codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3 (a) **CX/FH 08/40/3**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD HYGIENE
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MATTERS ARISING FORM THE WORK OF FAO, WHO AND OTHER INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

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 40th 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* (*Cronobacter* spp.) in powdered formula *(Relevant to Agenda Item 4)*

i) Expert meeting on *Enterobacter sakazakii* (*Cronobacter* spp.) in Powdered Follow-up Formula (Washington DC, USA, 15–18 July 2008)

The meeting was implemented to specifically address the request of the 39th Session of the CCFH to provide scientific information and advice and to inform of the decision-making process on the development of microbiological criteria for *Enterobacter sakazakii* (*Cronobacter* spp.) for powdered follow-up formula for infants and young children.

The meeting reviewed the available information on the production and consumption of powdered follow-up formula (FUF) and cases of *E. sakazakii* illness in infants and young children. A review of documented *E. sakazakii* (*Cronobacter* spp.) infections worldwide has identified approximately 120 individually documented cases among infants and young children up to 3 years of age. Six of these cases are known to have occurred among infants 6-11 months and two cases among children in the age group of 12 - 36 months. Of the 5 invasive cases in the 6 – 11 month age group, 3 had other active medical problems. However, globally, there appear to be very few surveillance data for *E. sakazakii* (*Cronobacter* spp.) related illnesses. Although a couple of passive surveillance systems exist, no active surveillance system for *E. sakazakii* (*Cronobacter* spp.) disease has been identified. The available data did not enable a detailed breakdown of numbers of cases by month for infants under 12 months, although laboratory surveillance data from two countries reiterate the findings of earlier meetings that amongst infants, neonates and infants less than 2 months of age are at the greatest risk of infection. The prevalence of factors such as nutritional status, HIV status, other clinical conditions, low birth weight etc., which contribute to immune status vary widely and

thus the meeting concluded that there will be a wide variation in the prevalence of immuno-compromised infants.

The meeting noted two main differences between the manufacturing processes for PIF and FUF: 1) a wider variety of dry-mix ingredients in used in FUF manufacture (e.g. cocoa powder, fruit and vegetable powders or flakes, and flavours), and 2) microbiological criteria, and therefore hygiene control measures, are more stringent for PIF. Very few data were available on the prevalence of *E. sakazakii* (*Cronobacter* spp.) in products categorized as FUF for infants between 6 and 11 months. The absence of such data is most likely due to the fact that there is no mandated requirement for testing FUF for *E. sakazakii* (*Cronobacter* spp.). While data on FUF consumption was limited, most countries reported that FUF is marketed for infants 6 months of age or older. However, the available data also indicated that FUF is consumed by infants less than 6 months of age in both developing and developed countries and is sometimes consumed by infants less than 1 month old.

The meeting reviewed all the available information in the context of whether or not a microbiological criterion for *E. sakazakii* (*Cronobacter* spp.) should be established for FUF and weighed the scientific evidence for and against. Although not making an explicit recommendation on this, by presenting the available evidence, the meeting sought to highlight the currently available data and how it contributes to our knowledge base, identify issues of concern (e.g. consumption of FUF by very young infants) and facilitate risk management decisions. In addition, the limitations of that data are provided. In this context the analysis aims to provide guidance to risk managers in determining the most appropriate actions to be taken whether that is in the establishment of a microbiological criterion for FUF or some other type of risk management measures. These outputs are described in the report of the expert meeting which is available at www.fao.org/ag/agn/agns/jemra_riskassessment_enterobacter_en.asp.

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

The WHO/FAO guidelines are now available in 7 languages and can be accessed at www.who.int/foodsafety/publications/micro/pif2007/en/index.html.

ii) Web based model

A web-based interface for the risk assessment model for *E. sakazakii* in PIF has now been completed and is available for use at www.mramodels.org. 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 is available, in English only, on the webpage, in order to ensure correct use of the model.

iii) World Health Assembly

A report on the work undertaken to address the risks posed by pathogens in powdered formulae for infants and young children was presented to the 2008 session of the World Health Assembly (WHA) as follow-up to the WHA Resolution 58.32 in 2005. The WHA was encouraged by the work of FAO, WHO and the CAC and urged Member States to implement the WHO/FAO guidelines on the safe, preparation, storage and handling of PIF and to take action, through the implementation and monitoring of food safety measures, to reduce the risk of contamination of PIF with *E. sakazakii* (*Cronobacter* spp.) and other pathogens during both manufacture and use.

Follow-up action by CCFH

The Committee is requested to make every effort possible to advance the advice to be provided on the management of the risks posed by powdered FUF for infants in light of the output of the requested expert meeting.

2. Microbiological hazards in fresh produce *(Relevant to Agenda item 7)*

Following the request of the 39th session FAO and WHO have implemented an expert meeting to examine the issue of microbiological hazards associated with leafy vegetables and herbs to provide scientific advice to facilitate the development of an annex to the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables specifically addressing the risks associated with leafy vegetables and herbs.

The meeting was implemented in Bangkok, Thailand on 5 – 9 May 2008 and 17 experts from 13 countries participated. The diversity of production systems around the world made it difficult to provide very specific recommendations, therefore the meeting sought to use the available science to identify the specific issues that need to be considered when developing guidance in this area.

