From ICDC’s desk in Penang...

This year marks the 25th anniversary of the International Code of Marketing of Breastmilk Substitutes. As the Code is central to ICDC’s work, it has been a commemorative year for us too – not only for celebrations but for reflection and stock-taking. In a departure from our usual style of reporting, we reproduce below a parody of the Code and key players in the field of infant and young child feeding. Written in the first person from the perspective of the Code, this piece was initiated by a couple of senior IBFANers who saw the humour in satirising the Code issue to convey hard messages where plain writing could not. Many will wonder where the Code is heading after a quarter of a century. No simple answer there and the road ahead promises to be bumpy.

It has been a packed half-year once again.

As Code Task Force Coordinator for the World Alliance for Breastfeeding Action (WABA), ICDC was busy with World Breastfeeding Week which had the Code as its theme this year. We also did our rounds as Code emissaries for breastfeeding events in Thailand and Bangladesh.

This year, the biannual meeting of the IBFAN Coordinating Council (IBCoCo) which has a rotating venue rolled into Penang so the ICDC office was host to some 20 visiting IBFANers from around the world. Soon after IBCoCo, we spent 10 days in Australia at the invitation of the Uniting Church of Australia. Our host took us far and wide through Melbourne, Canberra and Sydney with an ambitious programme to reignite interest in the Code within the Australian community. It was a wake-up call to see how difficult it was to raise public interest on our visit but talks with leading politicians, professional associations and the NGO community already have promising outcomes, including a parliamentary inquiry.

In the meantime, our collaboration with UNICEF continues. In cooperation with UNICEF CEE/CIS and IBFAN Europe, a training course on Code implementation for Central Asia, Georgia and Turkey took place in July.

Another course was held in Penang end November for participants from South Asia under the auspices of the UNICEF Regional Office.

ICDC will continue to help UNICEF build capacity on the Code by conducting a series of courses at the regional level. Also in the works, before the year draws to an end is a Code monitoring course for IBFAN groups in the Arab World.

This more or less wraps up the year for ICDC. Next time you hear from Legal Update, we will be in the New Year - so, glad tidings to all.

Yeong Joo Kean & Annelies Allain

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**HIGHLIGHTS**

- The Code Story—A parody to celebrate 25 years of the International Code
- Israel—Regulators in a fix over sub-standard formula and non-compliant labelling
- Finland—Row over Formula Research
- Newsflash—laws adopted in the Gambia, Palau, Zambia and Bolivia
I'm 25 years old. I was born on 21 May 1981 in Geneva, Switzerland, but I'm a citizen of the world. Like you, I have a mother, her name is World Health Organization, nickname WHO. She was a good mother when I was very small, but nowadays she often forgets that I exist. For example, she remembers my birthday only once every two years and it's never much fun. She's boring and complicated. On my birthday she gives me always the same present, a cake, wrapped in paper called “WHA resolution”. When I get my cake I think: well, now all my problems will be solved! No way. The trouble is that the cake is baked with a strange recipe, so convoluted that often I have to look for legal help to understand what kind of cake I'm about to eat. Lately, the cake comes double-wrapped, imagine, the second wrapper tells how much money is needed to enjoy the cake. It's like the old saying: you can't have your cake and eat it!

Unlike you, though, I have several fathers. Some of them are very good. The Children's Fund, nickname UNICEF, for example, has always protected me during these 25 stormy years, but recently he seems to think that I'm growing up and that I don't need the same kind of support. Other fathers have not been as kind: some of them failed to recognise me at birth, others have neglected me, still others have pretended to respect me but actually don't. Some keep on threatening me by saying that if I talk too much, the big bad WTO down the hill will beat me up. I get scared and run to my auntie, nickname IBFAN. She is more like a real mom to me, she has cared a lot for me, speaks up for me and keeps on giving courage and support. With all these troubles though, I'm still, at 25, carrying many of my childhood and adolescent problems.

