Background

1. Although no proposals for new work were received in response to CL 2016/18-FH, the 48th Session of CCFH reviewed and revised the Forward Workplan and agreed to re-establish the Working Group for Establishment of CCFH Work Priorities under the chairmanship of the United States of America to meet in conjunction with CCFH49 (see REP 17/FH, paragraphs 56-59).

2. CL 2017/68-FH was sent out to all Members and Interested International Organisations in June 2017. Member Governments were invited to propose new work for consideration by the above working group by 1 September 2017, in accordance with the Criteria for the Establishment of Work Priorities (see Codex Procedural Manual) and in accordance with the “Process by which the Codex Committee on Food Hygiene (CCFH) will undertake its work” (available at http://www.fao.org/fileadmin/user_upload/codexalimentarius/committee/docs/INF_CCFH_e.pdf).

Based on the above:

3. In response to the above mentioned Circular Letter, proposals (project documents) were submitted, as described below.

Proposals to prepare new standards and codes of hygienic practice

4. Two proposals were submitted to prepare new standards and codes of hygienic practice.

PROPOSAL SUBMITTED BY AUSTRALIA AND THE UNITED STATES OF AMERICA


6. The purpose of the Code of Practice (CoP) is to provide guidance to food business operators and government to manage allergens in food production, including controls to prevent cross-contact and the role of labelling. While food allergies may affect a relatively small proportion of the population, an allergic reaction can be life threatening or fatal. Allergens are an ongoing food safety concern for both allergic consumers and food business operators. The scope of the CoP will cover allergen management throughout the supply chain, including during manufacturing and at retail and food service end points. It will address good hygiene practice (GHP) in manufacturing and food preparation practices in food service. The CoP will complement the revised General Principles of Food Hygiene, which will include information on the importance of controlling food allergens.

7. The CoP will address aspects such as the role of competent authorities, food business operators and consumers in managing risk from food allergens; training employees in awareness and best practices; allergen management practices at receipt, storage, manufacturing, and food service; formulation and labelling; and validation and verification of allergen control.

PROPOSAL SUBMITTED BY THE EUROPEAN UNION

8. The European Union prepared a project document on Development of a Guidance Document for the Management of (Micro)Biological Foodborne Crisis/Outbreaks (Appendix 2).
9. The purpose of the new work is to provide guidance to competent authorities on the management of foodborne outbreaks/crises. Such guidance intends to contribute to the limitation of the extent of such events by enhancing preparedness and improved management. The scope would be limited to biological hazards, but an extension to other hazards (chemical) might be considered at a later stage.

10. The guidance will address aspects such as alert networks for public safety; the use of molecular typing data of pathogens facilitating the detection of links between human cases and food; tools for exchange of information between public health and food safety authorities; rapid assessments of risk; tracing affected food back and forwards; and communication to consumers and trade partners.

**Comments and proposals to revise existing standards and codes of hygienic practice**

11. No proposals were submitted to revise existing standards and codes of hygienic practice.

**CCFH Forward Workplan**

12. CCFH48 revised the Forward Workplan (See REP17/FH para. 57 and Appendix IV) to remove the work on (1) development of annexes on tomatoes and carrots to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* based on the conclusion of the EWG on the revision of the Code of Hygienic Practice for Fresh Fruits and Vegetables not to have specific provisions for tomatoes and carrots and (2) the *Code of Hygienic Practice for the Processing of Frog Legs* (CAC/RCP 30-1983), as no interest had been expressed. The revised Workplan is re-produced as Appendix 3 to this document. One country (Uruguay) submitted its rankings of items in the Forward Workplan.

**Recommendations:**

13. In respect of proposals to prepare new standards and codes of hygienic practice, members may review the proposals to consider whether it is appropriate for CCFH to undertake the work and to prioritize them.

14. CCFH49 should review its forward workplan in accordance with the “Process by which the Codex Committee on Food Hygiene (CCFH) will undertake its work” (http://www.fao.org/fileadmin/user_upload/codexalimentarius/committee/docs/INF_CCFH_e.pdf) to determine if revisions in priority are needed.
1. The purpose and the scope of the Code of Practice

The purpose of the Code of Practice (CoP) will be to provide guidance to food business operators and government to manage allergens in food production, including controls to prevent cross-contact and the role of labelling.

The development of a CoP for allergen management will contribute to the health and safety of consumers in a globalised food supply chain. It will facilitate a proactive approach to managing allergens in food production, rather than a reactive response once a food safety hazard is identified.

