processes. To strengthen its role as the internationally recognized body for deliberation regarding food safety, consumer health and fair trade, the CAC has initiated a plan of action encompassing 6 major elements:

- Improved efficiency and speed of the Codex process and consensus building
- Further strengthened scientific support and science based decision making
- Increasing the participation of developing countries to the CAC deliberations
- Establishment of a Trust Fund by FAO and WHO
- Greater transparency and participation of Non Governmental Organizations
- Increased support from FAO and WHO

15. Regarding fishmeal, there continues to be no epidemiological evidence of BSE being transmitted to ruminants or other animals by fishmeal and there continues to be no evidence for the transmission to humans of the Creutzfeld Jacob Disease (vCJD) caused by prions using fish or fish products as vectors.

- As reported at the eighth session of the Sub-Committee the feeding of fish meal to ruminants in the EU has been banned since December 2000, although slow progress has been made on lifting the ban since that session. The ban devolves from a Council Decision (2000/776 4 December 2000), which states that: "*as a precautionary measure, it is appropriate to prohibit on a temporary basis the use of animal protein in animal feed, pending a total re-evaluation of the implementation of Community legislation in Member States. As this prohibition could have environmental implications if not controlled properly, it is necessary to ensure that animal waste is collected, transported, processed, stored and disposed of in a safe manner. This prohibition shall not apply to the feeding of fish meal to animals other than ruminants*".
- It should be noted that the feeding of mammalian meat and bone meal (MMBM) to ruminants was banned in 1994 and the effect of the December 2000 Decision was to extend the ban on MMBM to all animals while adding fish meal to the banned ingredients for ruminants. The quantity of fish meal used for ruminants (70 000 tonnes) is not substantial but the significant fact is that the ban on MMBM for all animals opens up an additional potential market of 2 million t/year for fish meal, dramatically increasing the incentive for unscrupulous merchants to adulterate fish meal with MMBM. According to the EU the inclusion of fish meal in the temporary measures is due to the lack of effective analytical methods to identify such adulteration.

⁸ The National Academy of Sciences.2003. Scientific criteria to ensure safe food. The National Academic Press. Washington D. C. Available at <http://www.nap.edn/openbook/030908928X/html/R3.html>

- The European Commission was to have decided on whether to lift the ban by 30 June 2003 but this decision was delayed until the Commission could be assured that an official analytical method was available that would identify 0.1 percent of MMBM in feed, the level established by the Commission. The present official EU method is only effective down to 0.5 percent of MMBM in the final feed, if fish meal is also present. At the same time there is growing pressure on the Commission to make the above temporary measures permanent.
- The situation has stimulated considerable research activity in methods of analysis of feed composition. The present official method is based on feed microscopy and recent research and ring tests between laboratories, arranged by the Commission and IFFO has developed a refined and improved method. The Commission has also commissioned a group of internationally recognised laboratories to investigate a number of other possible techniques including: Polymerase chain reaction (PCR), Enzyme-linked immunosorbent assay (ELISA), near infrared microscopy (NIRM) and near infrared spectroscopy (NIRS). Some of these show promise for the future but need more work.
- The successful ring testing of the improved microscopic method has resulted in it being approved by an EU Expert Group, whose recommendation should allow the Standing Committee to vote favourably on its adoption as the EU official method in November 2003. Subsequently the Commission envisages that another working group of experts will meet in December to consider lifting the ban on fishmeal in ruminant feed. Only if this group of national experts is in favour will the lifting of the ban be presented to the Standing Committee in January 2004. A favourable vote by this committee would allow the ban to be lifted by mid-2004 at about the same time that the improved method of analysis is adopted in EU member states.

FAO ACTIVITIES

16. The FAO Department of Fisheries (FI) has continued its support to the normative work of FAO, by contributing i) to the work of the Codex Committee on Fish and Fishery Products, of the Committee on Food Hygiene and ii) to the FAO/WHO initiatives on Risk assessments relevant to fish trade and iii) provision of scientific advice to the CAC. Likewise, FI continued its assistance to member countries to broaden the application of good hygienic practices HGP, good manufacturing practices GMP, HACCP, and for the implementation of the FAO/WHO fish standards, guidelines and Codes of practices. This assistance is in the form of training of personnel from government authorities and the fish industry, provision of technical advice on legislation and organization of fish inspection and building national capacity in HACCP, fish quality and safety research.

17. Ongoing and planned FI activities encompass i) technical assistance and training on the application of SPS and TBT agreements, HACCP and risk analysis in the fish industry, ii) preparation of technical guidelines for good aquaculture practices and HACCP and organization of workshops for their practical application in fish farming, iii) efforts to promote harmonization of fish standards in ASEAN and Latin America, iv) studies on the causes of detentions/rejections of fish and fishery products in international trade, v) development and maintenance of the Aquatic Food Product Initiative (AFPI) with the participation of scientists worldwide to create an integrated knowledge base on safety and quality of aquatic food products. In the long term this knowledge base is expected to contribute to a more level playing field between developed and developing countries in activities such as hazard analysis, risk assessment, quality evaluation and product development for a better harmonization of fish safety standards.

SUGGESTED ACTION BY THE SUB-COMMITTEE

18. Recent development and the globalization of fish trade, while offering many benefits and opportunities, also present new safety and quality challenges. The Sub-Committee may wish to discuss the implications of safety and quality on fish trade, both domestically and internationally. The Sub-Committee is further invited to comment on the work of FI and recommend directions for GAP/GHP/HACCP implementation, contribution to the work of the Codex, capacity building and institution strengthening.