



WORLD HEALTH ORGANIZATION

EXECUTIVE BOARD
115th Session
Provisional agenda item 4.4

EB115/7
23 December 2004

Infant and young child nutrition

Report by the Secretariat

BACKGROUND

1. In connection with the discussion at the Fifty-seventh World Health Assembly on infant and young child nutrition,¹ a draft resolution was proposed by the delegations of Federated States of Micronesia, Fiji, Kiribati, the Marshall Islands, Nepal and Palau.² The draft resolution reflected concerns regarding the ready availability and intensive marketing of breast-milk substitutes in some developing countries, and the recent findings regarding *Enterobacter sakazakii* and other microorganisms in powdered infant formula. Member States also expressed their wish to ensure that the Codex Alimentarius Commission should give full consideration to recommendations made by the Health Assembly concerning quality standards for processed foods for infants and young children.
2. Some delegations expressed reservations in view of the short time available to analyse the text of the resolution in detail. In order to allow time for further discussion, it was therefore agreed to submit the draft resolution to the Executive Board at its 115th session, to be forwarded to the Fifty-eighth World Health Assembly for its consideration.
3. The Health Assembly has on several occasions called upon the Codex Alimentarius Commission to give full consideration, within the framework of its operational mandate, to relevant public health strategies, particularly the global strategy for infant and young child feeding (resolution WHA55.25) and the Global Strategy on Diet, Physical Activity and Health (resolution WHA57.17). Resolution WHA54.2 on infant and young child nutrition, paragraph 2(9), also called on Member States "... to encourage the Codex Alimentarius Commission to take the International Code [of Marketing of Breast-milk Substitutes] and relevant subsequent Health Assembly resolutions into consideration in developing its standards and guidelines; ...".
4. In order to address the concerns raised by reports that powdered infant formula had led to serious illness in infants caused by *E. sakazakii*, and consistent with the need to provide safe food for all infants, FAO and WHO jointly convened an expert workshop in February 2004 on *E. sakazakii* and other microorganisms in powdered infant formula.³ The meeting was organized in response to a

¹ See document WHA57/2004/REC/3, summary record of the eighth meeting, section 3.

² Document A57/A/Conf.Paper No. 4.

³ *Enterobacter sakazakii* and other microorganisms in powdered infant formula. Geneva, FAO/WHO, 2004 (Microbiological Risk Assessment Series, No. 6.).

specific request to FAO and WHO for scientific advice from the Codex Committee on Food Hygiene, in order to provide input for the revision of the Recommended International Code of Hygienic Practice for Foods for Infants and Children. It also aimed to provide pertinent information to the Members of both Organizations.

5. Resolution WHA56.23 on the Joint FAO/WHO evaluation of the work of the Codex Alimentarius Commission endorsed WHO's increased direct involvement in the Codex Alimentarius Commission and requested the Director-General to strengthen WHO's role inter alia in complementing the work of the Codex Alimentarius Commission with other relevant WHO activities in the areas of food safety and nutrition, with special attention to issues mandated in Health Assembly resolutions. This resolution also called for a strengthening of WHO's role in the management of the Codex Alimentarius Commission and a higher profile to be given to the Commission and related work throughout the Organization. These measures should also contribute to facilitating the flow of information between WHO and the Commission.

6. The Codex Alimentarius Commission is a joint subsidiary body of FAO and WHO with primary responsibility for implementation of the FAO/WHO Food Standards Programme. It was established through parallel decisions of the Health Assembly and the FAO Conference. The standard-setting functions of the Commission are of a special character and require a large degree of autonomy as a safeguard of the scientific integrity and credibility of the Commission's work. At the same time, the Codex Alimentarius Commission is part of the overall structure of its parent organizations and, as such, is subject to general oversight on their part. It should act consistently with the general policies adopted by their respective governing bodies so as to contribute to their implementation within its special area of work. This relationship was highlighted in resolution WHA56.23, whereby the Health Assembly requested the Director-General, inter alia, "to consider means to improve the efficiency of the Codex standard-setting process by meeting the unique governance needs of Codex within the overall structure of WHO and FAO".

