

Foreword

This Guidance Document, PNS/BAFS __:2017, intends to provide guidance to food safety regulatory agencies on the appropriate risk management options based on decisions of the Codex Alimentarius Commission (CAC) and national situation and trade. It covers risk management options to address food and feed safety concerns related to the primary production, processing, storage and distribution of fresh, primary processed and processed commodities intended for human consumption.

A Technical Working Group (TWG) for the Adoption of Guidance for Risk Management Options in light of Different Risk Assessment Outcomes was organized and represented by several agencies of the Department of Agriculture particularly the Food Safety Regulatory Agencies, National Food Authority (NFA), College of Home Economics - University of the Philippines Diliman, Food and Drug Administration (FDA), Philippine Coconut Authority (PCA), National Dairy Authority (NDA), National Meat Inspection Services (NMIS), Bureau of Fisheries and Aquatic Resources (BFAR), Fertilizer and Pesticide Authority (FPA) and Sugar Regulatory Authority (SRA).

The Bureau in collaboration with the members of the TWG conducted a series of technical reviews and a national public consultation in NCR. Comments gathered from the public consultation were carefully assessed and deliberated prior to the finalization and approval of the standard.

Introduction

This document intends to provide guidance to food safety regulatory agencies on the appropriate risk management options based on decisions of the Codex Alimentarius Commission (CAC) and national situation and trade. The relevant Joint FAO/WHO Expert Committees perform the risk assessments upon which the CAC base their risk management recommendations. Relevant research institutions and experts can perform risk assessment activities as basis for risk management recommendations.

Codex embraces the use of risk analysis in the development of risk-based approaches for the management of public health hazards in food. Risk analysis is made up of three interactive components:

a) Risk Assessment: itself comprised of four components, hazard identification, hazard characterization (including dose-response analysis), exposure assessment, and risk characterization. While these are recognized as separate components, in reality, these risk assessment components are not performed in a series of four subsequent steps (i.e., one component following the other), but are usually performed interactively and iteratively.

b) Risk Management: process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options. Usual risk management components consist of preliminary risk management activities, recognizing and evaluating possible risk management options (based on the risk assessment outcome), implementation of management decisions, and monitoring and review of subsequent actions to see if the risk management options implemented are working to protect public health.

c) Risk Communication: interactive exchange of information and opinions throughout the risk analysis process about risk and related issues. It includes all stakeholders involved in the risk analysis process.

For further discussion and detail on the risk analysis process/framework and the components of risk analysis, refer to the *Codex Procedural Manual, the Environmental Health Criteria document 240: Principles and Methods for the Risk Assessment of Chemicals in Food* (EHC 240 (FAO/WHO, 2009)), and the *FAO Food and Nutrition Paper 87: Food Safety Risk Analysis – A Guide for National Food Safety Authorities* (WHO/FAO, 2006), among many possible references.

1 Scope

This Guidance Document covers risk management options to address food and feed safety concerns related to the primary production, processing, storage and distribution of fresh, primary processed and processed commodities intended for human consumption.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1

Codex Committee on Contaminants in Foods (CCCF)

primarily responsible for recommending risk management proposals for adoption by the Codex Alimentarius Commission (CAC)

2.2

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

primarily responsible for performing the risk assessments upon which CCCF and ultimately the CAC base their risk management recommendations

2.3

confiscation

action of legally taking or seizing a product from the market done by government or other public authorities

2.4

maximum level (ML)

maximum concentration of that substance recommended by the Codex Alimentarius Commission to be legally permitted in that commodity

2.5

primary processed food

food refers to any substance or product whether processed, partially processed or unprocessed that is intended for human consumption.

2.6

public health alerts

statement containing a finding about a hazardous substances/products which pose a significant risk to human health

2.7**recall**

actions taken to remove a product from the market

2.8**risk assessment**

itself comprised of four components, hazard identification, hazard characterization (including dose-response analysis), exposure assessment, and risk characterization

2.9**risk communication**

the interactive exchange of information and opinions throughout the risk analysis process about risk and related issues. It includes all stakeholders involved in the risk analysis process

2.10**risk management**

process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options

2.11**Food Safety Regulatory Agencies (FSRA)**

refer to the following national government agencies under the Department of Agriculture– the Bureau of Animal Industry, the National Meat Inspection Service, the Bureau of Fisheries and Aquatic Resources, the Bureau of Plant Industry, the Fertilizer and Pesticide Authority, the Philippine Coconut Authority, the Sugar Regulatory Administration, the National Food Authority and the National Dairy Authority; and under the Department of Health – the Food and Drug Administration, the Center for Food Regulation and Research and the Bureau of Quarantine.

