

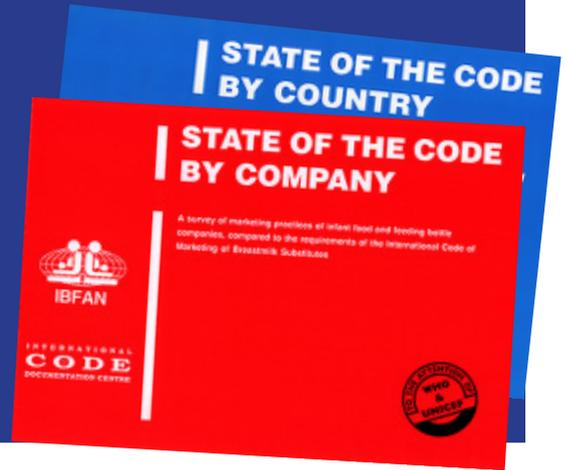


INTERNATIONAL
CODE
DOCUMENTATION CENTRE

IBFAN/ICDC
P.O.Box 19
10700 Penang, Malaysia
Fax: +604-890 7291
Email: ibfanpg@tm.net.my
Web: www.ibfan.org

ICDC LEGAL UPDATE

March 2005



From ICDC's desk in Penang:

After our **Legal Update** in August 2004, ICDC went fullsteam ahead into its training programme. In quick succession, we held our Annual Training Course on International Code Implementation in Penang, followed by a Code Awareness Course in Seoul for East Asian countries and finally a Regional Code Implementation Course in Fiji for Pacific Island nations. As usual, we received support from local IBFAN groups and UNICEF in our training projects but this year for the first time, WHO's Western Pacific Regional Office co-funded the Pacific training.

In October, we took part in the bi-annual meeting of the IBFAN Coordinating Council in San José, Costa Rica, and helped organise the celebrations to commemorate IBFAN's 25th Anniversary. Annelies also did a Code-Codex training at WABA's Partners meeting, which took place after the IBFAN meeting. In the run-up to the New Year, we recruited new staff and are pleased to introduce our new communications person – Angelina Ong - who is instrumental in bringing out this issue. Angelina joins Sita, Komala and part-timer Karyn in providing back-up support for ICDC's core functions – training, monitoring, legal advice, documentation and advocacy.

Just as we were winding down for 2004, the Tsunami disaster hit Asia, including Penang. The office and staff were unaffected even though Penang suffered 52 casualties and property damage. The trail of destruction in nearby southern Thailand, Sumatra and Sri Lanka served to highlight the vital importance of breastfeeding and the danger of any other infant feeding methods when disaster strikes. This Legal Update highlights the danger of donations of baby milks in emergencies and how the International Code is relevant in that context.

Also in this issue, we have added a two-page insert to our standard 4-page newsletter. One page a record of countries which have adopted the WHA recommendation for 6 months exclusive breastfeeding as a national policy. IBFAN fought long and hard to encourage adoption of such a policy. Page 2 is a list of product recalls from 2000 onward. It shows that intrinsic contamination of formula products by *Enterobacter sakazakii* is quite frequent. For this and more news and information on what IBFAN-ICDC is doing, read on!

Don't forget to keep in touch; even a short email will be appreciated.

Yeong Joo Kean & Annelies Allain

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Ties that bind...

IBFANers cheer as they finished threading a symbolic network with strings

25-plus, going for 30!

On 12 October 2004, the International Baby Food Action Network (IBFAN) celebrated its 25th Anniversary. IBFANers from around the world came together in San José, Costa

Rica to celebrate IBFAN's 25th birthday. The local IBFAN group, CEFEMINA, acted as host.

IBFAN was born on 12 October, 1979 when six NGOs joined forces in the common goal to protect breastfeeding and now numbers some 200 groups in 100 countries in all regions. IBFAN actively advocated for the adoption of the International Code in 1981. More than two decades later, the International Code still underpins much of the work that IBFAN does. Code implementation and its positive impact on children's health around the world are due largely to efforts by IBFAN groups.

At the intimate, yet ebullient party, Annelies, as one of IBFAN's co-founders, asked 25 networkers to give short testimonies of the past or to look to the future. People who sparked the movement, those who are keeping its spirit alive and those who moved on or who could not make it to the party were fondly remembered.

May the Network continue to thrive!

