IBFAN CODEX ALIMENTARIUS WORKING GROUP REPORT, 2014

I. Introduction

IBFAN Codex Working Group members

Convener: Elisabeth Sterken

Members: JP Dadhich, Patti Rundall Joyce Chanetsa, Hussein Tarimo

Supported by: ILCA, Maryse Arendt; ENCA, Helen Crawley and IACFO, Patti Rundall

Codex Alimentarius Committees monitored or attended

- Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)
- Codex Committee on Food Labelling (CCFL)
- Codex Committee on Food Hygiene (CCFH)
- Codex Committee on Food Additives (CCFA)
- Codex Alimentarius Commission (CAC)

IBFAN’s aim for Codex participation is to ensure that standards and guidelines set for complementary food products and milks for infants and young children are in compliance with the International Code and WHA resolutions; that the compositional nutritional, safety and labelling standards are as health protective as possible and do not undermine breastfeeding and the use of nutritious family foods during the complementary feeding phase.

During 2014 the IBFAN Codex Working Group concentrated its work on infant and young child food products; infant formula, infant formula for special medical uses, cereal based foods for underweight children, ready to use (complementary) foods (RUFs), and ready to use (complementary) supplementary foods (RUSFs), with special attention to labelling and marketing. Importantly we also focus on the safety of these products and submit our comments on the use of food additives, hygienic criteria and nutritional adequacy as well as the problem of “spill-over” resulting in inappropriate use of these products.

This report will focus on the outcomes of the agenda items at the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and report on how the outcomes of the related committees impact on decisions on infant and young child food products addressed at the CCNFSDU.
II. WHY IBFAN'S CODEX WORK IS IMPORTANT

The Codex Alimentarius Commission is a joint World Health organisation (WHO) and Food and Agriculture Organisation (FAO) body, set up in 1963 as the mechanism to set global food and commodity standards for national governments. Codex has two goals: to protect the health of consumers, and to ensure fair practices in the food trade. These goals are accomplished by the development of food standards, food guidelines, codes of hygienic practices, and other actions.

In reality, because of the predominance of the food and related industries, who sit on government delegations and as observers, the globalized trade in foods and food products invariably takes precedence over health protection. Codex is largely overlooked by NGOs, but is never ignored by the food industry, who use it to influence policies and meet their marketing and trade objectives.

Since 1995, when Codex assumed greater importance as the reference for food safety for the World Trade Organisation, IBFAN has participated in Codex meetings. Before that we contributed information via WHO and Member States. IBFAN’s aim has been to ensure that the International Code of Marketing of Breast Milk Substitutes and subsequent relevant WHA resolutions are incorporated into Codex standards, guidelines and codes of practice and that Codex standard setting and scientific advice is protected as far as possible from undue commercial influence.

IBFAN and its partners monitor and expose the extent of influence and presence of the baby foods industries in the Codex meetings, critiquing the evident institutional bias and lack of consensus building that is especially present in the Nutrition Committee (CCNFSDU) under the German secretariat. Supported by WHO and Member States from developing countries, IBFAN works to prevent the food and drinks industries from exploiting the Codex process to maximize profits.

III. COMMITTEES ATTENDED BY THE IBFAN CODEX WG

Codex Committee on Nutrition and Foods for Special Dietary Foods (CCNFSDU)
Bali, Indonesia, Nov 24 to 28, 2014

Delegation to the CCNFSDU, Bali Nov, 2014
IBFAN delegation: Elisabeth Sterken, head of delegation (IBFAN NA)
    Joyce Chanetsa (IBFAN Africa)
    JP Dadhich (IBFAN Asia)
    Adisti Bakri (AIMI, IBFAN Asia)
ENCA delegation : Helen Crawley, Head of delegation (First Steps Nutrition Trust)
IACFO delegation: Patti Rundall, Head of delegation (Baby Milk Action, IBFAN-UK)
ILCA delegation: Maryse Arendt, Head of delegation (ILCA, IBFAN Luxembourg)
CCNFSDU is one of the most important Codex committees for IBFAN’s work to protect optimal IYCF. Although occasionally held in developing countries, the German secretariat remains firmly in control of proceedings, ensuring that the interests of the producing nations are protected.

Of the 299 participants from over 50 countries in Bali, over 120 (>40%) were from food and related industries - with over 50 on country delegations. Just 7 infant feeding health advocates from NGOs such as the global network, IBFAN, were present.