For example, there is the problem of my scope. The father who didn’t even recognise me at birth, nickname IFM, is constantly undermining me, saying that I'm only about “infant formula”. But I know that I'm more than that! He makes me feel very inadequate and small, so insignificant that I sometimes feel like crying. My auntie then picks me up and comforts me, and says: “Look at yourself, you're a universal citizen! You’ve got great potential, you can save lives. You can stop kids from growing up stunted, from getting contaminated with ...” oh, I forget ... no, now I remember: “Enterobacter sakazakii”. That's it! Scientists took ages to confirm it existed but now they can’t deny it. In fact, I know that my IFM dad is behind it all, he doesn't want to refurbish his factories to get rid of intrinsic Enterobacter; he says it costs too much money; at the same time, he doesn't want to write it on labels and because that would alarm customers about the the hazards of using the product. He's very sly, that father!

It reminds me of another problem that I had when I was small and that was also denied. It was about 'supplies', free infant formula for small babies and people took a long time to understand that it was a trap. Sounded good but I knew it was a vicious circle: get some free and you're addicted to that brand. It took seven years and four birthday presents from my mom to get that into people's heads. Solved? Not really, it still comes back to haunt me now. Gosh, I wish my mother would learn to stop mumbling and write my presents in clear terms without looking over her shoulder at that IFM dad all the time.

Over the years I've watched how marketing has changed but it's still just as harmful as it was when I was born. It has become more subtle and uses round-about ways in many different types of media now, including the world wide web. Its promotion is hidden for example in these so-called internet baby clubs, using my beloved babies, to bypass me. But nothing has been as disturbing as the attitude of many paediatricians around the world. When I was born, their associations said that I was welcome and badly needed; but when it came to defend me in their countries, support national laws and apply all the principles to their own practices, their reaction often was "we don't need you, we are clever enough to accept gifts from companies and not let it affect our judgements on what's best for babies". Many don't seem to have any idea how much harm they're doing. Thankfully others are realising this: some researchers, some wonderful individuals and editors of medical journals. And fortunately other doctors are joining them and are asking their colleagues to stop accepting gifts from those sneaky companies.

What can I expect in my next 25 years? Will my mom stand up for me? Will I be respected in every country in the world? When its my birthday will I get a present that's clear and straightforward and helps me counter the new marketing tactics that are sure to come along? No more humbug about special formulas or exceptional circumstances; excuses from the uncles who make bottles and teats and say they weren’t told I was born; no more health and nutrition claims which pretend that these products match the golden standard of breastmilk.

I have already travelled to many countries, but there are many others that I haven't seen and many more that I'd like to know better. An old auntie who lives in the Far East and keeps track of my trips tells me that there are 39 countries (see categories 6 and 7–State of the Code by Country...
2006) waiting for my first visit and many more looking forward to entertain me better than they did the first time. Enough to keep me busy for the next 10 years! I hope that Auntie IBFAN and my UNICEF dad will organise my journeys through these savage and mysterious lands. It’s incredible how some of these wild countries think they are “civilised” while in reality they don’t even bother to take care of their smallest citizens.

Moreover, my friends are telling me that older children are also threatened by marketing. They tell me that TNCs – what a funny name – want kids to have lots of sugary drinks, salty snacks and fried foods. Junk foods, they call them. So the same babies that I helped bring up healthy will grow obese and will be seriously ill when they get older. I cannot accept this; I was raised to defend children. But I realised that I’m too little and at the same time too old for this new challenge. I’ll ask my mother to conceive again. A little brother? A little sister? I don’t mind, provided she picks the right fathers and they all promise to take care of him or her every single day and not just on birthdays.

It must be said that on my 25 birthday, my WHO mum gave me a surprise. She celebrated my birthday with banners and posters and she actually said that I save lives. It was the proudest day of my life – recognition from mummy at last!

