GUIDANCE FOR RISK MANAGEMENT OPTIONS IN LIGHT OF DIFFERENT RISK ASSESSMENT OUTCOMES

Contents

I. Background

1. The 4th Session of the Codex Committee on Contaminants in Foods (CCCF) agreed to establish an electronic Working Group to develop guidance on risk management options to consider when dealing with the results from risk assessment approaches used by the Joint FAO/WHO Committee on Food Additives (JECFA) (ALINORM 10/33/41; paragraph 111). The resulting discussion paper was discussed at CCCF's 5th Session.

2. Due to the general support for further work, the Committee agreed to re-establish the electronic Working Group, under the lead of the United States of America, co-chaired by The Netherlands, working in English only and open to all Codex members and observers with the following terms of reference:

   - To prepare a discussion paper for consideration at the next session on risk management options in addition to MLs and codes of practice in light of different risk assessment outcomes focusing on:
     - A description of different risk assessment outcomes in language understandable for risk managers and related uncertainties; and
     - Implications of different risk assessment outcomes and description of possible risk management options.

3. An electronic Working Group was established and the members are listed in the Appendix. Comments to the working drafts were provided by many members of the workgroup and incorporated into the present document for presentation at the CCCF 6th Session.

II. Discussion and Conclusions

4. Traditionally in the food area, risk assessment is based on deterministic endpoints, i.e., use of the no observed adverse effect level (NOAEL) or no observed effect level (NOEL) and the mean or high level of exposure. Methods to assess the dose responses of toxicity assays have evolved beyond just determination of a NOAEL. Further, as the available data allow, probabilistic and distributional methods can be used to characterize the hazard(s) as well as the exposure(s). These approaches allow for more description of variability in the population and uncertainty in the risk estimates. Additional risk assessment outcomes are also used and reported, such as the margin of exposure (MOE), which gives a relative indication of the level of health concern without actually quantifying the risk. These expansions of risk assessment tools and the information they provide may require additional consideration on the part of risk managers as they evaluate risk management options.

5. Further, in many instances, exposure information has greatly improved which has improved the risk assessment of food borne chemicals. This in turn, has allowed for the consideration of different exposure scenarios (e.g., for different susceptible populations) and better and more precise estimates of risks in these populations. This more detailed information needs greater scrutiny by risk management as well as considerations for what fraction of the population will be affected by different measures (though not discussed in this discussion paper).

6. The purpose of this discussion paper is to discuss options for how the different risk assessment outputs may be considered in the choice for risk management options. CCCF explored whether it is possible to link specific risk management options to specific risk assessment outcomes. However, in the area of contaminants, such a one-to-one association does not seem feasible as the origin and characteristics of these compounds, and thus the risk assessment outcomes, vary greatly. In addition, it was recognized during the plenary of the 5th CCCF that there is no fundamental difference in available risk management options for the different risk assessment outcomes. Therefore, the choice was made for this discussion paper to include an extensive discussion on the factors of a risk assessment outcome which could be taken into account in the choice for a relevant risk management option.

   To this purpose, the heart of the document is found in three sections:

   i. Risk assessment outcomes (a discussion of principles and techniques used)

   ii. Interpretation of the risk assessment outcomes (a discussion of which factors to consider and options on how to do this)

   iii. Risk management options (a discussion of different options and their possible use)

7. This document aims at risk communication and is intended to be an informal overview. It is not aimed to prepare or change any standards..

III. Introduction

8. This discussion paper elaborates on the guidance to CCCF found in the "Working Principles for Risk Analysis For Application in the Framework of the Codex Alimentarius" found in the Codex Alimentarius Commission (Codex) Procedural Manual. 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:

   - 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.

   - Risk Management: The 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.

   - Risk Communication: is 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.

9. Although it is desirable to have a clear separation of the functional activities and roles of risk assessment and risk management in order to ensure scientific independence as well as transparency, it is acknowledged that risk managers should communicate and interact with risk assessors throughout the process, particularly during the problem formulation and planning and scoping phases at the beginning of the risk analysis process. This will help focus and direct the risk assessment on the appropriate risk management issue(s) and question(s). Thus, the relationship between risk assessment and risk management is an interactive, often iterative and complementary, process.