ISSUES

7. The resolutions mentioned above indicate that the Codex Alimentarius Commission, when elaborating standards, guidelines and recommendations for the relevant foods, should contribute, within the framework of its operational mandate, to full implementation of international public health policies.

8. With respect to the risks associated with *E. sakazakii* and other microorganisms in powdered infant formula, after reviewing the available scientific information, the expert workshop concluded that intrinsic contamination of powdered infant formula with *E. sakazakii* and *Salmonella* has been a cause of infection and illness in infants, including severe disease which could lead to serious developmental sequelae and death. No link has been established between illness and other microorganisms in powdered infant formula, although such a link was considered plausible for other *Enterobacteriaceae*.

9. *E. sakazakii* has caused disease in all age groups. From the age distribution of reported cases it is deduced that infants (children less than one year old) are at particular risk. Among infants, those at greatest risk of *E. sakazakii* infection are neonates (first 28 days), particularly preterm infants, low-birth-weight infants, or immunocompromised infants. Infants of HIV-positive mothers are also at risk, because they may be more likely to receive infant formula and, if they are HIV-positive, are more susceptible to infection. Feeding of infants of HIV-positive mothers, and of low-birth-weight infants,

may be of particular concern for some developing countries, where the proportion of such infants is higher than in developed countries. Powdered infant formula that meets current standards is not a sterile product and may occasionally contain pathogens. The workshop did not identify a feasible method, using current technology, to produce commercially sterile powders or completely eliminate the potential for contamination.

10. In some countries, the government entities responsible for food regulation and standard setting are not organizationally related to the public health authorities that are traditionally responsible for implementing international recommendations emanating from WHO. This has led to some degree of uncertainty on the best way to advance the health agenda, mandated by the Health Assembly through its resolutions, working under standards, guidelines and recommendations. Concern has been expressed among standard-setting bodies – a considerably broader grouping (including those from the agriculture and trade sectors) – that health policy is separate from technical standards and that the two have different purposes and different applications. It is thought that although wider technical standards may be mindful of, or responsive to, health policy directives, they also have to take account of other aspects of risk management including practicability, and economic and legal matters.

11. The mandate of the Codex Alimentarius Commission is to establish standards for food products, including for processed foods for infants and young children; confusion should be avoided between such technical standards and any recommendations to caregivers on using the products in an appropriate manner. Given the special relationship between WHO and the Commission, and having regard for the uncertainty among food regulators about the role of food regulation in the broader context of public health policies, further guidance on this issue would be desirable in order to facilitate the Commission's work.

ACTION BY THE EXECUTIVE BOARD

12. The Executive Board is invited to consider the draft resolution, proposed at the Fifty-seventh World Health Assembly, containing suggestions introduced by the Secretariat in the light of issues raised. For comparison purposes, the original draft resolution,¹ indicating suggested amendments, is attached as an Annex.

The Executive Board,

Having considered the report on infant and young child nutrition,² and the draft resolution proposed by Federated States of Micronesia, Fiji, Kiribati, the Marshall Islands, Nepal and Palau at the Fifty-seventh World Health Assembly,

RECOMMENDS to the Fifty-eighth World Health Assembly the adoption of the following resolution:

The Fifty-eighth World Health Assembly,

¹ Document A57/A/Conf.Paper No. 4.

² Document EB115/7.

