



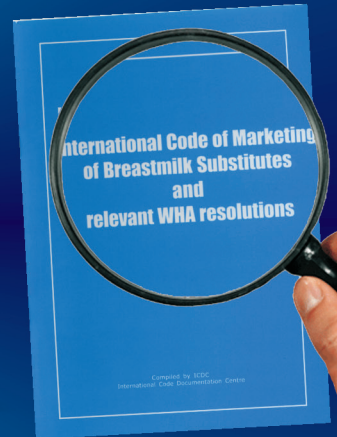
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ICDC LEGAL UPDATE

Jan 2012



From ICDC's desk in Penang...

A new year and a revamped look for ICDC Legal Update. The new masthead highlights our focus on the International Code – our main point of reference. Here are the main events of the second half of 2011.

Training in Jordan

During the second half of 2011, ICDC conducted a Regional Training Course on Implementing the International Code of Marketing of Breastmilk Substitutes in Amman in September, with both the ICDC Director and Legal Adviser participating. Co-organisers were UNICEF MENA, UNICEF New York and IBFAN Arab World. In total there were 36 participants from 14 countries: Algeria, Bahrain, Djibouti, Egypt, Iran, Iraq, Jordan, OPT, Qatar, Saudi Arabia, Southern Sudan, Syria, United Arab Emirates and Yemen.

Lebanon launches law

Several years ago, some Lebanese lawyers and NGOs attended a Code implementation training by ICDC. As so often, it took a long time before the draft reached its final stages and was adopted. On 29 September, in a Beirut hospital, the law was officially launched and the ICDC experts were very pleased to be invited to speak at the launch.

The launch was organised by the Lebanese Association for Early Childhood Development (LAECD), the IBFAN Lebanon group, together with IBFAN Arab World.



The IBFAN team with Lebanese Health Minister Ali Hassan Khalil

Conference in Kuwait

The Kuwait Ministry of Health held its first Infant and Young Child Feeding Conference from 3-5 October 2011. ICDC's Director was one of the invited speakers, making it the second trip for ICDC to Kuwait. The first trip was undertaken by Yeong Joo Kean and Jean-Pierre Allain in June 2011. (see LU July 2011)

Training in Laos

The Government of Laos PDR needed to upgrade its 2007 agreement into an enforceable decree. The UNICEF Laos Country Office organised a visit for ICDC and the Nutrition Legal Officer from New York in November 2011. They consulted with various branches of government and did a 5-day training on the contents of the agreement and methods to monitor the market.



Group picture at the end of the monitoring training in Vientiane.

Participants came from 6 provinces as well as Vientiane. It is hoped that a new decree will result in higher rates of exclusive breastfeeding and do away with current unethical marketing practices.

S T O P P R E S S

Dangerous liaisons – More corporate concentration?

After wreaking havoc with the Code in several countries and getting caught in some, Pfizer is now selling Wyeth (makers of S-26 & SMA), which it bought in 2009. Both Nestlé and Danone are bidding – Danone may team up with Mead Johnson to avert anti-trust issues.

Have a pleasant read!
Raja Razak, Publication Support

HIGHLIGHTS

- Enforcement in Zambia
- No Code, no remedy in the US
- Intrigues surrounding Enfamil death in the USA
- Pfizer restrained from unlawful advertising in Bahrain
- A wolf in sheep's clothing
- Breastfeeding advocates thwart attempts to influence health workers

Enforcement in Zambia

In 2006, the Government of Zambia promulgated regulations under its Food & Drugs Act to control the negative practices in the marketing of baby foods. It was intended as part of an intervention tool in its child survival programme. In 2009, ICDC was retained in 2009 by UNICEF to provide capacity building training to Zambian enforcement officials. With the help of ICDC, the Ministry of Health developed an enforcement manual to give effect to the regulations. Enforcement proceedings began in 2011.

Products worth millions of kwacha were confiscated from multinational chain stores because the labels were not in compliance with Zambian regulations which prohibits all promotional text and graphics on labels. According to news reports, products confiscated had labels bearing messages and pictures which aim at persuading mothers to opt for bottle feeding.