10. Although risk communication encompasses communication among all stakeholders all through the risk analysis process, there is a critical discussion between risk assessors and risk managers at the end of the risk assessment when communicating the outcomes to the risk managers. These outcomes will help the risk managers determine what food safety decisions may or may not be needed.

11. As detailed in the Codex Procedural Manual (Section IV: Risk Analysis, Sections 2, 3, CCFA/CCCF and 4, JECFA), there is an interrelationship between CCCF and JECFA which requires comprehensible and transparent communication. JECFA is primarily responsible for providing CCCF with science-based risk assessments, comprised of the four components mentioned above. This serves as the basis for CCCF's food safety discussions and recommendations for risk management options, such as maximum limits (MLs) in foods.

12. 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.

13. The definitions to the terms relevant to this paper (i.e., glossary), and detailed descriptions and considerations of the risk assessment techniques used in this discussion paper can be found in:

    FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization). 2009. Environmental Health Criteria 240: Principles and methods for the risk assessment of chemicals in food.

    At: http://www.who.int/foodsafety/chem/principles/en/index1.html

IV. Risk Assessment Tools and Outcomes

14. Risk assessment is a process intended to estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system (IPCS Risk Assessment Terminology; WHO, 2004). There are several outcomes that are possible from a risk assessment, e.g. a quantitative estimation of the risk at specified exposure levels, a Health Based Guidance Value (HBGV), a Margin of Exposure (MOE), a qualitative description of a possible prioritization of risks.

15. Probabilistic approaches to describe the range of responses and exposures can also be used when appropriate data are available. Since modeling with probabilities and distributions requires more intensive effort and resources, a decision on whether it is worthwhile to engage in such modeling over the deterministic approaches needs to be made, i.e., does the increased transparency of the uncertainty and variability addressed in these models make a significant difference in public health safety over the deterministic approaches. For exposure analyses, probabilistic approaches are increasingly being utilized as they help better characterize the variability and variety of possible exposures. For hazard characterization, JECFA currently relies more extensively on dose response modeling which is described below.

16. The Threshold of Toxicological Concern (TTC) approach is a screening tool that has been developed in order to assess substances of unknown toxicity present at low levels in the diet. Application of the TTC approach requires knowledge of the chemical structure and adequate information for a conservative estimate of human exposure. This information is compared to structurally related chemicals of known toxicity. In this respect, the TTC approach has the potential to be used both for qualitative risk assessment and for priority setting, to enable efficient use of available resources.

Point of Departure (POD)

17. The POD serves as the basis for the hazard characterization, i.e., for the derivation of the HBGV or MOE. The POD, or reference point, is the appropriate (i.e., low- or no-effect) dose associated with the critical endpoint(s) and critical study(ies) (i.e., based on the most sensitive species; most sensitive endpoint of relevance to humans). The POD can be based on the NOAEL (no observed adverse effect level) or LOAEL (lowest observed adverse effect level). However, if the data allow a benchmark dose (BMD) or benchmark dose lower confidence limit (BMDL) to be derived from dose-response modeling, these can be used as the POD (EHC 240).

18. The NOAEL is the highest experimental dose level for which the response is not statistically significantly different compared with the response in the control group. If a NOAEL could not be identified from the most relevant study, then the LOAEL can be selected as the POD.

19. The BMD method involves fitting a series of dose response models to the data, and a BMD is estimated from each model as the dose corresponding to a specified change in effect over background (i.e., the benchmark response, BMR; this could be the 5 or 10% effect level for instance). The lower bound 95% confidence limit on the BMD is calculated, i.e. the BMDL, to account for uncertainty in the data (e.g., the BMDL10 would be the lower confidence bound on the BMR at the 10% effect level). For those models that provide an acceptable fit to the data, the BMDLs are calculated and the range of BMDLs expressed. As a conservative approach,, the lower end of the range of BMDLs is often used as a POD. JECFA has proceeded with this approach, but there are other approaches, e.g., model averaging, that can be used if so decided. Also, a more or less conservative approach (e.g., smaller or larger effect level for the BMR) might be considered in some cases if more statistically or biologically appropriate models are selected, or more reliable data sets are used for modeling.