American interference in the Philippines

A judicial storm brewed up in the Philippines when the Department of Health issued new Implementing Rules and Regulations (IRR) to restrict marketing practices. The IRR augments the 1986 “Milk Code” which implements the International Code of Marketing of Breastmilk Substitutes. The Milk Code had become somewhat outdated, in view of changing marketing practices and the more recent World Health Assembly resolutions.

In protest over the IRR, the Pharmaceutical and Health Care Association of the Philippines (PHAP) representing the three main US formula companies – Abbott Ross, Mead Johnson and Wyeth, and other pharmaceutical giants took the Filipino government to court, claiming among other things that the Department of Health had exceeded its powers in enacting the IRR. At first, the Supreme Court declined PHAP’s application for a temporary restraining order (TRO) to stop the IRR from coming into effect.

Upon PHAP’s application for a review, the Supreme Court overturned its own decision by granting a TRO. While a court case is pending, no one should comment on its merits. But, a leaked letter from the U.S. Chamber of Commerce to the President of the Philippines showed how direct pressure was exerted on the Executive to withdraw the IRR. Within days the TRO was granted.

In the glibly worded letter, the President of the Chamber of Commerce, Thomas Donohue, had warned President Arroyo “the risk to the reputation of the Philippines as a stable and viable destination for investment” if she did not “re-examine this regulatory decision”. He was particularly concerned about the effect of the marketing restrictions on companies and voiced his concern over the way the IRR threatens infant formula as a potential health hazard by requiring warning labels. This letter has since been countered point by point by the Secretary of Health.

The letter by the U.S. Chamber of Commerce struck a raw nerve with the international breastfeeding community and the Philippine public. It was perceived as a direct threat to the independence of the judiciary. This should never happen, not in the Philippines or in any other country. Slowly but steadily, petitions and letters have been pouring in to support the Department of Health. (see http://www.babymilkaction.org/CEM/cemnov06.html) They call upon the business sector to exercise restraint and for the various arms of the Government of the Philippines – Judiciary, Executive and Legislature – to carry out their duties independently and without any fear or favour to fulfill the right of the children of Philippines to the best attainable standard of health.

In the meantime, as if to pre-empt whatever decision the Supreme Court makes on the case, 4 new bills representing different interests have been presented to the Senate to replace the existing Milk Code.

Note: This case has given a special insight into the highly lucrative profits of formula companies. In its submission to the Supreme Court, PHAP gave an estimate of the potential cost of complying with the IRR at approximately US$128 million which is broken down as follows:

• Withdrawal and destruction of non-compliant promotional materials and samples –US$2 million
• Removal of existing stock and change in packaging –US$6 million.
• Loss of sales during the shift towards compliance –US$120 million.

These figures are probably exaggerated but are indicative of the cost and the effectiveness of promotion.

Latvia – Right versus Might law suit culminates in victory for IBFAN group

The Latvian Breastfeeding Promotion and Protection Association (LKEVAB, an IBFAN group) emerged as the final victor in the Supreme Court in Latvia in a case brought against them by the Latvian Paediatric Association (LPA). Legal Update September 2005 first reported this defamation case. At the first instance, LKEVAB managed to defeat LPA’s complaint that a letter they wrote accusing LPA of unprofessional and illegal conduct in endorsing a Nestle formula product, was injurious to LPA’s honour and reputation and that of its president. The District Court ruled in favour of LKEVAB and held that their letter expressed the truth and that product endorsement is a form of advertisement which violates the International Code. LPA filed an appeal to Regional Court in Riga which was dismissed on a procedural point. LPA persisted by filing
yet another appeal, this time to the Supreme Court, the highest court of the land. In May this year, the decision of the court below was upheld by the Supreme Court, bringing the anguish of LKEVAB to an end.

The victory of LKEVAB is tinged by sadness. Ieva Ranka, the president of LKEVAB and a party to the suit died while the appeal was still pending. IBFAN members remember leva as a person of courage and integrity and regret that she did not live to witness the happy outcome.