Approximate number of industry delegates 125
Number of countries with industry representatives: 21
Approximate number of industry representatives on country delegations: 55
Number of observer and international organizations – these include industry associations fronting as non-governmental organizations: 30
The only independent public interest international organizations present are IBFAN, IACFO, ENCA, ILCA, the African Union, Consumers’ Union.

IBFAN was joined by Adisti Bakri from the Indonesian breastfeeding support group AIMI, (IBFAN Asia) as a participant to the CCNFSDU delegation.

From left to right: Helen Crawley, Joyce Chanetsa, Elisabeth Sterken, Patti Rundall and JP Dadhich
Agenda items addressed by IBFAN

AGENDA ITEM 2:
MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION
AND/OR
OTHER CODEX COMMITTEES (Agenda Item 2a)

IACFO/IBFAN made several interventions regarding the need for health policy setting to be protected from Conflicts of Interest and the Chair’s lack of attention to consensus building. The Report of the meeting noted the following: IACFO/IBFAN made several interventions regarding the need for health policy setting to be protected from Conflicts of Interest and the Chair’s lack of attention to consensus building. The Report of the meeting noted the following: IACFO/IBFAN suggested that more guidance could be given to Member States regarding the composition of delegations in relation to conflict of interest, especially those hosting committees or eWGs, in order to ensure the protection of health. IACFO/IBFAN also expressed concern about consensus building to ensure that the interests of developing countries were not overlooked.

Discussion paper on a standard for Ready-to-use Foods (RUF) (Prepared by UNICEF)

UNICEF had prepared a discussion paper proposing a standard for Ready – to- Use Foods (RUFs)

IBFAN submitted comments with the following concerns about the use and standardization of RUFs. These comments were also circulated to IBFAN regions for input at national level.

IBFAN submission:

1. Although the use of RUFs in the treatment of SAM is suitable for at-home treatment, the evidence that RUFs are effective when compared to other treatments is weak. The UNICEF paper notes that the treatment aims are to allow catch up growth; prevent death from acute malnutrition; strengthen resistance to infection; allow for convalescence from prior illnesses and help to restore normal mental, physical and metabolic status, however there is little or no evidence to substantiate that RUFs are effective for all these aims when compared to home based family food treatments.

2. The treatment with RUFs requires the child to consume extra water. Research on access to safe water and the risk of natremic dehydration with the use of RUFs appears to be lacking.

3. The concentrated energy content of RUFs risks the reduction of breastmilk consumption, critical for nutritional recovery and for its immunological capacity as breastfed children regulate their intake.

4. Additional concerns include:
   - RUFs do not contribute to sustained nutritional rehabilitation,
   - a single treatment food will not develop a taste for normal, local, bio-diverse, family foods essential for recovery, rehabilitation and long term health,
   - use of RUFs is very expensive, 77% of the products are manufactured in Europe and the US, in 2013 UNICEF and WFP $(USD) 195 million without solid evidence of effectiveness,
   - nutrition education is essential to optimize complementary feeding,
   - a standard will not address the root causes of malnutrition, alleviate poverty or reduce the global economic disparity,
funding for the treatment of malnutrition is primarily dependent on external donors, humanitarian and emergency aid and is often short term and not sustained,

sound, independently funded evidence of their effectiveness and their safety is needed, this also raises concerns about the ethical nature of the testing of products on malnourished children in poverty settings,
treatment of all forms of malnutrition must be based on human rights principles and must address the right to adequate food,
safeguards such as controls on marketing must be in place to prevent the inappropriate spill over of these products into the normal complementary feeding,
RUFs must not be allowed to undermine confidence in the use and efficacy of normal sustainable family based foods. Advertisements suggesting RUFs are superior have already been noted in Africa, India and elsewhere. Their widespread use and distribution by health authorities creates the impression that they are “superior” to local foods which consequently has a negative impact on the use and perception of local family foods that are invariably more nutritious and culturally appropriate,
conflicts of interest, inherent in the “scaling-up” are a serious problem,. The close integration between manufacturers and programs to address malnutrition create situations where governments and health facilities have become facilitators for the marketing of these products. It is important to note the incestuous nature of the argumentation for scaling up these products. Donor-industry based countries support the research, develop the programming, manufacture the products and also do advocacy to use the products. Developing countries, where the bulk of malnutrition exists, have hardly any say.

Many of the delegates especially delegates from Bangladesh, India and African countries made strong interventions, raising concerns about the UNICEF proposal for a standard whose primary aims seemed to be to facilitate international trade. They suggested instead a guideline that could be adapted to suit national situation so as not to undermine the use of local, culturally acceptable family foods.