The meeting sought to highlight the critical importance of knowing and understanding the production and processing system of concern and to marry that with information on possible hazards and risks. Thus, for example, the need to undertake an assessment of a production site in terms of the potential of factors such as wildlife, domestic animals, human activity, proximity to urban areas, climate, topology, weather, hydrology, prior land use and geographical features to contribute to an increased risk of microbiological contamination of leafy vegetables and herbs during the growing phase was emphasized. Similarly, the differences in post-harvest practices were highlighted in terms of risks and mitigations. The meeting reemphasized the importance of implementing existing recommendations and highlighting the value and utility of the existing knowledge in identifying and implementing further measures to minimize pathogens on leafy vegetables and herbs to the extent possible. Further information and the report of this expert meeting can be obtained from: www.fao.org/ag/agn/agns/jemra_riskassessment_freshproduce_en.asp.

Follow-up action by CCFH

Based on this, FAO and WHO are requesting consideration of the scientific advice provided on leafy greens and herbs in the elaboration of the Annex and the definition of any further requests for scientific advice in this area.

3. 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 to 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 viruses 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.

Full details are available in the report of the meeting which is available at www.fao.org/ag/agn/agns/jemra_riskassessment_viruses_en.asp.

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.

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 implemented an expert meeting on chlorine-containing disinfectants used in the food production and food processing in Ann Arbor, Michigan, United States of America on 27- 30 May 2008.

The expert meeting drew from the experience of 20 experts from 13 countries and was devoted to assessing the benefits of the reduction and control of contamination of food with pathogenic microorganisms, and thereby the reduced risk of foodborne disease, by direct treatment of food with disinfectants at various steps of food production and processing and to compare these benefits with the potential health risks from ingestion of chlorine and non-chlorine chemical disinfectants and their reaction by-products. The predominating world-wide treatment scenarios for poultry, red meat, fish and fishery products, fresh produce (fresh fruit and vegetables, including sprouts and hydroponics) and food contact surfaces were used in the assessment of the benefits and risks in a step-wise qualitative approach and conclusions and recommendations were agreed. Several disinfectant use scenarios were defined where there were no health concerns identified but for which there was a benefit. The level of evidence in some areas was recorded in the report. As further extensive drafting and editing of the report is necessary, a prepublication issue of the report is only foreseen by the end of 2008. The Secretariat extends their appreciation to all those who supported this activity and to the USA for resources provided to facilitate implementation of this meeting.

C) OTHER RELATED ISSUES

Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials (Rome, Italy, 26-30 November 2007)

The objectives of the meeting were to find an appropriate balance between animal health needs and public health considerations with regard to critically important antimicrobials; to identify current and potential hazards to public health; to identify priority combinations of human-pathogen-antimicrobial species, review current management strategies and options for maintaining the efficacy of critically important antimicrobials for humans and animals and provide recommendations on future FAO, WHO and OIE activities. The expert meeting compared the WHO and OIE lists of critically important antimicrobials for human and veterinary use respectively noting that these lists should be considered when establishing priorities for risk assessment and management. The need for access to antimicrobials in both human and veterinary medicine was acknowledged. Key principles for the establishment of a prioritization scheme for the risk assessment of antimicrobial resistance resulting from the use of antimicrobials in food animals were identified. The meeting identified and characterized preliminary risk management activities for antimicrobial resistance associated with food animals and made recommendations to FAO, WHO, OIE and national governments on addressing the risks. Further information and the report of this expert Meeting can be obtained from: www.fao.org/ag/agn/agns/micro_antimicrobial_en.asp and www.who.int/foodborne_disease/resistance/en/index.html.

FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety (Rome, Italy, 8-12 October 2007)

The purpose of the meeting was to review the current knowledge on animal feed and its impact on food safety and international food and feed trade and to provide orientation and advice on this matter to FAO/WHO member countries and to international organizations. The meeting addressed the large and evolving list of hazards that present human health risks and disrupt trade in the context of expanding global trade of food and feed as well as the need to improve the efficiency of animal production to provide better access to affordable protein. The continuing occurrence of trade problems as a result of countries establishing different national tolerances for residues, the lack of harmonization with international standards, and sometimes the lack of international standards and differences between countries' capabilities to conduct analyses were identified as contributing to trade problems. Economics and technological advances are driving the development of new feed products which may challenge established regulatory approaches to feed and food safety. The meeting identified potential measures to ensure safe feed and made a number of recommendations in relation to reducing the risk to food safety from feed. The report of the meeting in English and French (Spanish is forthcoming) is available at:
http://www.fao.org/ag/againfo/resources/en/pubs_food.html.

Nanotechnology in food and agriculture

In response to concerns raised by member countries on the possible food safety implications of the applications of **nanotechnologies to food and agriculture,** FAO and WHO will implement an expert meeting to address this issue. The meeting will aim to develop a common view of actual and anticipated nanotechnology applications in the food and agriculture sectors and of their implications for food safety, to review current risk assessment procedures and evaluate their adequacy for the assessment of nanoparticles in foods, to agree on priority research to fill information gaps related to potential food safety issues and to develop guidance on the possible roles of FAO and WHO in addressing food safety issues linked to nanotechnology applications. FAO and WHO convened a meeting of a core group of experts from 14-15 May 2008 to further define the issues and initiate preparation of background papers for an expert meeting scheduled for early 2009. A call for data and call for experts will be issued well in advance of the expert meeting. Appreciation is extended to the Government of Australia for their support of this initiative to date.

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 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.

Appreciation is extended to the governments of the USA and Italy for the resources which they have provided to GIFSA to date to support the provision of scientific advice in 2008. 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.