3 Risk Management Options

3.1 General Considerations

3.1.1 FSRA have a number of risk management options it can recommend that could achieve the desired level of protection of public health – based on national situation and trade. There are risk management options that FSRA can directly adopt from CAC and implement, e.g., adoption of an ML for contaminants in specific foods into a national standard. CAC guidance documents can be used to issue guidance to industry, e.g., providing guidance for good agricultural practices (GAPs) during production to minimize contamination.

3.1.2 In some cases, a single option may have the potential to successfully manage the risks associated with a particular food contaminant. In most cases, a combination of options may be necessary. For example, the setting and enforcement of MLs by FSRA may stimulate good practices by food business operators. Also, where a high level of uncertainty is indicated by the risk assessment, FSRA may need to consider whether a graduated implementation is warranted, e.g., the introduction of guidance to reduce exposure while commissioning further work to refine the estimates.

3.1.3 The choice of a risk management option will depend on a number of factors, including the severity of the health risk, the probability of its occurrence, the number of individuals potentially affected, the level of protection required or desired, and the anticipated effectiveness of the proposed risk management option(s) on the reduction of health risk.

3.1.4 Risk management options are implemented by a variety of parties, including government, the food industry, and consumers, each of which has different responsibilities depending on the risk management option being used. The Codex Alimentarius assists national authorities with its development of food standards, guidelines, and related texts. While risk management options recommended by CAC can relate directly to actions that FSRAs may adopt or adapt and then implement, there is not always a one-to-one correspondence between a particular risk management option and a subsequent action by the implementing body (be it a national authority, industry, or consumers).

3.2 Specific Risk Management Options for FSRA

3.2.1 Regulatory Requirements

3.2.1.1 One of the major risk management options for FSRA is to establish regulatory requirements, such as regulatory levels. A regulatory level is usually based on the Codex ML for a contaminant in a food or feed commodity.

3.2.1.2 The FSRA establish the regulatory level through a technical regulation (the process usually entails proposing the new level in a policy statement and then soliciting stakeholder/public input on the proposed new policy before instituting the regulatory level). The DA usually adopts or adapts Codex standards but it can establish or maintain a different standard if there is a scientific/public health risk – based on national situation and trade. When an ML is not recommended by the Codex, national government agencies can establish an ML based on national data available or on data from other countries, if relevant. It should be kept in mind that the rationale for the setting of a national ML should follow the principle of transparency of Codex, WTO and other international standard setting bodies.

3.2.2 Guidelines/Guidance/Codes of Practice

3.2.2.1 The FSRA, the food industry, or a 3rd party expert body can draft more specific guidances based from Codex to further explain how the industry can implement these good practices. For example, these documents could identify those points between production and consumption where food safety measures could be implemented to prevent or limit initial levels of contaminants in raw materials (e.g., select ingredients that do not contain a known contaminant), reduce potential for environmental contamination or cross-contamination (e.g., mandate primary production controls), and/or reduce contaminant levels in foods (e.g., physical inspection processes). Industry-led quality assurance programs at the producer level are examples of good practices.

3.2.2.2 FSRA can utilize Codex guidelines to publish guidances, notices, or directives to address food safety issues (these can be new or updated policies that are not regulations). For example, notices and directives can be written instructions for FSRA, but serve as information sources to industry and the public since these

guidances generally are publicly available. Furthermore, FSRA can develop (or encourage the development of) specific documents and guides on good practices, e.g., good agricultural practices (GAPs), good hygienic practices (GHPs), and Hazard Analysis and Critical Control Point (HACCP) plans.

3.3 Other possible actions of FSRA

In addition to adopting or adapting specific risk management options from CAC (i.e., MLs, guidances, codes of practice), FSRA can take a variety of other actions that can be based on the options provided by CAC.

3.3.1 Labeling and Advice

3.3.1.1 FSRA can issue advisory documents on safe intake levels [(for instance, quantity/portion of specific foods, in the context of the trade-off of risk of consuming the contaminant and nutritional benefits in food consumption (e.g., methylmercury in fish versus omega-3 fatty acids)] for certain food products across specific demographics (e.g., pregnant women, children, elderly, immunocompromised). Pregnant women exposed to methylmercury in fish can be advised through education campaigns to decrease the consumption of fish with high contamination levels (e.g., predatory fish). This provides information to consumers so that they can voluntarily limit exposure.

3.3.1.2 FSRA can require labeling to inform consumers how to avoid specific contaminant levels (e.g., provide specific cooking directions to minimize acrylamide formation).

3.3.1.3 Proper labeling includes information that instructs the consumer regarding safe handling practices and, where appropriate, briefly informs the consumer of the food safety issue.