Warning against donations of breastmilk substitutes for Tsunami victims

The Tsunami tragedy in Asia and parts of East Africa highlights the vital importance of breastfeeding when populations are cut off from their usual food supplies. Some organisations started receiving infant formula donations. The lack of potable water and the bacterial load of dried milk powders, where basic infrastructure is poor, makes bottle feeding extremely dangerous.

Guidelines on infant feeding in emergency situations can be found on the UNICEF, IBFAN, and the Emergency Nutrition Network websites. ICDC popularized these guidelines by putting out a fact sheet on feeding babies in emergencies outlining the increased risks of bottle feeding and the need to establish a responsible help chain. (See IBFAN or WABA websites.)

IBFAN also made an intervention at the WHO Executive Board meeting in January 2005 to remind governments and agencies involved in the Tsunami relief efforts about the importance of breastfeeding in emergency situations. Recalling the recommendation in WHA Resolution 49.5 (1994), IBFAN stressed that feeding with substitutes should be undertaken only after careful assessment to ensure distribution only to those children who need



them, for as long as they need them, and to avoid their use as a sales inducement.

In line with the International Code, IBFAN also advocates that orphans and infants separated from their mothers who may need baby milks are better served by sourcing these products locally, so that labels are in the correct language, and distributed with appropriate training on safe use.

WHO Executive Board battles with old and new resolutions on “the baby milk bug”: *Enterobacter sakazakii*

In May 2004, a draft resolution had been tabled at the World Health Assembly by 5 Pacific nations and Nepal to deal with newly discovered evidence of contamination of powdered infant formulas by the bacterium *Enterobacter sakazakii*, also called the “killer bug”. Serious illness, such as meningitis, sepsis, necrotizing enterocolitis, and death can result from infection. Even though the overall incidence of infection caused by *E. sakazakii* seems to be low, mortality rates of 20% to higher than 50% (for neonates) have been reported in the few outbreaks investigated. For survivors, severe neurological disorders may remain.

For decades, when babies got ill, mothers were blamed for lack of hygiene, inadequate sterilization of feeding bottles, etc. Now we discover that the contamination can also start during the production process. This is called ‘intrinsic’ contamination. What is in those sealed cans is not a sterile product. Manufacturers admit to it and consumers deserve to know it. A call for warnings on labels was the main, but not the only, item in the May 2004 draft resolution.

The August 2004 issue of Legal Update reported that the draft resolution had been deferred to 2005 on points of procedure by 6 industrialised countries even though some 16 other countries were in favour of an immediate decision. By Jan 2005, at the Executive Board Meeting (EB) of WHO, fresh debate ensued.

Infant deaths in industrialised countries gave the deferred draft resolution new impetus. In July 2004, *E. sakazakii* killed a preterm baby in New Zealand; in October 2004, 9 infants in four different neonatal wards in France were infected by *E. sakazakii*: 2 died and 4 were severely affected. The French EB member urged the Board to make quick decisions due to very real

danger posed by intrinsic contamination of powdered infant formula: “All these babies were hospitalized in special units that were meant to protect them. We need to act now and to act fast”. Mead Johnson’s *Pregestimil* powdered infant formula, which had caused the deaths in France, was recalled in all countries.



E. sakazakii: what is it?
NO, it is not a motorbike...



...it's a “killer bug” originating in factories that mix the formula

Apologies to the Pacific and consensus on a compromise

At the EB, delegates led by Tonga first took the WHO Secretariat to task over the unprecedented step of re-writing the “Pacific” draft resolution without even telling the co-sponsors. This hi-jacking was done in October by WHO’s Food Safety Unit which wanted to ensure that contamination issues were dealt with by the Codex Alimentarius Commission rather than by the Assembly. The Secretariat apologized for not following WHO procedures.

The substantive debate at the EB ranged from requests to discuss the original draft resolution to a suggestion by the USA to leave it all to the industry-dominated Codex Alimentarius Commission. Work at Codex is a slow process which can take 10 years or more but the USA maintained that the resolution under discussion at the EB would be “counter-productive and premature”. A drafting group, chaired by Australia, met three times for a total of 7 hours and did a line by line rewrite of old and new resolutions.