Faced with stern government action, industry expectedly kicked up a fuss because sales and profits were adversely affected. There was also mixed reaction from other quarters who were concerned about continued supply of the products for those already using them. The furore from business quarters caused the government to suspend further enforcement action pending the outcome of a meeting with stakeholders.

The pressure made it necessary for the Minister of Health, the Hon. Joseph Kasonde, MP, to defend the regulations in Parliament. Stressing the importance of protecting breastfeeding, the Minister explained that both the regulations and the enforcement manual had involved all relevant stakeholders including manufacturers and retailers. Industry therefore had been forewarned and could not claim to be caught unaware. There were also sensitisation meetings to inform affected parties about the regulations.

Following the stakeholders' meeting in November 24 2011, manufacturers and retailers were given a one month ultimatum to justify why their products should not be completely withdrawn from the market and to start abiding with the regulations.

The saga with businesses will no doubt continue but in the meantime, ICDC congratulates the Ministry of Health for showing companies that when it comes to the law, they mean business.



Post-raid; near empty supermarket shelves (Source: www.africanews.com)

No Code, no remedy in the US

When the International Code was adopted in 1981 by the World Health Assembly (WHA), the US voted against it. In subsequent WHA resolutions which affirm the Code, the US no longer objects to it, implying an unspoken support for the Code. Indeed, there is now recognition of the Code in government papers (see *Legal Update, July 2011 – Still at the bottom of the pile* for discussion regarding US Surgeon General's Call to Action to Support Breastfeeding).

However, so long as the International Code is not implemented as law in the US, consumers will have little protection or remedy against the excesses of company promotion. Authorities too have no power to act against negligent misrepresentations made by companies.

So much is manifest from the dismissal of a claim brought against Abbott Laboratories, makers of Similac in the now infamous 'beetle formula' debacle. (see *Legal Update, July 2011 – Lawsuits on false advertising and product liability in the US; Case against Abbott Laboratories*).

Following the recall of millions of cans of Similac which were found to be infested by beetles in Sept 2010, one Chalonda Jasper filed a class action against Abbott for deceiving the public about the nutritional benefits and quality of its formula.



Ms. Jasper bought a Similac product prior to the recall and fed it to her son relying on Abbott's ad slogans such as "when it comes to the science of nutrition, Similac stands apart". Ms. Jasper said that Abbott misrepresented its products as healthy while omitting information about the history of beetle infestation in an Abbott plant which the company had known about. She claimed to have suffered extreme mental anguish, pain and suffering when babies were reported to have fallen ill after ingesting contaminated formula.

Ms. Jasper's claim was dismissed by a US District Court because there was no physical injury and she was unable to prove emotional distress. Also, Jasper did not allege that she purchased a defective product, merely that the product she purchased was subject to a recall. In her judgement, presiding Judge Virginia Kendall said, "Jasper's complaint includes no marketing statements from Abbott that claims Similac is safe. Instead Abbott's advertisements only refer to the nutritional value and nutrient blend of Similac. The plaintiff did not allege that a formula containing beetles fails to contain a balanced blend of nutrients."

The judgement is technically correct based on the law and facts. Abbott escaped liability in this particular case but the reasoning behind the judgement is no cause for celebration for the company. Abbott's product safety record is not redeemed by the judgment. There is, however, no remedy for companies' continuing misrepresentation through advertisements until the Code is implemented in the US.

Intrigues surrounding Enfamil deaths in the USA

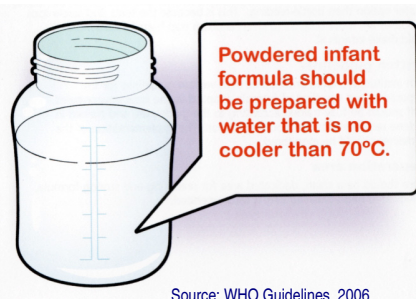
One of the main aims of the Code is to ensure safe and adequate nutrition for infants. 'Safe' becomes a loaded concept when parents opt for formula feeding because powdered infant formula (PIF) is not a sterile product. The Food and Agriculture Organization warns that "even a product meeting existing Codex standards can be contaminated with pathogens that can cause serious illness."