The delegate from Senegal reminded the committee that:
“*We wish to remind you – nutrition has a very strong cultural phenomenon so there is a need to have local foods. We don’t need to have standards, but we may have guidelines....We will go for local products.*”

Several producer countries supported the UNICEF proposal, favouring more product-based solutions. Some claimed that these foods would “*save millions of lives.*” The EU opposed the proposals on several grounds, including the legality of creating a standard for a therapeutic food/cure. The food industry offered its support, suggesting that it wanted to work in partnership with NGOs. This intervention inadvertently highlighted the risk that the standard could be exploited commercially.

**Chizuru Nishida, representing WHO,** made constructive comments and reported that they are engaged in a systematic review to address a number of question raised about the use of RUFs. “*She informed the Committee that specific questions that were being examined by the systematic reviews included whether lipid-based*
nutrient supplements (LNS) were safe and effective for health, nutrition and development outcomes, whether
LNS was more effective than other foods, and whether there were differences by dose and duration of the
intervention, as well as the economic implications and cost-effectiveness of the intervention using LNS. She
confirmed that these reviews were looking at not only children 6 to 23 months of age and pregnant women, but
also at treatment of children 6 to 59 months of age with moderate acute malnutrition (MAM) and also with
severe acute malnutrition (SAM). She stated that the systematic reviews were scheduled to be completed by
2015.”.

Outcome: The decision to develop a standard or a guideline was considered premature before the report on the
WHO systematic review on safety, impact and cost-effectiveness of RUFs. UNICEF is to redraft the document
based on the WHO review for resubmission at the next 2015 meeting.

AGENDA ITEM 5:
Proposed Draft amendment of the Standard for Processed Cereal-Based Foods for Infants and Young
Children, Codex Stan 074-1981, Rev – I 2006 Part B for Underweight Infants and Young Children

IBFAN recommended that this work be discontinued since this product is not necessary; that a separate section
to accommodate energy and protein needs for underweight children could readily be achieved under the existing
standard and that the marketing of these foods can undermine local, culturally appropriate family based
complementary feeding.

IBFAN Submission: IBFAN does not agree that a separate Part B is necessary. IBFAN is of the opinion that
this Codex Standard for Processed Cereal-based Foods for Infants and Young Children should be opened up
and renamed as a standard to cover all foods for children 6-36months.¹ In this way all products for this
vulnerable group could be covered by over-arching strengthened principles regarding safety, composition,
labeling and marketing. Such harmonization would facilitate the easy transposition into appropriate legislation
and cover the needs of all older infants and young children.

Outcome:
The delegate from India recommended that this proposal be discontinued and this was supported by a number
of African countries. Although some countries wanted to develop this work the overall decision of the
committee was to stop the work.

based Foods [Codex Stan 74-1981] Guidelines on Formulated Supplementary Foods for Older Infants and Young Children
(CAC/GL 08-1991)
AGENDA ITEM 6:  
Review of the Codex Standard for Follow-up Formula (CODEX STAN 156-1987)

IBFAN participated in the electronic working group led by New Zealand to address nutritional composition and to determine the age for the use of these products. IBFAN made several interventions on this agenda item noting that FUFs are not necessary and that the marketing of these products would increase the detrimental practice of artificial feeding, code violations and conflict with recommended IYCF practices.

Two WHO representatives, Chizuru Nishida and Marcus Stahlhofer, made excellent statements that this product is not necessary (quoting WHA resolution 39.28) and that the continuation of this work risks creating policy conflicts on recommendations for exclusive and sustained breastfeeding.

“The Representative of WHO stated that continuing the work on this Standard risked creating policy conflict. Member States had adopted resolutions at the World Health Assembly on infant nutrition and breastfeeding and, more recently at ICN2 in Rome, the role of Codex in promoting healthy diets had explicitly been mentioned. And that WHA resolutions…should therefore guide and inform the work undertaken by Codex Committees, including CCNFSDU, so as to ensure policy coherence across various intergovernmental bodies. And if the work does progress, WHO would request the Committee to include clear language as to the need for strong regulatory measures to avoid inappropriate marketing of FUF, not only through necessary labelling requirements, but in line with the marketing restrictions on breast-milk substitutes, as reflected in the International Code. “

IBFAN, together with several member states and the strong comments by India, who requested a vote on this issue – proposed that the cut-off age for FUFs should be 12 months and not 6 months, since routine IF is already marketed for infants from 0 to 12 months. However the chair ignored this and despite reaching no consensus declared that the cut-off age should be 6 months. IBFAN questioned if this would mean that there would be 2 standards for the ages 6 to 12 months. IBFAN’s recommendation is that all formulas be rolled into one standard and renamed Standard for Formulas for infants and young children. This is the best way to ensure that the International Code’s marketing safeguards cross over to the formulas for older babies. In a separate standard this is highly unlikely to happen.