Although *E. sakazakii* and the need for warnings on labels dominated work in the drafting group, other issues from the original Pacific resolution were resurrected. Some had been removed altogether in the Secretariat re-write of the resolution, others had been minimised. They included a ban on health and nutrition **claims** for breastmilk substitutes and infant foods, restrictions on **sponsorship** and the need to allow only **independent research** as the basis for public health policy making. All three issues are reinstated in the final compromise text but they were severely diluted.

- Claims (such as DHA/AA and Probiotic) are “not permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation”.
- On sponsorship, the text simply

repeats what already was in a 1996 resolution.

- Independently funded science became independently reviewed research.
- Warnings regarding possible *E. sakazakii* contamination were recommended to Member States with the weakening phrase “where applicable”. Nepal tried to have this removed but had to compromise when Russia proposed to delete the reference to warnings altogether. The consensus text was adopted as an EB resolution and will go to the World Health Assembly in May 2005.

Recalls and warnings regarding contamination by *Enterobacter sakazakii*

Just as the debate on *E. sakazakii* ended at the WHO, one of the largest newspapers in Brazil, *Folha de Sao Paulo*, reported on 26 January 2005 that the Sao Paulo State Health Control Centre took the precautionary measure of banning a batch of **Aptamil** powdered milk, a Milupa brand, due to the presence of *E. sakazakii*.

On the other side of the globe, government departments in Hong Kong are closely monitoring an incident of intestinal infection, noting the international recall by Mead Johnson of **Pregestimil** powdered infant formula.

The proactive stance taken by authorities in Brazil and Hong Kong are to be lauded. ICDC believes that there is significant underreporting of infections especially in developing countries where surveillance systems are poor. To give readers a fair idea of how widespread *E. sakazakii* contamination is, ICDC has collated a general list of product recalls from the year 2000. It shows that 7 of the 21 recalls were due to *E. sakazakii*.

The public must know that powdered infant formula is not a sterile product and that it is potentially harmful even if this information is bad for business. Unless a resolution is adopted at the next World Health Assembly recommending Member States to issue appropriate warnings to parents and to promote breastfeeding as the optimum infant feeding option, infant health is at risk.

India Law under threat

In May 2003, **Legal Update** issued a stop press statement to announce new amendments to India’s national law – the IMS Act (Infant Milk Substitutes, Feeding Bottles and Infant Foods, 1992). The amendment elevated the IMS Act to new heights by extending its scope to all products for children under 2 years and banning industry sponsorship of the medical profession.

In January 2005, the Indian Ministry of Food Processing Industries announced a surprise plan to repeal the IMS

Act through the Food Safety and Standards Bill to bring about a single statute relating to food, with emphasis on food safety. Since the IMS Act is a law which bans the commercial promotion of products that compete with breastfeeding, its ambit is quite different from the proposed bill. ICDC joins the local IBFAN group – the Breastfeeding Promotion Network of India – in giving feedback to the Ministry of Food Processing Industries and is hopeful that the Indian government will revise its stand.

Saudi Arabia emerges on the Code front

In October 2004 a Royal Decree for Handling Mother's Milk Substitutes was issued in Saudi Arabia. ICDC has trained several Saudi officials on Code implementation so news of Code implementation in Saudi Arabia is welcome indeed.

The Decree manages to substantially implement major Code provisions through its 28 articles despite a few weaknesses and loopholes. As with all national measures the success of the Decree will largely depend on implementation and enforcement.

Ghana enforces its Regulations

The Breastfeeding Promotion Regulations of Ghana (otherwise known as LI 1667) are going into full swing with the recent appointment of a National Committee to oversee its implementation.

In an effort to quell promotion of breastmilk substitutes, LI 1667 has a provision which prohibits labels showing any photograph, drawing or other graphic representation other than for illustrating methods for preparation. Another provision prohibits the display of information that bears the name, logo or trademark of infant foods, feeding bottles, teats and pacifiers in health care facilities or to the general public.

Recent national monitoring revealed that many companies contravene these provisions and the Ghanaian officials are poised to bring all these into compliance.

Efforts are also being made to stop the advertising of cereal-based products on billboards. Further, enforcement officials recently stopped a 20-foot container load of Nestlé's Lactogen and Nan formula products from entering a Ghanaian port because the product labels bear the new drawing of the Nestlé family of birds.