(<http://www.fao.org/docrep/007/y5502e/y5502e0d.htm>)

The deaths of at least two babies in USA in December 2011 as a result of being fed formula contaminated with *Cronobacter/Enterobacter sakazakii* (*E.s.*) highlight again how risky formula feeding is. Mead Johnson, the manufacturer of the Enfamil formula that was linked to the death of the babies is fighting hard to prove that the product was not responsible for the deaths even though the babies tested positive for the *E.s.* pathogen. *E.s.* has a fatality rate of 40-80%. Mead Johnson shares fell 11% when there was a massive recall by retailers.

The Food and Drug Administration (FDA) and the Center for Disease Control and Prevention (CDC) were quick however, to clear Enfamil of suspected contamination, explaining that tests of factory sealed tins showed no contamination. The two agencies declared Enfamil to be safe to use following Mead Johnson's directions on the printed label. Suggesting that contamination could have occurred during preparation, the blame was shifted onto the babies' carers. This leaves a lot to be desired because Enfamil labels do not have the FAO/WHO recommendation that formula should be diluted in boiled water cooled to 70°C.

This recommendation is ignored by most manufacturers because the additives that make the formula highly desirable are destroyed by hot water.



Valerie McClain, a breastfeeding advocate, sums up the feeling of disbelief that prevails over the fact that no *E.s.* organisms can be found in suspected PIF. See these blogspots:

<http://www.vwmclain.blogspot.com/2012/01/emerging-pathogen-enterobacter.html>
<http://www.vwmclain.blogspot.com/2012/01/testing-testing-testing-for.html>

Ms. McClain questions the methodology. *E.s.* was found in 20% of samples in 2003 and 2006. She casts doubt on the integrity of the 2011 tests because of industry funding of researchers and public private partnerships between government agencies and food and drug industries. Powdered infant formula isn't manufactured to be sterile*; it would require expensive changes in the production process.

(<http://www.hc-sc.gc.ca/fn-an/secureit/kitchen-cuisine/pif-ppn-eng.php>)

The blogs make very cogent points which provide food for thought. Nothing is as clear cut as it seems.

Pfizer restrained from unlawful advertising in Bahrain

When two Ministry of Health officials in Bahrain spotted a Pfizer-Wyeth ad on a van (see picture below), they knew something was very wrong. Although the ad seemed to advertise the **Progress Kids Gold** growing-up milk, the conspicuous cubes on the left of the pack shot seemed to be promoting something else – the **S-26** infant formula and **Promil** follow-on formula belonging to the same 'Gold' range. They took photographs and sent an official warning to Pfizer Bahrain, stating that the ad was illegal and requested it be removed within a week or face action.



If the cubes do not represent 1 and 2 formulas (inset right) why are they on the van?

Pfizer was condescending at first. While claiming to be committed to the International Code and Decree No. 4 of 1995 on the Control of the Use, Marketing and Promotion of Infant Milk Substitutes in Bahrain, Pfizer maintained that the ad did not involve any product covered by the Bahraini Decree. They argued that the ad - for a product recommended for children 3-6 years - is permissible because the Bahraini Decree merely prohibits advertising of infant formula for children up to 1 year.

Unfazed, the officials stood firm and maintained that the ad on the van violated the Bahraini Decree because it promoted infant formula through cube 1 and follow-on formula through cube 2. Pfizer was given an ultimatum – remove the violations within 2 weeks or face imprisonment for a period not exceeding one month and a fine up to two hundred Dinars or both of these penalties. Four days after the firm stand taken by the Ministry of Health, Pfizer gave in.

The case shows the usual modus operandi of companies when it comes to compliance. First, find ways to get around the law and carry on with business as usual. When faced with the law, try their luck by using standard excuses in case government officials don't know better. If faced with action, relent because it is bad for business to be caught breaking national laws.

In this case, Pfizer's luck ran out because the two Ministry officials attended Code training just months before and they knew how to interpret their law and were committed to give effect to it. ICDC congratulates the vigilant health officials on their success!

A wolf in sheep's clothing

IBFAN-ICDC recently sent out an alert to warn about a new entity known as Asia Pacific Infant and Young Child Nutrition Association (APIYCNA). It is based in Singapore and managed by a PR firm called Edelman which specialises in 'forming relationships'. Although APIYCNA sounds like an innocent NGO, its members are Pfizer, Nestlé, Danone, Fonterra, Friesland, Abbott and Mead Johnson – practically all the global key players in baby foods. They are competitors, so why are they getting together?