**Outcome:** The chair ignored the lack of consensus and ruled that the work would continue. She said that the cut-off age should be 6 months and ignored the request for a vote by India. IBFAN will again participate in the electronic Working Group on FUFs to voice our positions and concerns.

**IBFAN submission:**

Is FUF necessary?

1. IBFAN supports the WHO Statement on follow-up-formula “Information concerning the use and marketing of follow-up-formula” that these products fall under the scope of the International Code.” (released July 17, 2013).
2. The WHA resolution 39.28 (1986) states that "the practice being introduced in some countries of providing infants with specially formulated milks (so called follow-up milks) is not necessary."

Marketing risks
1. IBFAN notes that the marketing of follow-up formulas is misleading, undermines breastfeeding and promotes artificial feeding, putting infant and young child health at risk.
2. As these products may be marketed at a lower cost than routine formulas, they risk being fed at too early an age, compromising exclusive and sustained breastfeeding.
3. If marketed to the age of 36 months, they risk being bottle fed for this duration and seriously damaging oral development and other negative health impacts.

Amendment to the Standard for Infant Formula
1. IBFAN is of the opinion that a separate standard is redundant since fortified milk products are not necessary. It is our opinion that the Standard for Infant Formula is sufficient to take care of any artificial milks that may be required for non-breastfed children over the age of 12 months.

Agenda Item 7:

Proposed Draft Revision of the List of Food Additives

IBFAN made several comments that food additives are for technical and cosmetic purposes only - to give IF, a suspension of various industrial ingredients, appear like milk. The industry made several interventions claiming safety and technical reasons for the addition of several additives (on a “wish list” of additives to be approved) to the existing list in the IF standard on a “wish list”.

Outcome:

Although there is an acknowledgement that the JECFA requirement that all additives for IF should be proven safe for infants under the age of 12 weeks, this principle appears to be words only that are not put into practice when considering the approval of more additives for IF.

Some substances such as carrageenan would remain on the “wish list” despite objections from a number of delegates.

IBFAN commented that the JECFA principles of 1971 be reinforced and fully implemented when adopting the standards for baby foods: “Baby foods should be prepared without food additives whenever possible. Where the use of a food additive becomes necessary in baby foods, great caution should be exercised regarding both choice of additives and its level of use.” (Annex 3 of TRS 488). We strongly urged the committee to apply it.

IBFAN submission:

Are the food additives necessary?
1. IBFAN notes that the majority of food additives used are for cosmetic purposes in order to give the artificial milk products the appearance and consistency of milk. Hence this imposes known and unknown risks for newborn infants, older infants and young children who are fed these milks.
2. IBFAN agrees with a number of countries that thickeners such as Guar Gum, Xanthan Gum and Gum Arabic are not necessary and should be deleted from the list. Additionally IBFAN agrees that mono and di glycerides should be removed from the list.

**Are the food additives safe?**

IBFAN wishes to note and concur with the JECFA principle:

“*Baby foods should be prepared without food additives whenever possible. Where the use of food additives becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use.*” (Annex 3 of TRS488):

“*Proposals for the inclusion of an additive in Codex standards for foods intended for infants below 12 weeks of age require a separate evaluation by JECFA since food additives used in foods for this population the toxicological investigations should be more extensive and include evidence of safety to young animals…(REP11)/FA para 43).*”
IV. IBFAN Briefing for Codex member state delegates

The IBFAN Codex Working Group held 2 briefing sessions for the Codex delegates. The briefing sessions were attended by Member States delegates as well as industry representatives and public interest organizations.

IBFAN presented our positions on all agenda items affecting IYCF. This gave us an opportunity to give more depth to our positions and stimulated a vigorous Q and A.