The scope of the CoP will cover allergen management throughout the supply chain including during manufacturing, as well as at retail and food service end points. It will address good hygiene practice (GHP) in manufacturing and food preparation practices in food service.

Most food allergies are caused by an adverse immune reaction (hypersensitivity) to certain food proteins. In addition there may be other reasons why a consumer needs to avoid certain foods, such as intolerance, which does not cause anaphylaxis but can significantly impact quality of life.

Allergy to food and some food intolerances can be classified by their immune mechanism:

- immunoglobulin E (IgE)-mediated,
- non-IgE mediated (cell-mediated), and
- mixed IgE and non-IgE mediated

The proposed scope of this Code of Practice will cover causative agents in food which result in both IgE and non-IgE mechanisms.

2. Relevance and timeliness

The protection of consumer health and the safety of food is a Codex priority. Food safety, as defined in the General Principles of Food Hygiene is an ‘assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use’ (CAC/RCP 1-1969).

While food allergies may affect a relatively small proportion of the population, an allergic reaction can be life threatening or fatal. Allergens are an ongoing food safety concern for both allergic consumers and food business operators.

The revision of the General Principles of Food Hygiene will include allergenic contamination as a key hygiene control measure, noting that the allergenic nature of some foods should be part of hazard identification and should be managed with appropriate controls to prevent their presence in food where they are not labelled. The increased recognition of allergens as a potential food safety hazard means that there is an expectation for food business operators and competent authorities to consider allergen management in a hygiene control system.

The development of a CoP will provide additional support to both food business operators and competent authorities and facilitate the implementation of the revised General Principles.

2.1 Global perspective

Food allergies have been an increasing food safety issue globally and have emerged as a major public and personal health burden.

In the USA it is estimated that 2 percent of adults and about 5 percent of infants and young children suffer from food allergies. Approximately 20,000 consumers require emergency room treatment and a number of Americans die each year because of allergic reactions to food (USFDA, 2016a).

In Europe, the cases of food allergies have doubled and the number of hospitalisations caused by severe allergic reactions has increased 7-fold over the last decade (EAACI, 2015).
In Australia, food allergy is estimated to occur in 10 percent of Australian infants, 4 to 8 percent of children under five years of age, and around 2 percent of the adult population. Hospital admission rates for anaphylaxis have been increasing. While the highest rates are in children under five, there has also been a doubling in admission rates for older children (aged 5-14 years). Between 2005 and 2012 there was a 50 percent increase in food allergy related anaphylaxis admissions, compared to the previous seven years (Mullins et al., 2015).

2.2 Root cause analysis

Australia analysed its recall data for the last ten years and found that the most common reason for recalls in Australia is undeclared allergens, accounting for approximately 1/3 of all recalls. During this period undeclared dairy (milk) was the most common allergen-related recall reason followed by the presence of peanut. Undeclared allergen was the most common reason for recalls involving imported food (53%).

A root cause analysis for recalls in 2016 to early 2017 identified the following key reasons for how food safety issues with allergens occurred:

- Lack of skills and knowledge of labelling requirements
- Supplier verification issues
- Packaging errors
- Accidental cross contact

Similarly, in the United States, unlabeled allergens continue to be a leading cause of recalls and the leading cause of reportable foods for FDA-regulated foods (reportable foods are foods that pose a risk of serious adverse health consequences or death to consumers.) Reports of foods with undeclared allergens to FDA’s Reportable Food Registry increased from about 30 percent of reports in the first year of the registry (September 8, 2009 to September 7, 2010) to 47 percent of reports in year 5 (September 8, 2013 to September 7, 2014) (USFDA, 2016b). Milk was the most common specific undeclared major food allergen. Root causes were similar to those identified by Australia (Gendel et al., 2014).

Processed foods including multiple ingredients are primarily involved with undeclared allergen recalls.

2.3 Impact on trade

With the increasing health burden posed by food allergens comes the expectation that food business operators and competent authorities take steps to manage allergenic contamination. In a global market it is crucial that there is international understanding of this issue and of the measures required to address it. An internationally developed guidance document for best practice allergen management will facilitate this outcome.