For the baby food industry, the Asia Pacific region holds plenty of promise. Sales of baby foods are projected to grow 39% by 2015 so it makes sense for companies to band together to address common issues like trying to dismantle government efforts to control their marketing via the Code. So APIYCNA may be their strategic arm.

What individual companies cannot be seen to be doing for fear of smearing their public image can now be done through APIYCNA. One of APIYCNA's stated aims is to "improve the nutritional well-being of infants and young children in Asia". Only, the nutrition won't be breastmilk or what mom buys from the local market and prepares in the kitchen, it will be what members of APIYCNA promote as good for babies. It will be processed, come in nice packages and have many mysterious ingredients and unproven claims.

APIYCNA has been up and running for a few months and is inspiring national clones. Case in point, Hong Kong - where finally, the Department of Health is moving for controls and the Hospital Authority has come with exciting initiatives like a ban on free supplies. The same companies as in APICNYA have created the Hong Kong Infant and Young Child Nutrition Association and formulated an industry code to counter any government initiated Code.

Another case in point - Laos – where a group of international NGOs loudly denounced unethical marketing by Nestlé. Finally, in Indonesia through Edelman affiliate, Cognita, APIYCNA is trying to engage opinion leaders in the breastfeeding world as part of a bigger plan to suppress criticism and to construct a good public image. Such PR does not always work well because breastfeeding groups have been quick to cry wolf. Could this be the reason why the wolf now comes in sheep's clothing?

Lansinoh's new Momma logo



Before



After

More complaints and results. The Momma logo looked suspiciously like a breast with a nipple. After registering complaints, Lansinoh removed the nipple.

Breastfeeding advocates in South Africa and Canada thwart attempts to influence health workers

Although Article 7.5 of the International Code allows for sponsorship, subject to disclosure, subsequent World Health Assembly resolutions, such as WHA 58.32 [2005] and WHA 61.20 [2008], clearly warn against conflicts of interest regarding financial support for programmes and health professionals in infant and young child health. Companies often ignore these resolutions in their bid to foster cosy relations with health professionals. Once in a while, companies get thwarted in 'holding events' – three success stories are described below.

South Africa

■ A "fun event" for registered nurses and dieticians in South Africa was organised to "celebrate" Pelargon – an infant formula. A hotel in Nelspruit was to host a breakfast/lunch "scientific" meeting. Colorful invitations, sporting a huge packshot of the product, had been sent out far and wide. Dieticians and nurses were asked to bring more colleagues to enjoy the free meal.

Concerned invitees sounded the alarm and sent the invitation to the regional IBFAN office which passed it on to ICDC. With only two days to the start of the event, ICDC complained to Nestle headquarters and within 24 hours, the order to cancel was sent to South Africa. Surprisingly quick and positive action. In addition, Nestlé headquarters said they would do a "full investigation and assessment and make sure this is an isolated incident. We will put into place actions to ensure that it doesn't happen again."

Canada

■ A meeting on infant nutrition for health workers, organised by the Royal Victorian Hospital (RVH) and sponsored by Mead Johnson, met a similar fate when monitors wrote protest letters to RVH. Mead Johnson tried the same tactic elsewhere, but failed to get meetings going when faced with protests.

■ A small group of breastfeeding advocates in Canada were up in arms over the launch of a webcast sponsored by Abbott Nutrition in a hotel in Edmonton, Alberta. The webcast was to introduce additives such as lutein, DHA and probiotics in Abbott products. Health workers were invited to the launch with dinner thrown in. ICDC was roped in to provide an international element to the protest. Letters were issued to a Canadian health association which was endorsing the event as well as to the CEO of Abbott Nutrition.

Although the national webcast proceeded as scheduled, the breastfeeding advocates managed to get the launch and dinner in Edmonton cancelled at the eleventh hour. Topics discussed during the webcasts (across the time zones) were also much more balanced with fair treatment to breastfeeding. This is a major coup for the organisers of the protest in view of the short time they had to stop Abbott in the publicity spree.