Legal Update notes that the International Paediatric Association fully supports the International Code and subsequent World Health Assembly resolutions and does not involve itself in product endorsement. It is unfortunate that not all their members subscribe to the same ethical stand.

Israel – Regulators in a fix over sub-standard formula and non-compliant labelling

In December 2003, Legal Update reported on the outbreak of thiamine deficiency in Israel which affected 15 infants and caused 2 deaths. The outbreak was associated with the use of a kosher soy-based infant formula—Remedia Super Soy 1. Subsequently, Legal Update also reported that Humana, the German manufacturer of Remedia Super Soy, paid off between US$16 to US$22 million to the affected families. Humana’s local partner Remedia also came to a settlement with 3 families whose babies suffered permanent disabilities by paying a reputed amount of US$2.2 million to each family. But the legal woes of Remedia were far from over.

In September this year, the Israeli State Prosecution announced that three former executives of Remedia will face charges of involuntary manslaughter, criminal negligence, obstruction of justice, involvement in acts that may spread disease, misleading the public, fraud and conspiracy. Five Health Ministry employees will also face charges for failing to verify that the formula sent from Germany did in fact contain the ingredients listed on the labels. A senior prosecutor said there were fundamental deficiencies in the Ministry’s regulatory mechanism.

The indictment of health officials, in particular, will hopefully alert regulators everywhere that they cannot rely on companies to comply with regulatory requirements. In Israel where the Remedia debacle still strikes a raw nerve, the Haaretz newspaper criticised the Ministry of Health for again letting its guard down by relying on manufacturers to pass on new safety guidelines on use and storage of formula products. Apparently, the labelling on Materna and Similac formulas failed to comply with safety guidelines 9 months after they were issued by the Ministry of Health.

The newspaper laments that reliance is still being placed on compliance by manufacturers. Meanwhile, Similac (Abbott Ross) decided to take on the Health Ministry by stating that in the absence of regulations it will stick to the old label. The losers in this tug-of-war between regulator and manufacturer may be babies and parents who are left in the dark.

Finland - Row over formula research

In 2004, the Breastfeeding Support Association of Finland, member of IBFAN, lodged a complaint with the Finnish Parliamentary Ombudsman about a study led by the Finnish National Public Health Institute. The study aimed at finding out whether removal of bovine insulin from infant formula would reduce type 1 diabetes (IDDM) and the mechanisms of the condition. It involved giving infant formula to newborns, and continuing to provide free formula after discharge of mother and child from the hospital.

Studies of such nature conducted at the institutional level are allowed under Article 7.4 of the International Code but investigation by the Ombudsman discovered that the study proceeded for six months before ethics approval was sought. More and more irregular practices were disclosed as investigations continued. It was recently revealed that participants were not told that the study was funded entirely by Valio, a Finnish baby food manufacturer. Or the fact that the principal investigator of the study was the inventor and beneficiary of the patent for the formula. Participants were also not told that they were in a product development study for a private company. Nor were they adequately informed about the benefits of breastfeeding as opposed to formula-feeding. The researchers have been requested to respond to the Ombudsman findings before a ruling is made.

The Head of the National Health Institute, Pekka Puska, had approved the study. He assured that it complies with the law on medical research and that the distribution of infant formula does not deviate from legal norms. Mr. Puska was a leading candidate for the position of Director-General of the World Health Organization, since filled by Dr. Margaret Chan of Hong Kong.

When it rains, it pours. Since the last Legal Update, 4 new laws have been adopted. Two small nations; the Gambia and Palau took a giant leap for infant health by adopting strong laws reminiscent of ICDC’s Model Law. These laws are a credit to the regional training on Code implementation jointly conducted by ICDC with UNICEF and regional IBFAN offices. Both countries will be listed under category 1 on the IBFAN Scale.

Zambia and Bolivia too adopted new laws but these were classified as category 2 on the IBFAN scale due to several overarching weaknesses in the texts. Nonetheless, the laws are great strides forward for both countries.

ICDC extends its congratulations to all four countries and is glad to have made an impact.