Nestlé will be given a grace period not exceeding two years to remove the drawing of the ubiquitous birds but old habits die hard and the company is pushing for the drawing to be replaced by an enlarged company logo on the principal panel of the labels. The Ghanaian authorities are currently consulting with experts on intellectual property.

Nestlé gets a shaming award

On 26 January 2005, Nestlé was given the *Public Eye Award* for corporate irresponsibility at the *Public Eye on Davos* meeting. The Berne Declaration, a Swiss NGO, holds the *Public Eye* meeting annually in conjunction with the World Economic Forum.

The giant Swiss food and beverage company is criticised for labour conflicts in Colombia and for its aggressive marketing methods of baby food which jeopardise breastfeeding.

Nestlé became a "laureate" following the result of a global voting exercise conducted on the *Public Eye* website. Nestlé's emergence as a clear "winner" is testimony of the public's poor impression of the company. Shame on Nestlé!

Breastfeeding boost in Scotland

Following poor breastfeeding statistics and incidences where mothers were told not to breastfeed in public, Scottish MP, Elaine Smith, decided in 2003 to table a bill in the Scottish Parliament making it an offence to prevent or stop a child under the age of two from being breastfed or bottle-fed in public places. A hefty fine of up to £2,500 will be imposed on offenders.

The new law was passed on 18 November 2004 and received Royal Assent on 18 January 2005.

Stop Press! New Peru Law!

As this issue of Legal Update goes to print, ICDC received news that Peru, the first country in the world to implement the Code as law in 1982, adopted a new law, *Reglamento de Alimentación Infantil - Decreto Supremo No 007-2005-SA* as of January this year. The new law is up to date as it includes recommendations from recent WHA resolutions, such as: 6 months exclusive breastfeeding, conflicts of interests and provisions on monitoring. The local IBFAN group, CESIP, is to be congratulated for its contribution in the legislative effort.

Countries with 6 Months Exclusive Breastfeeding Policy (by Region)

AFRICA

Cameroon
Cape Verde
Central African Republic
Cote d'Ivoire
Djibouti
Egypt
Eritrea
Gabon
Gambia
Ghana
Guinea
Kenya
Liberia
Malawi
Morocco
Mozambique
Niger
Nigeria
Rwanda
Sao Tomo & Principe
South Africa
Uganda
Zambia
Zimbabwe

AMERICAS

Argentina
Belize
Bolivia
Brazil
Canada
Chile
Colombia
Costa Rica
Dominican Republic
Ecuador
El Salvador
Guatemala
Haiti
Honduras
Nicaragua
Panama
Paraguay
Peru

Uruguay
USA
Venezuela

OCEANIA

Australia
Kiribati
Micronesia
Palau
Samoa
Fiji

ASIA

Afghanistan
Bangladesh
Cambodia
Hong Kong
India
Iran
Jordan
Kazakstan
Kyrgyzstan
Maldives
Mongolia
Pakistan
Philippines
Singapore
Sri Lanka
Tajikistan
Turkmenistan
Uzbekistan
Yemen

EUROPE

Azerbaijan
Belarus
Bosnia
Bulgaria
Czech Republic
France
Georgia
Germany
Luxembourg
Netherlands
Slovakia
United Kingdom

Total: 82 out of 192 Member States of WHO

Pending

Malaysia
Italy
Poland
Sweden

- This list is compiled by ICDC from various sources including national governments, IBFAN groups and UNICEF
- Last updated in February 2005.
- ICDC welcomes corrections or additions.

PRODUCT RECALLS

The following is a list of infant formula recalls known to IBFAN over the period of 2000-2005. The list is compiled from various sources including Internet news bulletins, IBFAN groups and other publications.

Recalls due to intrinsic contamination by *Enterobacter sakazakii* are highlighted.