20. The BMD method has a number of advantages over the use of a NOAEL or LOAEL for deriving a POD. Whereas the NOAEL/LOAEL are discrete doses used in a study(ies), the BMD approach involves modeling the dose-response curve in the range of all the relevant observable data, and then using that model to estimate a dose that corresponds to a particular level of response. The BMD method therefore makes use of the full dose response data in the statistical analysis, which also allows for the quantification of the uncertainty in the data. Higher uncertainty in the data, for example due to small group sizes or high variation within a group, would be reflected in a lower POD (EHC 240).

Uncertainty/Safety Factors

21. Uncertainty, or safety, factors are used to address the uncertainty and variability surrounding the data being used to estimate risk. An uncertainty/safety factor is usually a composite factor by which the selected POD is divided to derive a HBGV. Critical in the application of uncertainty/safety factors is always the transparent description and explanation for the selection of all factors applied.

22. A default uncertainty/safety factor of 10 or 100 is used depending on whether human or animal studies are used in deriving the POD. If a human study is used then a factor of 10 is usually used to account for the variability in responses between average humans and those who are highly sensitive. If an animal study is used then an additional 10-fold factor is used to account for differences between the average responses in the experimental animals used in the study identified to derive the POD and those in average humans. Additional uncertainty/safety factors can be used "case-by-case," mainly to account for deficiencies in the database, to extrapolate from sub-chronic to chronic exposure, or to extrapolate from a LOAEL to a NOAEL.

23. In some cases a chemical specific adjustment factor (CSAF) can be used (EHC 240). CSAFs enable the incorporation in risk assessment of specific quantitative data on species differences or human variability in either toxicokinetics or toxicodynamics to replace part of the default uncertainty factor described above (IPCS, 2005).

Health-Based Guidance Values (HBGVs)

24. HBGVs are the quantitative expression of an oral exposure (either acute or chronic) that would be expected to be without appreciable health risk. They are established for compounds that produce adverse effects via a mechanism that demonstrate a non-linear dose-response relationship, i.e., an exposure level is observed where an adverse effect cannot be discerned above background. HBGVs are derived by dividing the POD by suitable uncertainty factors to result in a tolerable or acceptable daily or weekly intake. Expressed on a per kg body weight basis, it is applicable to the whole population, but derived attempting to also protect the most sensitive part of the population.

25. For some contaminants, it may be useful to establish more than one reference value (e.g., for acute and chronic exposures). There are occassionswhere a provisional HBGV is determined (e.g., a provisional tolerable weekly intake, PTWI). The tolerable intake is generally referred to as "provisional" as there is often a paucity of data on the consequences of human exposure at low levels.

Margin of Exposure (MOE)

25. The MOE is the ratio between a POD and an estimate of human exposure. For genotoxiccarcinogens, the traditional assumption is that there is a linear dose response down to zero dose and that some degree of risk may exist at any level of exposure. Thus, JECFA does not establish HBGVs for substances that are known to be genotoxic. In these cases, a MOE is derived. However, the MOE approach can also be used for substances with a non-linear dose response, particularly for which the database is not sufficient to set a health-based guidance value.

26. This approach provides advice to inform risk managers of how close estimates of human exposure are to those that produce a measurable effect in laboratory animals or humans. In addition, MOEs for different substances derived by the same methodology can be compared to assist risk managers in prioritizing risk management actions for various chemical substances.

Quantitative Risk Estimates

27. If sufficient data are available, JECFA can also perform a fully quantitative risk assessment, describing the quantitative risk estimated at defined levels of exposure. This has been done for contaminants like aflatoxins, cadmium, and lead, where the risk (i.e., number of estimated cases per year) per ingested dose was estimated for different populations at risk. Quantitative risk assessment outcomes allow for other subsequent analyses such as a quantitative health impact assessment and cost-benefit analysis. However, detailed quantitative risk assessments require a considerable amount of data that are often not available.

V. Interpretation of Risk Assessment Outcomes

Uncertainty and Variability

28. Uncertainty in risk assessment is due to lack of knowledge and it increases when data are of poor quality or inadequate. It is not the same as variability. Variability refers to true heterogeneity or diversity. For example, a risk assessor may be very certain that different people drink different amounts of water, but may be uncertain about how much variability there is in water intakes within the population. Uncertainty can often be reduced by collecting more and better data, whereas variability is an inherent property of the population being evaluated. Variability can also be better characterized with more data, but it cannot be reduced or eliminated. Distinguishing between variability and uncertainty is important in characterizing risk.