Recalling the adoption by the Health Assembly of the International Code of Marketing of Breast-milk Substitutes (resolution WHA34.22), resolutions WHA39.28, WHA41.11, WHA46.7, WHA47.5 and particularly WHA54.2 on infant and young child nutrition, appropriate feeding practices and related questions;

Concerned that nutrition and health claims are being used inappropriately to promote the sale of breast-milk substitutes instead of breastfeeding;

Aware that the joint FAO/WHO expert workshop on *Enterobacter sakazakii* and other microorganisms in powdered infant formula held in 2004 concluded that intrinsic contamination of powdered infant formula with *E. sakazakii* and *Salmonella* has been a cause of infection and illness in infants, including severe disease which can lead to serious developmental sequelae and death;

Noting that such severe outcomes are especially serious in low-birth-weight infants and immunocompromised infants, and therefore of particular concern to developing countries;

Bearing in mind that the Codex Alimentarius Commission is revising its recommendations on hygienic practices for the manufacture of foods for infants and young children;

Acknowledging that the Codex Alimentarius Commission plays a pivotal role in providing guidance to Member States on the proper regulation of foods, including foods for infants and young children;

Bearing in mind that on several occasions the Health Assembly has called upon the Commission to give full consideration, within the framework of its operational mandate, to evidence-based action it might take to improve the health standards of foods, consistent with the aims and objectives of relevant public health strategies, particularly the global strategy for infant and young child feeding (resolution WHA55.25) and the Global Strategy on Diet, Physical Activity and Health (resolution WHA57.17);

Recognizing that such action requires a clear understanding of the respective roles of the Health Assembly and the Codex Alimentarius Commission, and that of food regulation in the broader context of public health policies;

Taking into account resolution WHA56.23 on the joint FAO/WHO evaluation of the work of the Codex Alimentarius Commission, which endorsed WHO's increased direct involvement in the Commission and requested the Director-General to strengthen WHO's role in complementing the work of the Commission with other relevant WHO activities in the areas of food safety and nutrition, with special attention to issues mandated in Health Assembly resolutions;

1. URGES Member States:

- (1) to continue to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, followed by timely, adequate, safe and appropriate complementary feeding, with maintenance of breastfeeding up to two years of age or beyond, by encouraging the formulation of a comprehensive

national policy, a detailed plan of action to implement, monitor and evaluate the policy, and allocation of adequate resources for this process;

(2) to ensure that nutrition and health claims are not permitted on foods for infants and young children except where specifically provided for in relevant Codex Alimentarius standards or through the development of national legislation;

(3) to ensure, in situations where infants are not breastfed, that clinicians, health-care providers, community workers and family caregivers, particularly of infants at high risk, are regularly provided with information and training geared to the particular needs of developing countries, on the preparation, use and handling of powdered infant formula in order to minimize health hazards;

(4) to work closely with manufacturers to continue to reduce the concentration and prevalence of pathogens, including *E. sakazakii*, in powdered infant formula, and to continue to ensure that they adhere to Codex Alimentarius, or national, food standards and regulations;

(5) to ensure policy coherence at national level by stimulating collaboration between health authorities, food regulators and food standard-setting bodies;

(6) to ensure that national public health agencies participate in defining national positions that promote in all relevant forums, including the Codex Alimentarius Commission, the international health policies established by the Health Assembly;

2. REQUESTS the Codex Alimentarius Commission:

(1) to continue to give full consideration, when elaborating standards, guidelines and recommendations, to those resolutions of the Health Assembly that are relevant in the framework of its operational mandate;

(2) to establish standards, guidelines and recommendations on foods for infants and young children formulated in a manner that ensures safe and appropriately labelled products that meet their known nutritional needs, thus reflecting WHO policy, in particular the global strategy for infant and young child feeding and the International Code of Marketing of Breast-milk Substitutes;

(3) to address the risk of microbiological contamination of powdered infant formula and, if deemed necessary, establish appropriate microbiological criteria or standards related to *E. sakazakii* and other relevant microorganisms in powdered infant formula;

3. REQUESTS the Director-General:

(1) in collaboration with FAO, to draw up guidelines for caregivers on the preparation, use and handling of infant formula to minimize health hazards, and to address the particular needs of developing countries in establishing effective measures to minimize risk in situations where mothers cannot, or choose not to, breastfeed;

- (2) to promote research in order to gain a better understanding of the ecology, taxonomy, virulence and other characteristics of *E. sakazakii*, in line with the recommendations of the joint FAO/WHO expert workshop on *E. sakazakii*, and to find ways to reduce its levels in reconstituted powdered infant formula by collecting evidence from different parts of the world;
- (3) to issue guidance so that the Codex Alimentarius Commission may contribute, within the framework of its operational mandate, to full implementation of international public health policies;
- (4) to report regularly to the Health Assembly on progress in the consideration of matters referred to the Codex Alimentarius Commission for its action.