No	Date	Country	Company	Brand	Problem
1	18/2/05	Finland	Nutricia	Valio (Peptide Tutteli & Gefilus Peptide Tutteli)	10 times overdose of Vitamin D.
2	2/2/05	USA	Abbott Ross	Similac Advance (with Iron) 12.9 oz	Presence of black plastic particles.
3	25/1/05	Switzerland France	Nestlé	Ready to feed Guigoz milks	The liquid milks looked abnormal (curdled) or had unpleasant smell due to tiny leaks in the packaging.
4	25/1/05	Brazil	Support Produtos (Milupa)	Aptamil	Product batch banned due to detection of <i>Enterobacter sakazakii</i> bacteria. Imposition of temporary ban of 6 months on product.
5	1/1/05	Brazil	Mead Johnson	Pregestimil, Enfamil Pregestimil	ANVISA (Brazilian Food Control Agency) banned the use, marketing, distribution and entry into Brazil of these infant formulas following the ban in France.
6	10/12/04	France, UK Hong Kong & worldwide	Mead Johnson	Pregestimil	France: 2 out of 9 infants died of <i>Enterobacter sakazakii</i> infection after consuming Pregestimil. 2 more remain severely affected.
7	9/6/04	Australia	Nestlé	NAN 1 Probiotic Starter infant formula	Incorrect mix of formulation, not meeting the Food Standards regulation. Possible changes in the protein and iron levels, leading to constipation and/or diarrhoea.
8	21/4/04	UK, Ireland	SMA Nutrition (Wyeth)	SMA Wysoy	Small fragments of metal in some tins of soy milk formula powder, up to 8mm long and 2mm wide from a damaged sieve at the plant.
9	31/3/04	Canada USA	Mead Johnson	Enfalac Pregestimil Hypoallergenic	Incorrect size of scoop, results in over-concentrated formula preparation, with severe medical problems such as diarrhoea and dehydration.
10	10/11/03	Israel	Remedia (Humana)	Tzimchit Super Formula - soya-base	Lack of vitamin B1 or thiamine, all babies hospitalised had been fed with Tzimchit Remedia. 2 infant deaths since 3 June, 2003 in critical condition in hospital, 10 suspicious case under investigation. Health Ministry said 7 infants fed with formula suffered beriberi.
11	9/1/03	USA	Mead Johnson	Enfacare LIPIL	Recall of 505 cases of EnfaCare LIPIL 12.9 ounce. Contaminated with <i>Enterobacter sakazakii</i> .
12	Nov-02	China	Wyeth-Ayerst	Nursoy	Nursoy contained <i>Enterobacter sakazakii</i> . Recall of over 100 million tins of milk formula.
13	2/11/02	USA	Wyeth	Baby Basics, Kozy Kids, CVS, Hill Country Fare, HEB Baby, American Fare Little Ones, Home Best, Safeway Select, Healthy Baby, Walgreens, Parent's Choice	FDA testing at the Wyeth plant found contamination by <i>Enterobacter sakazakii</i> .
14	8/5/02	China	Wyeth-Ayerst	Promise	Promise milk powder contained "unacceptable level of nitrites".
15	2/5/02	Belgium	Nestlé	Beba 1	5 day old infant died due to <i>Enterobacter sakazakii</i> infection after discharge from hospital. On 2nd May 2002, nearly seven weeks after the infant died, the Federal Agency for Food Safety in Belgium asked Nestlé Belgium to recall Beba 1.
16	2002	USA	Mead Johnson	Portagen	Recall was prompted by the death of a premature infant in April 2001 from meningitis caused by Portagen contaminated with <i>Enterobacter sakazakii</i> .
17	14/9/01	USA	Nestlé	Nestlé Carnation, Carnation Follow-Up	120 cans distributed only to WalMart stores in Texas cities. Excessive magnesium in Follow-Up Formula cans. Long term use may cause severe adverse health effects such as low blood pressure and irregular heart beat.
18	15/8/01	UK	Wyeth	SMA Gold, SMA White	Infant botulism. A 5-month-old girl became seriously ill.
19	7/7/01	USA	Mead Johnson	Nutramigen	Spanish label errors - incorrect preparation instructions. Incorrect amount of water alters formula's precise mixture of nutrients and could cause seizures, irregular heartbeat and even death if consumed for several days.
20	2000	USA	Abbott Ross Mead Johnson	Isomil powder and concentrate; Similac with iron, low iron powder and concentrate; Neosure. Enfamil low iron and with iron powder, Enfamil Lacto-free powder; Prosobee soy powder; Nutramigen	Infant formulas were packaged in cardboard tray/boxes which were misbranded. Recall concern all lots of cardboard cases and trays that were repackaged, labeled and distributed by Unity Wholesale Grocery since April 25, 2000.
21	18/3/00	USA	Nestlé	Good Start Nestlé, Alsoy, Carnation Follow-up	Not properly sterilized, voluntary recall as precaution. Concern that formula may not have reached a high enough temperature during sterilisation.