3. Main aspects to be covered

The main aspects of this code of practice for the management of allergens in processed food include:

- **Scope** - The application of the code of practice, what points in the food supply chain it covers and the allergenic foods identified as highest priority risk.
- **Definitions** – what are food allergens requiring management and what is allergenic contamination (e.g., “cross-contact”).
- **Role of competent authorities, food business operators and consumers** - Enforcement agencies, food businesses and consumers all have a role in the risk management of food allergens. Understanding the nature of this issue, the appropriate control measures and the information needs of consumers, informs requirements for compliance and enforcement to deliver safe food outcomes.
- **Training and supervision** – best practice allergen management and awareness for employees.
- **Raw materials** – allergen management practices to minimise risk.
- **Storage and distribution** – identification and segregation of allergens.
- **Manufacturing and food service** – control measures, including equipment, process design and cleaning.
- **Formulation and labelling** – ensuring all allergens in the food are included on the label.
- **Testing and analysis** – validation and verification of allergen control.
- **Risk management tools** – Consumer complaints, corrective actions, recalls.
4. Assessment against the Criteria for the establishment of work priorities

4.1 General criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed code of practice will meet this criterion by:

- Raising the importance of food allergen management for consumers, noting that food allergies are an increasing food safety issue globally.
- Establishing internationally agreed principles and controls for the management of allergenic contamination in foods
- Providing greater assurance that allergen management is understood and can be implemented consistently by all food business operators.

4.2 An assessment against the Criteria for establishment of work priorities

The US recently promulgated new regulations under the FDA Food Safety Modernization Act for preventive controls. The regulation specifically addresses the need for food allergen controls (appropriate labelling and prevention of allergen cross-contact) in facilities handling food allergens. The requirements apply to all domestic facilities and to foreign facilities that manufacture, process, pack or hold food for consumption in the US. The US is developing guidance on how to comply with the requirements. However, the need for allergen controls is global. In fact, because of the need to protect consumers, allergen labelling is required by many countries.

Of particular concern is the need for guidance on the controls to ensure that the label lists allergens and the product bears the correct label. Thus, the scope of work will focus on these types of controls, along with the controls to prevent the inadvertent addition of an allergen in a product that does not list the allergen on the label (cross-contact) resulting when the same equipment, utensils, etc. are used for foods with different allergen profiles without proper GHPs. These types of controls are broadly applicable by countries.

5. Relevance to the Codex strategic objectives

This proposal is consistent with the Strategic Plan of the Codex Alimentarius Commission 2014-2019, specifically Strategic goal 1 - Establish international food standards that address current and emerging food issues, Objective 1.2 Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.

The development of a code of practice for allergen management in processed foods has been identified by Members. The presence of undeclared allergens is a major food safety issue, particularly in developed countries where there have been increasing cases where food is a causative agent for anaphylaxis, and death from anaphylaxis.

The development of a Codex code of practice for allergen management is consistent with Objective 2.3 to increase scientific input from developing countries, in particular 2.3.3, Encourage sustained and continuous participation of technical and scientific experts from developing countries in the work of Codex, and Objective 3.1 - Increase the effective participation of developing countries in Codex. Existing allergen control guidance has been prepared without input from developing countries. This offers the opportunity to get input from these countries.

6. Information on the relation between the proposal and other existing Codex documents.

This proposal was developed following the proposed inclusion of allergen contamination as a key hygiene control measure in the revised General Principles of Food Hygiene (CAC/RCP 1-1969).

The General Standard for the Labelling of Prepackaged Foods (Codex STAN 1-1985) specifies that the following foods and ingredients, which are known to cause hypersensitivity, always be declared:

- Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
- Crustacea and products of these;
- Eggs and egg products;
- Fish and fish products;
- Peanuts, soybeans and products of these;
- Milk and milk products (lactose included);
- Tree nuts and nut products; and
- Sulphite in concentrations of 10 mg/kg or more.

7. **Identification of any requirement for and availability of expert scientific advice**

Not required

8. **Identification of any need for technical input to the standard from external bodies**

Technical input may be needed from food allergy experts in Member countries, including experts from organisations such as the Food Allergy Research & Resource Program (FARRP) in the US and the European Academy of Allergy and Clinical Immunology (EAACI).

9. **Time-line for completion of the new work (the time frame for developing a standard should not normally exceed five years.)**

- CCFH49 (2017): Endorsement of the new work proposal by CCFH
- CAC41 (2018): Approval of new work by CAC
- CCFH50 (2018): Start date - discussion paper and draft CoP at step 3
- CCFH51 (2019): Adoption at Step 5
- CAC42 (2021): Adoption at Step 8

**References**

EAACI, European Academy of Allergy and Clinical Immunology, Allergy Awareness Campaign. Published online, page updated: 26 October 2015


https://www.fda.gov/food/ingredientspackaginglabeling/foodallergens/default.htm

USFDA. U.S Food and Drug Administration 2016b. The reportable food registry: a five year overview of targeting inspection resources and identifying patterns of adulteration. Published online, page updated: 24 May, 2016

https://www.fda.gov/Food/ComplianceEnforcement/RFR/ucm200958.htm
1. Purpose and Scope of the Guidance Document

The purpose of the new work is to provide guidance to competent authorities on the management of foodborne outbreaks/crisis. Such guidance intends to contribute to the limitation of the extent of such events by enhancing preparedness and an improved management. It is proposed to limit the scope to biological hazards but an extension to other hazards (chemical) might be considered at a later stage.