29. Predictions of hazard estimated from a given deterministic model are only point estimates and, to a larger or smaller extent, uncertain. This uncertainty arises from at least three sources:

    - the sampling error arising from inferences about a larger population from a single experiment;
    - the reality that dose response estimates often differ among experiments with different experimental design, protocol or uncontrolled circumstances; and
    - the fact that the "true" model is not known, which results in additional uncertainty when interpolating between doses, but even more so when extrapolating outside the dose range containing observations.

    These uncertainties may all be represented in a dose response assessment through the use of probability distributions or probability trees. The latter technique involves using multiple alternative plausible assumptions about what data sets or models are to be used to produce an estimate, which results in a range of plausible estimates.

30. Efforts to clearly distinguish between variability and uncertainty and how they impact the hazard assessment outcomes are important when characterizing risk. Sensitivity analysis can provide some insight to the quantitative impact of either uncertainty or variability on estimates of risk. This analysis helps determine how changes in various inputs (data or assumptions) affect the outcomes of a risk assessment.

31. In addition to the hazard assessment, uncertainties in the risk assessment can also arrive from the exposure estimation, which uses chemical concentration and food consumption data. Uncertainties concerning the chemical concentration within the exposure estimation are related, among others, to the data source (legal limits or laboratory data), the food analyzed (raw commodity or ready-to-eat food), sampling protocols (if the sample is representative of the population sampled), the number of samples analyzed, and the analytical method used (sensitivity, precision and accuracy). Uncertainties in food consumption data are related, among others, to the type of data (e.g., GEMS Food diets or individual data), the number of individuals surveyed, the age of the data (as dietary patterns can vary over time), and whether the surveyed population can be extrapolated to the rest of the population.

HBGV

32. HBGVs such as the ADI, TDI, and RfD are deterministic values which imply a demarcation between what is assumed to be a "safe" level of exposure (i.e., exposures below the HBGV) versus a "non-safe" level (i.e., exposures above the HBGV). However, it should be kept in mind that due to uncertainty and variability, these apparent "bright lines" in reality are not as precise (i.e., not as sharp a boundary between safe and non-safe) as they appear to indicate. Moreover these are levels for chronic, life-time exposures, and are often based on conservative assumptions. Hence, short term exceedance may not be of health consequence. However, this needs to be determined on a case-by-case basis, since it is dependent on the characteristics of the compound.

Margin of Exposure

33. There is no general guideline for the interpretation of the MOE. The acceptability of a MOE depends on its magnitude and is ultimately a risk management decision. To aid that decision, the risk assessment should provide information on the nature, magnitude, and possible consequences of the inherent uncertainties and variability in both the toxicological and exposure data. The following are some points regarding the acceptability of a MOE that can be considered.

