

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 3

CX/FH 06/39/3
October 2007

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-ninth Session

New Delhi, India, 30 October - 4 November 2007

PROGRESS REPORT ON THE JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA) AND RELATED MATTERS

Prepared by FAO and WHO

INTRODUCTION

As Codex endeavours to provide risk management guidance on a wide range of issues pertinent to the safety and quality of food in international trade in order to protect consumer health, FAO and WHO aim to provide the relevant scientific advice in a timely manner. This paper describes the scientific advice and related outputs that FAO and WHO have developed relevant to the specific agenda items of the 39th Session of the Codex Committee on Food Hygiene (CCFH) and provides an update on follow-up activities to previous work of the Committee.

A) RECENT FAO/WHO ACTIVITIES RELEVANT TO THE ONGOING WORK OF CCFH

1 *Enterobacter sakazakii* and *Salmonella* in powdered infant formula (Relevant to Agenda Item 4)

i) Safe preparation, storage and handling of powdered infant formula: Guidelines

One of the recommendations from the FAO/WHO meeting on *Enterobacter sakazakii* and other pathogens in powdered infant formula (PIF) in 2004 was that guidelines should be developed for the preparation, use and handling of PIF in order to minimize the risk to infants. In May 2005, the 58th Session of the WHO World Health Assembly (WHA) adopted a resolution (WHA58.32) on infant and young child nutrition requesting inter alia WHO to develop, in collaboration with FAO, guidelines for the safe preparation, use and storage of PIF.

WHO and FAO have developed guidelines to this effect. The document which aims to deliver the guidelines requested by the WHA and recommended by the expert meeting are available on the FAO and WHO web sites (http://www.fao.org/ag/agn/agns/jemra_riskassessment_enterobacter_docs_en.asp) and (<http://www.who.int/foodsafety/publications/micro/pif2007/en/index.html>). These guidelines are available in English, French, Russian, Spanish, Arabic and Japanese.

The guidelines were made available to the CCFH working group which met in Ottawa in June 2007. The working group agreed to propose to the CCFH that a reference to these guidelines be included in the proposed draft code of hygienic practice for powdered formulae for infants and young children.

ii) Web based model

A web-based interface for the risk assessment model for *E. sakazakii* in PIF has now been completed and will be launched during the 39th session of the CCFH. Use of this model does not require any specialist software other than an Internet platform. The user does not require any specialist training but will need to follow the User Manual which will be available on the webpage in order to ensure correct use of the model. From November 2007, users will be able to access this model via the FAO (http://www.fao.org/ag/agn/agns/jemra_riskassessment_enterobacter_en.asp) and WHO (<http://www.who.int/foodsafety/micro/jemra/en/index.html>) websites.

iii) World Health Assembly

The WHA, in its resolution 58.32 on infant and young child nutrition, urged the Codex Alimentarius Commission to urgently complete the ongoing work to address the risk of microbiological contamination of PIF and establish appropriate microbiological criteria or standards related to *E. sakazakii* and other relevant microorganisms in PIF; and to provide guidance on safe handling and on warning messages on product packaging. WHO is requested to report back to the WHA on the progress of this work every other year. Thus, WHO will be required to report back to the WHA in 2008 on the progress made by the committee in the revision of international code of hygienic practice for powdered formulae for infants and children.

Follow-up action by CCFH

The committee is requested to take note of the two new products available from FAO and WHO and delegations are requested to provide any comments they may have on these products and their use in the coming year before the 40th Session of the Committee.

The committee is requested to make every effort possible to advance the code of hygienic practice for powdered formula for infants in light of the necessity to report to the next session of the WHA on progress made in this regard.

2. Viruses in Food: Scientific advice to support risk management activities. Report of an FAO/WHO expert meeting, Bilthoven, the Netherlands, 21 – 24 May 1997. (Relevant to Agenda items 9a)

In response to a request from the 38th session of the CCFH, FAO and WHO convened an expert meeting in May 2007 in Bilthoven, The Netherlands, in collaboration with RIVM and VWA, to review the current state of knowledge on viruses in foods and their public health and trade impact. The objective was to provide advice and guidance on the virus-commodity combinations of particular concern, the issues that need to be addressed by risk managers and the options available to them. In addition, the experts were asked to identify additional scientific information needed to provide scientific advice on managing the risks associated with viruses in foods.

While the meeting concluded that viruses play a major role in the burden of infectious intestinal disease, it was noted that under-reporting, the lack of surveillance systems and the inability of existing systems determine the proportion of disease that is transmitted by food borne routes relative to other common routes make it difficult to estimate the proportion of viral illness that is food-borne.