2. Relevance and Timeliness

Most Codex standards provide guidelines on general or sector-specific good hygiene practices, good manufacturing practices, etc. intended to prevent contamination and exposure of humans to hazards through the consumption of food. Unfortunately, exposure cannot always be prevented and sporadic cases or multiple cases linked to the same food source (outbreak, possibly crisis if very severe or extended) can occur. The proposed risk management guidance document therefore supplements the existing standards in cases where prevention was not fully effective.

3. Main aspects to be covered

The guidance will address recommendations on preparedness for outbreaks and on their management. Preparedness will focus on recommendations to have a structured approach in place and maintained before an outbreak occurs. It will address the following aspects, but may not be limited to these:

- alert networks for public health and food safety,
- the use of molecular typing data of pathogens facilitating the detection of links between human cases and food,
- structures and tools to ensure exchange of information between public health and food safety authorities,
- the establishment of permanent management and crisis communication networks,
- traceability provisions,
- simulation exercises and trainings.

As regards outbreak/crisis management, recommendations will focus on the following aspects, but may not be limited to these:

- investigations in humans in order to identify the likely food source,
- (rapid) risk assessments,
- tracing back and forwards of the affected food,
- robustness of information (such as molecular typing analyses, environmental and epidemiological investigations),
- communication to consumers and trade partners.

4. Assessment against the Criteria for the establishment of work priorities

4.1 Ensuring fair practices in food trade and taking into account the identified needs of developing countries

Food-borne outbreaks/crisis have a direct effect on public health (morbidity and sometime mortality). They are often accompanied by disproportionate reactions by consumers and trade partners, not only the affected batches. Guidelines on a structured approach for outbreak/crisis management and communication may limit these effects and result in a better preparation for such events in developing and developed countries.
4.2 **Diversification of national legislation and apparent resultant or potential impediments to international trade**

Legislation on food safety focuses on prevention, monitoring and corrective actions (if required). In case of a foodborne outbreak or crisis, the lack of a coordinated approach, e.g. between public health and food safety authorities, and of a communication strategy might create confusion and uncertainties, causing impediments to domestic consumption and international trade. The introduction of a approach, agreed at global level, could reduce the impact on trade.

4.3 **Scope of work and establishment of priorities between the various sections of the work**

See 4.7.

4.4 **Work already undertaken by other international organisations in the field and/or suggested by the relevant international intergovernmental bodies**

Relevant is the "FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies". The FAO/WHO guide is generic. The new standard would provide a more integrated approach including links with data from investigations in humans towards the source and elaborating the tracing back and forward of affected consignments. Attention should also be drawn to some new tools (e.g. molecular testing), which contribute to the investigations and are specific for microbiological hazards.

The WHO "Foodborne disease outbreaks: Guidelines for investigation and controls" focuses at investigations in human cases and provides a summary of preliminary risk assessment data.

The "FAO/WHO framework for developing national food safety emergency response plans" provides a generic basis for preparedness.

4.5 **Amenability of the subject of the proposal to standardization**

Although food-borne outbreaks/crises are caused by a large range of hazards and circumstances might be different, a guidance document is needed providing a structured approach for the management of foodborne outbreaks/crises in order to be well prepared, to limit the public health and trade impact and to act efficiently in a situation which requires immediate action.

4.6 **Consideration of the global magnitude of the problem or issue**

Food-borne outbreaks/crises occur everywhere in the world. As examples, in 2015 over 4 300 (micro-)biological foodborne outbreaks were reported in the EU, involving more than 36 000 human cases, over 3 800 of which were hospitalised and 17 died, despite the presence of relatively high preventive food safety standards.

4.7 **Criteria for the evaluation and prioritizing new Work by the Codex Committee on Food Hygiene**

4.7.1 **Currency of information:** Yes

Collecting and sharing experiences in order to enhance preparedness all over the world may reduce the public health and trade impact of future outbreaks/crises.

In addition, more and more data become available from new molecular analytical methods (e.g. whole genome sequencing), facilitating the identification of clusters human cases and the food source. This information allows earlier detection of outbreaks, an improved management of such incidents and enables to, better narrow the identification of involved batches, and hence reduce the impact of actions taken.