- When comparisons between the linear low dose extrapolation, used by some risk assessment authorities for genotoxic carcinogens, are made to MOE estimates, the risk of one in a million cancer risk from a linear extrapolation of a BMDL10 is equivalent of dividing the BMDL by 100,000 (see 64th JECFA report (WHO, 2006)). This might be considered an upper value for which greater MOE values would be considered of low risk for contaminants without data to establish a mode of action. When there are adequate data to determine a genotoxic mode of action, a MOE of 10,000 may be considered low concern from a public health point of view and might be considered as a low priority for risk management actions if it is based on a BMDL10 from an animal study (WHO, 2006). If the BMDL is based on a reliable human study, the appropriate MOE will need to be considered on a case by case basis.
- For compounds with other endpoints, particularly non-genotoxic ones, consideration of whether the identified MOE presents a concern for human health could follow a process similar to selection of appropriate uncertainty factors to be used in establishing a reference value (e.g., factor of 10 for interspecies differences, 10 for human variability and additional factors for important gaps in the database). Therefore, a MOE of 100 might be considered a lower value for some non-genotoxic contaminants. In case of higher or lower uncertainty, a higher or lower guidance value for the MOE can be recommended.
- Decisions on the acceptability of an MOE are made on a case by case basis depending on the level of public health protection needed or desired and the extent and nature of the population of people being exposed. Again, when the uncertainties and variability are clearly and transparently described, this will assist the decision on what is an acceptable MOE for that contaminant. Some considerations can assist the risk manager regarding an appropriate MOE level:
    - *POD from animal or human studies.* A smaller MOE may be acceptable when a MOE is derived from a human study, depending on the quality of the study.
    - *The number of assumptions and amount of uncertainty*. Greater uncertainty in the data, and consequently, the need to use a greater number of assumptions in the risk assessment, suggest the need for a larger acceptable MOE.
    - *The number of responses (adverse effects)*. A smaller MOE may be appropriate when a compound induces only one type of response. If a compound induces several different types of adverse effects, a larger MOE may be advised.
    - *The nature of the response(s)*. The severity of the effect (e.g., non-specific weight change versus tumor), whether the response is a precursor effect in the mode of action or a frank apical effect, and the slope of the dose response curve (e.g., steep versus shallow rise; over what range of doses it rises) help discern an acceptable MOE.
    - *Persistence of compound*. Information about the contaminant's persistence in the body would suggest a larger MOE for those compounds that persist longer in the body.
    - *Size of affected population.* If a great number of people are exposed versus a very small number, a larger MOE may be necessary for the first case to take larger variability of exposure level into account.
    - *Sensitive populations/lifestages*. The risk manager may decide that sensitive populations (e.g., children at risk) need to be considered and a larger MOE may be appropriate to take their sensitivities into account.

VI. Risk Management Options

General Considerations

34. CCCF has a number of risk management options it can recommend that could achieve a desired level of protection of public health. There are risk management options that national authorities can directly adopt from CCCF and implement, e.g., adoption of a ML for contaminants in specific foods into a national standard. CCCF guidance can be used by national authorities to issue guidance to industry, e.g., providing guidance for good manufacturing practices (GMPs) during processing to minimize contamination.

35. 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 national authorities may stimulate good practices by food business operators. Also, where a high level of uncertainty is indicated by the risk assessment, national authorities may need to consider whether a graduated implementation is warranted, e.g., introduction of guidance to reduce exposure whilst commissioning further work to refine the estimates.

36. 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.

37. 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 CCCF can relate directly to actions national authorities 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). In the section hereunder, a distinction is made between activities for CCCF and those for national authorities.

CCCF

Maximum Level (ML)

38. The Codex ML for a contaminant in a food or feed commodity is the maximum concentration of that contaminant recommended by Codex to be permitted in that commodity. The Codex Procedural Manual states that CCCF shall endorse MLs only for those contaminants for which:

    a. JECFA, or *ad hoc* FAO/WHO expert meetings, has completed a safety assessment or has performed a quantitative risk assessment, and

    b. The level of the contaminant in food can be determined through appropriate sampling plans and analysis methods. The setting of an ML for a contaminant may be considered where the risk is high and when it occurs in foods which make a significant contribution to total exposure.

39. The Principles for establishing MLs in food and feed for CCCF are described in the Preamble of the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995). CCCF generally refers to the HBGV or MOE level recommended by JECFA when considering an ML.

40. Although MLs are mainly set for primary commodities, it may be appropriate to set an ML for processed foods where the setting of an ML for the primary commodity is judged to be ineffective or where the contaminant arises as a result of processing (e.g., chloropropanols) or where appropriate processing may result in the removal of a toxin. In cases where the source of the contamination is sporadic, such as with biotoxins in bivalve mollusks, setting an ML can serve as an effective control against occasional poisoning outbreaks if regular monitoring is undertaken.

41. For a contaminant that has a chronic toxic effect and a lognormal exposure distribution among the population, the setting of an ML for that chemical in the food in which it occurs often has little impact on the mean exposure of the population. If a reduction in exposure is desired, a significant proportion of the food would have to be removed or recalled from the market in order to shift the mean value. However, it should be kept in mind that the setting of a well chosen ML can put pressure on preventive measures by food business operators, and these measures might result in a shift of the distribution curve as a whole, depending on the possibilities of prevention. In cases where the exposure of all consumers to a chemical is well below the HBGV, establishing an ML in the food is unlikely to have any impact in terms of public health. However, in case the low exposure is due to the existence and enforcement of a ML and effective preventive practices by food business operators, it can not be concluded that the ML has no impact on public health.