In terms of virus detection there has been much progress in recent years and it can be concluded that well established methods to detect enteric viruses in contaminated foods exist and are used in many countries. However, there is a lack of harmonization among methods. Although, there is some work ongoing to try and address this, harmonization efforts are primarily focused on virus detection in bivalve molluscs and additional efforts aimed at other foods, particularly fresh produce and prepared foods, are needed.

The criteria used to prioritize the virus-commodity combinations of public health concern were based on categorization of strength of causal evidence which in turn was based on a limited body of evidence.

Prioritization was done according to the following criteria: Disease severity, incidence/prevalence, probability of exposure, trade impact, public health cost, and ability to control food borne infections.

The meeting concluded that the virus-commodity combinations of highest priority are noroviruses and hepatitis A virus in shellfish, fresh produce and prepared foods. This list is based on current knowledge, which is acknowledged as being incomplete. However, the establishment of these combinations is important as we seek to develop mitigation/intervention strategies. It should be kept in mind that mitigation of one virus would probably help in preventing other viruses as they often have a common source. Because of a lack of epidemiological information, further ranking of virus-commodity combinations in order of public health priority is not currently possible.

The meeting identified three major routes of viral contamination of foods i) human sewage/faeces ii) infected food handlers and iii) animals for zoonotic viruses. However, large scale outbreaks are often the result of a combination of several transmission routes. Thus the meeting recommended that intervention strategies should be focused on the priority virus-commodity combinations. Where possible these combinations should be reviewed for a specific region using the specified criteria and revised as new information and data become available.

With regard to risk management the meeting made a number of recommendations as follows.

- The use of routine sewage monitoring to screen human transmission patterns and identify the potential for a greater likelihood of contamination during primary production should be evaluated.
- Emerging viruses should be monitored, particularly when new problems arise, in an effort to assess the potential for food borne transmission. The specific research needs to address this question should be defined at the early stages of their emergence.
- New and existing pre- and post-harvest processing technologies should be assessed for their virucidal potential in high-risk food products. Conducting an analysis in an effort to systematically understand virus persistence and inactivation in different food commodities is recommended.
- Virus/commodity specific guidance would assist risk managers in better addressing the issue of food-borne virus contamination and anticipate measures needed in the event of outbreaks.
- Food producers and risk managers must be aware of the potential for outbreaks. In the case of an outbreak, they should understand the need for complete cooperation with investigators in an effort to identify effective corrective actions and reduce the public health impact of the event.
- To adequately control food borne viral infections it will be necessary to: heighten the awareness about the potential for transmission by infected food handlers; optimize and standardize methods for detection of food borne viruses and food-borne disease outbreaks; enhance laboratory-based surveillance to detect large common-source outbreaks at an early stage; develop quality control measures specifically for virus control; take into consideration the role of viruses as food borne pathogens in the development of HACCP plans; inform consumers of the risks presented by foodborne viruses; and better understand transmission and risk through the application of risk assessment.

Full details are available in the report of the meeting. A preliminary version of the report will be made available for the 39th CCFH.

Follow-up action by CCFH

The committee is requested to take this information into consideration in the selection of its priorities for new work.

If the Committee decides to take on new work to address the problems of viruses in food, FAO and WHO would appreciate receiving explicit guidance as to any additional scientific advice required to undertake this work.

3. Microbiological hazards in fresh produce (*Relevant to Agenda items 9a*)

Following the request of the 38th session FAO and WHO have initiated work to provide scientific advice on microbiological hazards in fresh produce. Given the extensive scope of the request, FAO and WHO have

taken a stepwise approach towards addressing it. FAO and WHO issued a call for data and a call for experts and a request for information was also distributed via Codex Circular letter (CL FH-12). FAO and WHO would like to extend their appreciation to the 22 member countries, 1 member organization and several observers that responded to the request.

On 19 – 21 September 2007, FAO and WHO implemented a meeting of 10 experts to review the available data and identify the priority issues to be addressed from a global perspective. The report of the meeting is currently under preparation and a preliminary version will be made available for the 39th session of the CCFH. The meeting identified 3 levels of priority products and identified the pathogens of concern for each product group according to the established criteria. Leafy greens including leafy green herbs were identified as the highest priority. The next level of priorities included melons, tomatoes, berries, green onions and sprouted seeds. With regard to sprouted seeds the meeting recommended that the existing Codex guidance be reviewed in light of recent information in order to determine if it is still adequate. Despite this guidance outbreaks linked to sprouted seeds continue to occur. With regard to melons, tomatoes, berries and green onions, the meeting concluded that based on the available scientific data it was not possible to separate these in terms of priorities. The third level of priorities included all other products that had been identified by CCFH and member countries. While these products have been implicated in foodborne disease there is not adequate information available at the current time to address them specifically.