ANNEX

The Fifty-seventh~~eight~~^h World Health Assembly,

~~Recalling resolution WHA33.32 endorsing, in their entirety, the statement and recommendations made by the joint WHO/UNICEF Meeting on Infant and Young Child Feeding (1979) and noting that 2004 is the twenty-fifth anniversary of that landmark meeting;~~

~~Recalling the adoption by the Health Assembly of the International Code of Marketing of Breast-milk Substitutes (resolution WHA34.22), which stresses that adoption of, and adherence to, the International Code is a minimum requirement; Recalling also resolutions WHA35.26, WHA37.30, resolutions WHA39.28, WHA41.11, WHA43.3, WHA45.34, WHA46.7, WHA47.5, and particularly WHA54.2 and, in particular, resolution WHA55.25 endorsing the global strategy for on infant and young child feeding; nutrition, appropriate feeding practices and related questions.~~

~~Noting further resolution WHA49.15 which urges Member States to ensure that financial support for professionals working in infant and young child health does not create conflicts of interest;~~

~~Recognizing the responsibility of industry to make full disclosure of known public health risks;~~

~~Aware that several Member States have recently issued alerts to health professionals about the known public health risks regarding the presence of pathogens the joint FAO/WHO expert workshop on *Enterobacter sakazakii* and other microorganisms in powdered infant formula and the vulnerability of infants to them held in 2004 concluded that intrinsic contamination of powdered infant formula with *E. sakazakii* and *Salmonella* has been a cause of infection and illness in infants, including severe disease which can lead to serious developmental sequelae and death;~~

~~Noting that such severe outcomes are especially serious in low-birth weight infants and immunocompromised infants, and therefore of particular concern to developing countries;~~

~~Aware Bearing in mind that the Codex Alimentarius Commission Committee on Food Hygiene is revising its recommendations on hygienic practices for the manufacture of foods for infants and young children;~~

~~Concerned that, whereas consumers have the right to full and unbiased information, nutrition and health claims have become an effective means of are being used inappropriately to promote the sale of breast-milk substitutes ;~~

~~Encouraged by the progress made by several Member States in adopting legislation prohibiting commercial sponsorship of health professionals or their associations;~~

~~Having considered the summary biennial progress report on infant and young child nutrition;~~

~~Acknowledging that the Codex Alimentarius Commission plays a pivotal role in providing guidance to Member States on the proper regulation of foods, including foods for infants and young children;~~

Bearing in mind that on several occasions the Health Assembly has called upon the Commission to give full consideration, within the framework of its operational mandate, to evidence-based action it might take to improve the health standards of foods, consistent with the aims and objectives of relevant public health strategies, particularly the global strategy for infant and young child feeding (resolution WHA55.25) and the Global Strategy on Diet, Physical Activity and Health (resolution WHA57.17);

Recognizing that such action requires a clear understanding of the respective roles of the Health Assembly and the Codex Alimentarius Commission, and that of food regulation in the broader context of public health policies;

Taking into account resolution resolution WHA56.23 on the joint FAO/WHO evaluation of the work of the Codex Alimentarius Commission, which endorsed WHO's increased direct involvement in the Commission and requested the Director-General to strengthen WHO's role in complementing the work of the Commission with other relevant WHO activities in the areas of food safety and nutrition, with special attention to issues mandated in Health Assembly resolutions;