42. In order to evaluate their potential effectiveness, different hypothetical MLs can be examined for a contaminant under its exposure scenarios and help provide insights to risk management options and the ultimate ML established (e.g., aflatoxin in tree nuts).

43. There may be instances where JECFA concludes that a contaminant may produce adverse effects under a given exposure scenario, but due to the nature of the dose response relationship a HBGV cannot be established (e.g., lead). In these instances, JECFA may provide a qualitative description of its findings to CCCF so the Committee and national authorities understand the complexity of the situation. A national authority can take this information in account when deciding what course of action for their country to take.

Guidelines/Guidances/Codes of Practice

44. When the development of an ML is not warranted or is unlikely to be effective, other products can be developed. This may be in the form of a best practice guideline document or a code of practice.

45. Codex guidelines provide principles that set out policy in certain key areas; and guidelines for the interpretation of these principles or for the interpretation of the provisions of the Codex general standards. Guidances describe the current science-based thinking on a topic and should be viewed as recommendations for national authorities or those implementing such measures (such as industry), unless specific regulatory requirements are cited.

46. Codex Codes of Practice (CoP) can be useful measures to reduce occurrence levels and therefore exposure. Also, CoP can be developed when specific guidance is needed to facilitate compliance with a (future) ML, or where establishing an ML is not feasible. Codex CoP define the production, processing, manufacturing, transport, and storage practices for individual foods or groups of foods that are considered essential to ensure the safety and suitability of food for consumption.

National Authorities

Establish Regulatory Requirements

47. One of the major risk management options for a national authority 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.

48. The national authority establishes the regulatory level through legislation and/or rule making (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). Codex member countries usually adopt or adapt the Commission's adopted standard. Members can establish or maintain a different standard if there is a scientific/public health -basis for their national situation and trade. When a ML is not recommended by the Codex, national governments can establish a ML based on national data available or on data from other countries, if relevant. It should be kept in mind that the rationale for setting of a national ML is transparent to other member countries.

Guidelines/Guidances

49. The national authorities, the food industry, or a 3rd party expert body can draft more specific guidances based on those from Codex to further explain how 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 food processing controls), and/or reduce contaminant levels in foods (e.g., physical inspection processes). As a specific example, food additive/ processing aids that reduce the formation of a specific contaminant can be applied, e.g., the approved addition of asparaginase to reduce the formation of acrylamide. Industry-led quality assurance programs at the producer level are other examples of good practices.

50. National authorities 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 government personnel, but serve as information sources to industry and the public since these guidances generally are publicly available. Furthermore, national authorities can develop (or encourage the development of) specific documents and guides on good practices, e.g., good agricultural practices (GAPs), good manufacturing practices (GMPs), good hygienic practices (GHPs), and Hazard Analysis and Critical Control Point (HACCP) plans.

VII. Other Possible Actions by National Authorities

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

Dietary advice/Labeling

52. National authorities 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).

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

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

Mitigation strategies

55. National authorities 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.

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

Recalls/Public Health Alerts

57. National authorities (where they have the authority and sufficient evidence) and industry can invoke recalls of commodities when they are determined to be unsafe food products. Monitoring of adverse event reports and consumer complaints help determine if there are exposures to potentially unsafe food products.

Education/Training

58. An important risk management action is education and training for all stakeholders involved in food safety. Education can occur for those in national authorities, 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 national authorities and industry to institutionalize. Extension services, including provisions for practical educational training at colleges and universities, could be mobilized to support 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.

59. 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.

60. Technical training on proper food safety practices is paramount in ensuring safe food. Again, 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, stakeholder meetings.

61. Just as industry training and/or education by national authorities can be done, industry's input and/or contribution to authorities also is important as a source of information to evaluate existing risk in food processing-related processes.

Research

62. Laboratory 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. Research 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.

VIII. Risk Communication Considerations

63. 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 expectations.

64. Public meetings may be structured as simply informative, e.g., the national authority announces 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 national authority can solicit input from a neutral 3rd party expert group where risk management options to deal with a particular food safety issue are discussed and technical experts from academia/ research/ industry/ government are brought together to consider all relevant scientific information presented and provide recommendations.

65. National authorities 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.

66. 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.

67. 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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