Follow-up action by CCFH

Based on this, FAO and WHO are proposing to proceed with the elaboration of scientific advice on leafy greens. However, before proceeding FAO and WHO await confirmation from the committee as to which specific commodities it will undertake new work and what specific advice is needed.

4. Enterohaemorrhagic *Escherichia coli* in meat and meat products: approaches for the provision of scientific advice (Relevant to Agenda items 9a)

FAO and WHO together with the Food Safety Authority of Ireland convened a meeting on enterohaemorrhagic *E. coli* (EHEC) in raw meat and meat products in September, 2006 in Dublin, Ireland to provide guidance to FAO and WHO on future work in this area and to identify the key issues faced by risk managers in addressing the problems associated with EHEC in raw beef and beef products, and provide guidance on how to address them.

The meeting noted that to date most risk management issues associated with EHEC have been addressed in the absence of risk assessments. While a number of risk assessments have been developed over a ten year period which reflect a continuum of development of risk assessment approaches, these risk assessments were not developed to address specific risk management questions. However, their use to re-evaluate risk management actions is planned in some countries, for example the United States of America and Ireland. While risk assessments are not needed for common sense risk management activities, risk assessment is likely to assist when more difficult decisions or complex interventions throughout the food chain are needed. Considering the ongoing problems with EHECs, risk assessment could play an important role in the management of this problem.

Although this meeting specifically addressed the risk associated with *E. coli* O157 in beef, it noted the broader need to address risks associated with this and other EHECs in the environment and on other meats and foods. It was observed that elements of the existing risk assessments could potentially be applied to other products and routes of EHEC transmission associated with or impacted by beef production. The meeting made the assumption that EHECs other than *E. coli* O157:H7 will respond to food safety measures in the same manner and further concluded that that controls for EHEC will also impact on other pathogens. The report of this meeting is been finalized and a pre-publication version will be released in advance of CCFH.

Follow-up action by CCFH

The committee is requested to take this information into consideration in the selection of its priorities for new work by the Committee.

5. *Vibrio parahaemolyticus*.

The 38th session of the CCFH requested FAO and WHO to use the risk assessment on *Vibrio parahaemolyticus* in seafood, being developed to provide scientific advice to Codex, to address the following risk management question “ *Estimate the risk reduction from V. parahaemolyticus when the total number of V. parahaemolyticus or the number of pathogenic V. parahaemolyticus, ranges from absence in 25g to 1000 cfu or MPN per gram.*”

The work undertaken considered the impact of three different limits for *V. parahaemolyticus*: 100 cfu/g; 1000 cfu/g and 10000 cfu/g. These limits were considered to be applied when the products are cooled after harvesting, when the population of *V. parahaemolyticus* has stabilised i.e. when the temperature becomes too low for further growth but not so low that die-off occurs.

An estimation of the risk reduction associated with the implementation of such levels was developed based on information from three countries, Australia, New Zealand and Japan. However, where the appropriate data were not available surrogate data from the US was used. The estimation is based on the assumption that all (100%) harvested oysters meet a specified target limit compared with the baseline distribution of *V. parahaemolyticus* for each of these countries. The results as presented below include an estimation of both the reduction in human illness and the amount of product rejection that would occur if all product on the market were to meet the specified target.

Table 1: Reduction in illness, based on meeting specified target numbers of *V. parahaemolyticus*, together with commensurate rejection of product for raw consumption

| Specified target | Reduction (%) in the number of predicted illnesses | | | Product (%) rejected to achieve these reductions in illness | | |
|------------------|--|----------------------|----------------|---|----------------------|----------------|
| | Australia (summer) | New Zealand (summer) | Japan (autumn) | Australia (summer) | New Zealand (summer) | Japan (autumn) |
| 100 cfu/g | 99 | 96 | 99 | 67 | 53 | 16 |
| 1000 cfu/ g | 87 | 66 | 97 | 21 | 10 | 5 |
| 10000 cfu/g | 52 | 20 | 90 | 2 | 1 | 1 |