*IBFAN briefing of delegates attending the CCNFSDU, Bali, Indonesia.*

*JP. Dadhich, IBFAN Asia, presenting at the IBFAN briefing for CCNFSDU delegates.*

V. COMMITTEES MONITORED BY THE IBFAN CODEX WG
Decisions about labelling, hygiene, general principles, food additives are taken in their respective committees and it is essential for our working group to note these decisions as they impact directly on our advocacy efforts to further the aims and goals of our Codex work. This makes our work quite onerous, and requires our detailed knowledge of the complexities of “how the system works”.

Codex Alimentarius Commission, Geneva, July 14 to 18, 2014

Outcome:
UNICEF’s proposal for a standard for RUFs was presented to the CAC, while there was some support from Member States, WHO noted that they were planning a systematic review for 2015 to review effectiveness of these products. As well FAO noted that they were addressing microbial contamination and chemical contaminants of these products in their review of the safety of these products.
The committee decided that UNICEF should resubmit the discussion paper proposing a standard for RUFs and present this to the CCNFSDU to address this.

On Matters referred to CCNFSDU the CAC referred a request from Norway and Chile that from a public health perspective, nutrient addition (fortification) to energy dense and nutrient poor foods (such as sugar drinks) should be avoided. This request was taken up by the CCNFSDU. Norway subsequently presented their request to the CCNFSDU, which was strongly supported by WHO, citing the Global Strategy and the recent outcome of the ICN2, a number of Member States as well as ILCA and IACFO. The proposal was objected to by the grocery products industries and hence the chair ruled to include these provisions into the text for the addition of nutrients to foods.

Codex Committee on Food Labelling, Geneva, October 21 to 24, 2014
No significant issues relating to foods for infants and young children were on the agenda.

Codex Committee on Food Hygiene, Lima, Peru, Nov 17 to 21, 2014
Proposed draft code of practice for low-moisture foods
The proposed Code plans to cover GMPs/GHPs for the manufacturing of low-moisture foods for human consumption.

Primary pathogens of concern that are associated with low-moisture foods to date, include Salmonella spp. and Bacillus cereus. Furthermore, there is evidence that the composition of a food (especially, high fat content) may protect Salmonella against the acidic conditions of the stomach, potentially increasing the likelihood of illness from consuming low numbers of the organism. Pathogens such as Salmonella can be difficult to control in a low-moisture food operation environment, because they can persist for prolonged periods of time in the dry state and in low-moisture products. Microorganisms are more heat tolerant in food matrices at reduced water
As well this Code proposes to addresses Good Manufacturing Practices (GMPs) and Good Hygienic Practices (GHPs) that will help control microbial hazards associated with all stages of the manufacturing of low-moisture foods. Particular attention is given to minimize Salmonella spp., which is currently considered the primary pathogen of concern in these products. These GMPs and GHPs, if adhered to, should also be effective in preventing the risk from other pathogens that may be of concern.

While the Code covers GMPs/GHPs for the manufacturing of low-moisture foods for human consumption, it also applies to a number of foods that may be suitable for IYCF such as cereal-based products (e.g. breakfast cereals), peanut and other nut butters, dry protein products\(^1\) (e.g. dried dairy products and soy protein), of particular concern to IBFAN are the specialized lipid based nutritional products for the treatment of moderate and severely acute malnutrition.\(^2\)

IBFAN’s concerns are that it will become a voluntary document rather than a code that has more teeth as a regulation. This is potentially more effective to protect both food safety and the protection from inappropriate marketing for these baby food products. As a voluntary document monitoring and enforcement will be left to governments without assurances that this will indeed be accomplished and especially in countries where the resources and capacity for enforcement may be low. Since these guidelines cover foods that are extensively promoted and used for the treatment of malnutrition and foods used in situations of emergency, we are concerned about the vulnerability to manage microbial contamination for an infant and young child population that suffers from the malnutrition and is thus immune-compromised.

**Outcome:** The proposed Code of Hygienic Practice for Low-moisture Foods is at step 5/8 in the Codex process for adoption at CAC. IBFAN has joined the CCFH electronic Working Group to advocate its positions for the Code of Practice for Low-moisture Foods.

For more information please contact Elisabeth Sterken esterken@infactcanaca.ca on behalf of the IBFAN Codex Working Group.

\(^1\) Specialized lipid based nutritional products can be categorized as ready-to-use supplementary foods (RUSF) for the treatment of moderate acute malnutrition and ready-to-use therapeutic foods (RUTF) for the treatment of severely acute malnutrition.

\(^2\) Although the provisions of this Code could be applied in the production of powdered infant formula, this product is excluded from the scope, given the specific vulnerable group of consumers. These products are currently appropriately addressed in the *Codex of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008).