1. URGES Member States:

(1) to continue to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, followed by timely, adequate, safe and appropriate complementary feeding, with maintenance of breastfeeding up to two years of age or beyond, by encouraging the formulation of a comprehensive national policy, a detailed plan of action to implement, monitor and evaluate the policy, and allocation of adequate resources for this process;

(2) to ensure that false nutrition and health claims are not permitted for on foods for infants and young children except where specifically provided for in relevant Codex Alimentarius standards or through the development of national legislation;

~~(43) to ensure, in situations where infants are not breastfed, that clinicians, health-care providers, community workers and family parents and caregivers, particularly of infants at high risk, are regularly provided with information and training geared to the particular needs of developing countries, on the preparation, use and handling of powdered infant formula in order to minimize health hazards; and that addresses the particular needs of developing countries. are informed that powdered infant formula may be contaminated intrinsically by pathogenic microorganisms and that this information is conveyed through explicit warnings on labels; and to take into consideration other risk reduction strategies proposed by the Codex Alimentarius Commission;~~

~~(3) to take steps to prohibit sponsorship of health professionals and/or their associations by any manufacturer or distributor of products within the scope of the International Code of Marketing of Breast-milk Substitutes;~~

~~(4) to ensure that research on infant and young child feeding, which forms the basis for public policies, is free from commercial influence;~~

(4) to work closely with manufacturers to continue to reduce the concentration and prevalence of pathogens, including *E. sakazakii*, in powdered infant formula, and to continue to ensure that they adhere to Codex Alimentarius or national, food standards and regulations;

(5) to ensure policy coherence at national level by stimulating collaboration between health authorities, food regulators and food standard-setting bodies;

(5) to continue their active participation in the work of to ensure that national public health agencies participate in defining national positions that promote the international health policies established by the Health Assembly, in all relevant forums, including the Codex Alimentarius Commission in this area;

2. REQUESTS the Codex Alimentarius Commission: ~~to give full consideration to recommendations made by the Health Assembly concerning quality standards of processed foods for infants and young children and, within the framework of its operational mandate, to give close attention to action urgently required for the revision of standards and guidelines on labelling, quality and safety of processed foods for infants and young children;~~

(1) to continue to give full consideration, when elaborating standards, guidelines and recommendations, to those resolutions of the Health Assembly that are relevant in the framework of its operational mandate;

(2) to establish standards, guidelines and recommendations on foods for infants and young children formulated in a manner that ensures safe and appropriately labelled products that meet their known nutritional needs, thus reflecting WHO policy, in particular the global strategy for infant and young child feeding and the International Code of Marketing of Breast-milk Substitutes;

(3) to address the risk of microbiological contamination of powdered infant formula and, if deemed necessary, establish appropriate microbiological criteria or standards related to *E. sakazakii* and other relevant microorganisms in powdered infant formula;

3. REQUESTS the Director-General:

~~(1) to continue taking action on the relevant recommendations of the joint FAO/WHO meeting on *Enterobacter sakazakii* and other microorganisms in powdered infant formula in collaboration with FAO, to draw up guidelines for caregivers on the preparation, use and handling of infant formula to minimize risk, and to address the particular needs of developing countries in establishing effective measures to minimize risk in situations where mothers cannot, or choose not to breastfeed;~~

~~(3) to encourage and support independent promote research in order to get a better understanding of the ecology, taxonomy, virulence and other characteristics of *E. sakazakii* in line with the recommendations of the FAO/WHO expert workshop on *E. sakazakii*, and to find ways to reduce its level in reconstituted on intrinsic contamination of powdered infant formula, by and to collecting evidence in from different parts of the world;~~

~~(2) to uphold the mandate of WHO for the protection of health and safety of infants and young children in to issue guidance so that the Codex Alimentarius Commission standard-setting process may contribute, within the framework of its operational mandate, to full implementation of international public health policies;~~

(4) to report regularly to the Health Assembly on progress in the consideration of matters referred to the Codex Alimentarius Commission for its action.

= = =