Table 2: Predicted *V. parahaemolyticus* illnesses predicted by meeting specified targets

| Specified target | Predicted number of illnesses per year | | |
|------------------|--|-------------------------|------------------------|
| | Australia (summer) | New Zealand (summer) | Japan (autumn) |
| 100 cfu/g | Approx 1 every 5 years | Approx 1 every 10 years | Approx 1 every 2 years |
| 1000 cfu/ g | 1 | 1 | 1 |
| 10000 cfu/g | 5 | 3 | 4 |
| No limit | 17 | 4 | 38 |

When considering these results a number of issues need to be taken into account:

- The baseline data (i.e. levels of *V. parahaemolyticus* in oysters) are different for each country and therefore each country’s results must be considered individually because the reductions are relevant to their baseline only.
- In developing the risk assessment model some surrogate data were used as data on all the necessary parameters were not available for each country.
- These results relate to applying these limits after landing, at the cool down stage and assume that it is possible to apply an appropriate sampling plan for testing at that point. It would also be possible to apply these criteria at another stage of the harvest to consumption chain but further analysis would have to be undertaken to determine its impact.
- The targets considered here are for total numbers of *V. parahaemolyticus* (i.e. both pathogenic and non pathogenic strains).
- These results (Tables 1 and 2) assume 100% compliance with the established limit. Note that risk assessments for other pathogen:commodity combinations have indicated that the level of compliance

to an established limit is an important consideration in terms of the effectiveness of the limit as a risk reduction strategy.

Further details and discussion of these results are presented in the report which is currently being edited.

Follow-up action by CCFH

This information is brought to the attention of CCFH for information purposes only following the request of the 38th session. FAO and WHO will provide this information to the CCFHP for their consideration in the elaboration of microbiological criteria for bivalve molluscs.

B) FOLLOW-UP ACTIVITIES TO PREVIOUS WORK OF THE COMMITTEE

Terms of reference for the FAO/WHO expert consultation on the uses of active chlorine

Following the approval of the Terms of Reference for the expert consultation on the uses of active chlorine, developed by the 37th session of the Committee, and adopted by the 28th session of the Commission, FAO and WHO are in the process of planning the work necessary to address this issue. A core group of experts to assist in this work have been identified following a call for experts and this group will meet on 7 – 9 November 2007 to further define the work to be undertaken and agree the background papers and assessments that need to be developed. An expert consultation on this issue will be convened in 2008.

C) OTHER RELATED ISSUES

Framework for the provision of scientific advice

The FAO/WHO Consultative Process on the Provision of Scientific Advice which was initiated at the request of the 24th Session of the Codex Alimentarius Commission held in July 2001 and recommended that FAO and WHO carry out "a review of the status and procedures of the expert bodies in order to improve the quality, quantity and timeliness of scientific advice" has now been concluded. The provision of scientific advice has been enhanced through the harmonization of scientific approaches and operating procedures followed by both organizations in the provision of advice requested by Codex and FAO/WHO Member Countries. One of the important outputs of the consultative process has been the development and publication of a Framework for the Provision of Scientific Advice which documents the principles, practices and procedures currently applied by FAO and WHO for the provision of scientific advice. As procedures are updated, the Framework will be revised periodically.

The Framework has been subject to public comments and the final version is now available from the FAO (http://www.fao.org/ag/agn/agns/advice_en.asp) and WHO (<http://www.who.int/foodsafety/codex/consult/en/index.html>) websites.

Global Initiative for Food-related Scientific Advice (GIFSA).

In an attempt to meet the growing demand for scientific advice as challenges in the fields of food safety and nutrition continue to emerge, FAO and WHO established a Global Initiative for Food-related Scientific Advice (GIFSA). The initiative was launched at the 30th Session of the Codex Alimentarius Commission, 2 – 7 July 2007, to ensure the sustainable funding of the programmes of FAO and WHO on the provision of scientific advice to the Codex Alimentarius Commission and member countries.

Through this initiative FAO and WHO will aim to build awareness in member countries on the provision of scientific advice, actively seek financial and in-kind contributions from member countries, strengthen collaborations in order to ensure the availability of national experts to contribute to scientific meetings, facilitate the secondment of qualified experts to work directly on scientific advice issues, and facilitate submission of relevant scientific data to FAO and WHO as a basis for risk assessments and scientific advice. It is considered to be an important tool to promote timeliness and efficiency, while ensuring the continuation of the highest level of integrity and quality. Contributions will be accepted from governments, organizations and foundations in accordance with FAO and WHO rules. FAO and WHO have established separate accounts in each Organization to facilitate receipt of contributions.

Further information is available from the FAO (http://www.fao.org/ag/agn/agns/advice_en.asp) and WHO (<http://www.who.int/foodsafety/codex/gifssa/en/index.html>) websites.