3.3.2 Mitigation Strategies

3.3.2.1 FSRA may work with industry to reduce human exposure to contaminants by setting appropriate targets and establishing strategies to promote reaching such targets. Risk-based inspection of establishments, collection and analysis of samples, and/or monitoring of products can be implemented to ensure mitigation of any potentially harmful exposures to contaminants (e.g., monitoring of dioxin in foods so

dioxin sources could be tracked and identified and then targeted for reduction). This may likely require extensive advocacy and awareness creation.

3.3.2.2 FSRA may also ensure mitigation of risk via sampling and monitoring for enforcement of HACCP, GMP, GAP, and compliance with MLs.

3.3.3 Recalls and confiscation

FSRA (where they have the authority and sufficient evidence) can invoke recalls and confiscation of commodities when they are determined to be unsafe food products. Industry may also exercise voluntary recalls of their products if determined to be unsafe. Monitoring of adverse event reports and consumer complaints help determine if there are exposures to potentially unsafe food products.

FSRA may adopt established procedures for recall, confiscation and disposal of products.

3.3.4 Public Health Alerts

Appropriate risk communication activities shall be undertaken by FSRA (where they have the authority and sufficient evidence) to protect the public from the posed hazards. Such advisory shall be posted in FSRA website and/or other forms of media to alert the public.

3.3.5 Education/Training

3.3.5.1 An important risk management action is education and training for all stakeholders involved in food safety. Education can occur for those in regulatory agencies, industry, public health or consumer interest groups, agriculture, trade and the public at large. Appropriate training for those in food safety should be a priority for FSRA and industry to institutionalize. Extension services, including provisions for practical educational training at colleges and universities, could be mobilized to support the education of relevant groups. Every possible avenue for reaching out to stakeholders should be considered to maximize the education message(s), e.g., on-line capabilities and networks, public meetings, advisories.

3.3.5.2 Consumer education can provide guidance in terms of dietary advice for avoiding or limiting exposure to certain foods (e.g., methylmercury in fish; educating local fish-

eating communities), advice on cooking practices (e.g., correct preparation of kidney beans to break down phytohaemagglutinin or cassava to avoid hydrogen cyanide), and consumer education for handling foods in the home. For acrylamide, approaches could include educational campaigns among the population aimed at controlling the degree of cooking of home-made fried or roasted potatoes (lighter colored potatoes have lower acrylamide levels) and at decreasing the consumption of fried potatoes.

3.3.5.3 Technical training on proper food safety practices is paramount in ensuring safe food. Every possible avenue of reaching out to technical personnel should be considered to maximize training, e.g., webinars, on-line modules, on-site training, front line supervisor training and stakeholder meetings.

3.3.5.4 Industry's input and/or contribution to authorities are also important sources of information to develop training programs and evaluate existing risk in food processing-related processes.

3.3.6 Research

Research can provide additional data for refining risk assessments and contribute to better risk management decision(s) for determining food safety and can provide education and training opportunities. It can develop/improve methods for detecting contaminants in food, determine toxicological effects of food contaminants, determine effects of processing techniques on food composition, help elucidate factors that influence contamination, and elaborate preventive measures and mitigation strategies.

4 Risk Communication Considerations

4.1 An important risk management action is to ensure good communication with all stakeholders and impacted parties regarding the food safety measure(s) being taken. Communication can take many guises, through advisories, public meetings (often to inform and also to solicit input), technical meetings (with industry, other agencies, consumer groups; usually to solicit input), and constituent updates. This is also an opportunity for the constituents to become educated about new risk-related developments.

4.2 Public meetings may be structured as simply informative, e.g., the FSRA announce a new policy and invites written and oral comment. Public meetings can be also in the form of break-out groups as experts from all sectors are invited to participate

in deliberative exchanges or sessions with the outcome in the form of proposed action items for one or all parties to take or a revised policy. The FSRA can solicit input from a neutral 3rd party expert group (e.g., DA pool of experts) where risk management options to deal with a particular food safety issue are discussed and technical experts from academe/ research/ industry/ government are brought together to consider all relevant scientific information presented and provide recommendations.

4.3 FSRA can hold regular meetings with constituent groups for the purpose of allowing them to ask specific questions to the authority relative to a new or change in policy or regulation. This is an opportunity for the constituents to become informed about new risk management options/policies.

4.4 Because of international trade, communication is also important between authorities of different countries. One of the aims of Codex Alimentarius is to promote coordination of food standards.

4.5 An important aspect of communications is to assess if it is effective or not. The conduct of impact studies to evaluate the effects of risk communication on consumers, for example, would be very useful to see if the message(s) had any impact.

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