There is a need to deal with these new and complex data in an appropriate risk management and risk communication framework.

4.7.2 **Positive impact on public health – foodborne risk to public health:** Yes, high rating (20)

There are numerous descriptions of the public health impact of foodborne outbreaks. See also 4.6. In 2011, a single outbreak of STEC O104:H4 from sprouted seeds caused disease in at least 4 000 humans of which 55 died. Listeria in deli meat caused disease in 57 people, of which 24 died, in Canada in 2008. Better preparedness and management have a high potential to gain a positive impact on public health.

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1. [http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474_eng.pdf?ua=1)
4.7.3 Impact on trade due to public health risk: Rating of 10

The guidance is relevant for all food. Food outbreaks may result in reluctance of consumers to buy the specific culprit food or even other foods not directly associated with the outbreak. Consumers' confidence may further reduce by premature and inappropriate communication on the source of the outbreak. Restoring consumers' confidence is usually difficult and lengthy, putting food business operators in dire situations. During the 2011 STEC outbreak, farmers' losses in the fruit and vegetable sector were estimated at 812 Mio € in the first 2 weeks only. Export bans constituted an annual value of 600 Mio €. The lawsuit in Ontario was claiming damages of $350 million for the 2008 Listeria outbreak.

5. Relevance to the Codex strategic objectives

Strategic goal 1: Establish international food standards that address current and emerging food issues

(Micro-)biological outbreaks occur every day. Due to new analytical methods it is expected that the number of identified outbreaks will increase. This does not indicate an increased public health risk per se, as they were just not identified in the past, but it does enhance the need to manage outbreaks properly since they may have a significant economic impact (impact on consumption and on trade).

Strategic goal 2: Ensure application of risk analysis principles in the development of Codex standards

The guidance document will not address a specific hazard or food commodities. It is intended to be relevant to all micro-biological hazards in all kinds of food causing an outbreak. The guidance document will include the three components of risk analysis in a distinct way: it will provide recommendations on preliminary risk management activities, including an initial, quick risk assessment within an outbreak situation, on what risk management measures should be in place to be well prepared and to limit the extent of an outbreak and on how communication should try to re-assure consumers and trade partners on the safety of food produced.

Strategic goal 3: facilitate the effective participation of all Codex Members

As outbreaks can occur anywhere in the world, the proposed guidance is of relevance for all members. In particular competent authorities of developing countries may benefit from this guidance since they may not have the resources to develop such guidance themselves. We therefore anticipate electronic working groups and physical, adjacent to CCFH meeting, when possible, and providing translation in the official languages of the Commission to the extent possible.

Strategic goal 4: Implement effective and efficient work management systems and practices

During the development of the guidance, all working documents and electronic discussions will be distributed in a timely and transparent matter through the e-forum at http://forum.codex-alimentarius.net/. As the revision progresses, the latest versions of the texts will be translated to the official languages of the Commission ahead of the annual Committee meetings.

6. Information on the relation between the proposal and other existing Codex documents

The guidance will supplement the existing Codex standards that focus on the prevention of foodborne hazards and outbreaks. The proposed guidance provides recommendations in cases where prevention failed.

7. Identification of any requirement for and availability of expert scientific advice

Expert scientific advice is not needed as input to start this work since many different hazards and food commodities might be involved, for which risk assessments often already exist. The WHO “Foodborne disease outbreaks: Guidelines for investigation and controls” provide an overview of the epidemiology and methods of control and prevention of most important foodborne diseases.

8. Identification of any need for technical input in the standard from external bodies so that this can be planned for

No additional need is identified at this stage.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at step 5, and the proposed date for adoption by the Commission.

If the document is accepted for new work at CCFH 49 in 2017, conceivably it could go to Step 3 at CCFH50 in 2018. The 'guidance document' could go to Step 5 at CCFH51 (2019) and Step 8 at CCFH 52 (2020) with final adoption by CAC in 2021.
## CCFH FORWARD WORKPLAN

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<th>Ranking</th>
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<th>Currency of Information (Yes/No)</th>
<th>Positive impact of new work on public health (Yes/No)</th>
<th>Project document/discussion paper (Yes/No)</th>
<th>Public Health Risk (20/14/8)</th>
<th>Trade Impact (10/5/4/2/0)</th>
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4 Currency of information: Is there new information/data that would justify the need to review the existing code(s) or establish a new one? Are there new technologies that would justify the need to review existing codes or establish a new one? If there is an existing code in place and a determination is made that the code is sufficient, no new work should proceed.
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<th>Ranking</th>
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