



IBFAN
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

December 2003



From ICDC's desk in Penang:

Even more than other years, 2003 was a busy one. With minimum staff, multi-tasking becomes second nature! No effort was spared when it came to training, advocacy and documentation. We are thus able to bring out the third issue of *Legal Update* before year end. It focuses on corporate responsibility vis-à-vis product liability, the International Code and the Global Strategy.

Unfortunately, some projects like the supplement to the ICDC cornerstone *Code Handbook*, had to be put on the backburner.

The early part of next year will be taken up by the preparation of *Breaking the Rules, Stretching the Rules*, to be launched in May 2004.

Like everyone else in the Network, we hope to somehow live up to the IBFAN motto of "fast, furious and flexible." Season's Greetings from Penang.

Yeong Joo Kean & Annelies Allain

HIGHLIGHTS

- Humana - a case of product liability
- Corporate responsibility under the Global Strategy
- Contaminated formula – potential product liability cases
- Far from human - the Humana misnomer
- Landmark victory in the UK against Wyeth
- ICDC's new human rights poster
- UN committee gives the Code a boost
- Parliament adopts law in Azerbaijan
- More countries moving on to six months in Europe
- Brazil on the cutting edge again
- 2003 in retrospect
- STOP PRESS

Humana: a case of product liability

In November 2003, a WHO alert was issued regarding the outbreak of thiamine (Vitamin B1) deficiency in Israel which affected 15 infants and caused two deaths. This outbreak has been associated with the use of a kosher soy-based infant formula named *Remedia Super Soy 1*, produced by the German company Humana for export to Israel.

Despite claims on the label, Israeli Health Ministry officials did not find any vitamin B1 in the formula - the deficiency of which leads to nerve and heart problems. Some 5,000 Israeli babies were fed on the formula.



Humana product developer Dr. Ute Kramer holding up a can of Remedia Super Soy

Humana, which originally said it was not to blame has since admitted a mistake had been made in the production process. The Head of Humana's product development department is expected to be charged with manslaughter and causing grievous bodily harm by German authorities.

Civil law suits have already been filed in Israel against Humana, Germany's second biggest producer of milk products with an annual turnover of €2.53 billion.

Dr Chessa Lutter, Regional Advisor of the Pan American Health Organization said that "the *Remedia* deaths serve as a powerful reminder that formula is never as safe as manufacturers would have us believe ... Unless there is an easily identifiable cluster of sick infants like in Israel, the fact that formula is responsible for their symptoms is likely to go unnoticed."

The International Code dimension

The need to implement strong Code measures worldwide to protect infant health through safe labeling, quality control and the elimination of promotion takes on a new edge with the *Remedia* debacle.

- ❖ It is immediately obvious that Article 9.4 of the International Code was breached when Humana failed to accurately state the composition/analysis of the product on its label.
- ❖ The B1 deficiency means that the product did not meet the applicable food quality and safety standards required by Article 10.
- ❖ The brand name *Remedia Super Soy* might be seen as idealising the product in violation of Article 9.2 which prohibits idealising text on labels.

Foiled Code implementation in Israel

In July 2001, a bill which sought to implement the Code did not receive sufficient support in the Knesset. The recent furore surrounding the *Remedia* formula will hopefully revive interest in Israel to implement the Code in order to promote, protect and support breastfeeding. The Director of Food and Nutrition Services said in a recent e-mail to ICDC that the Ministry of Health will keep pushing for a law.



Corporate responsibility under the Global Strategy

The Global Strategy on Infant and Young Child Feeding sets out the responsibility of manufacturers and distributors to ensure that processed food products for infants and children meet the applicable Codex Alimentarius standards. The Strategy was adopted by the World Health Assembly by Resolution WHA 55.25 (2002) which also called for adequate labeling of products, consistent with the International Code. Manufacturers and distributors concerned such as Humana and Remedia (which is 51% owned by the US food giant HJ Heinz), should somehow be brought to account, either jointly or severally, for breaching their responsibilities under the Code, the Global Strategy and failing to meet Codex Alimentarius Standards.



Contaminated formula ... potential product liability cases

This Humana disaster brings to mind the case of the healthy full-term Belgium baby who died early last year after being infected by the resistant *Enterobacter Sakazaki* bacteria that can live in powdered milk and

can cause sepsis, meningitis and necrotizing enterocolitis. The baby had been fed on Nestle's *Beba* infant formula.

Companies Mead Johnson and Wyeth recalled products found to be contaminated with the bacteria in the US, prompting the US FDA and health authorities in Europe and the Gulf Region to issue a warning regarding the dangers of powdered formula which purportedly are subjected to stringent lab tests and quality control procedures.



Far from human – the Humana misnomer

Humana's poor quality control is not the only company practice which requires changing. The company produces infant formula based on cow's milk but called "Humana". The terms "humanised", "maternalised" or similar terms should not be used on infant formula labels under Article 9.2 of the Code.



Landmark victory in the UK against Wyeth/SMA Nutrition

In July 2003, SMA Nutrition, the UK subsidiary of the US-based baby food company Wyeth, was found guilty by the Birmingham Magistrates Court on six separate counts of illegal advertising and ordered to pay £60,000 in fines and costs.

The UK *Infant Formula and Follow On Formula Regulations 1995* which implement the International Code state that advertisements for infant formula can be published or displayed only through the healthcare system, in a scientific publication, or for trade purposes in a publication not widely available to the public.

Two years earlier, SMA Nutrition had placed an article in six parenting magazines which highlighted four ingredients that parents should look out for in an infant formula. Trading standards officials found the article tantamount to advertising because the only product in the market which contained all those ingredients was Wyeth's *SMA Gold*.

SMA claimed that the practice was "information" in paid advertising slots in the magazines, which is allowed by law provided the reader is not directed to a particular product.

In the eight-day trial, the court heard from witnesses on how they associated the SMA Nutrition logo shown in the article with a specific SMA infant formula. Judge Rod Ross chided the defence counsel for trying to infer that the witnesses were biased and unreliable because of their affiliations to pressure groups.

The Court heard that the Defendant's legal department had advised that the article needed to be "less promotional and more informative". Despite this legal advice, company director Graham Crawford approved the publication of the article. Crawford, whose testimony was found to be "extraordinarily evasive", is the Chair of the Infant and Dietetic Food Association, which has a long-running campaign against the UK's ban on advertising.

The Defendant brought in one Professor Alan Lucas, a world renowned researcher with extensive involvement with the baby food industry, as expert witness. Lucas gave evidence that the article was an industry standard which filled the need to disseminate company information to pregnant women and mothers, GPs and primary healthcare workers with poor understanding of infant nutrition. He conceded, however, that whether or not the article was an advertisement was a matter for the Courts.

The judge in his deliberations observed that not only were the four combinations of ingredients unique to SMA Gold formula, but the format of the blue and straw coloured "tick" box in the article was strikingly similar to the colours on the tin of SMA Gold. The judge ruled that when one looks at the different colours in the article and compares them with a tin of SMA Gold there is a very distinct similarity and that no other product of competing manufacturers appeared to have this combination of colours.

The European point

Citing "the European point", SMA also argued that the UK law unjustifiably fetters the free movement of goods within the European Community.

This argument was given short shrift by the judge, who held that the law provides selling arrangements for infant formula which apply to all traders operating in the country and affect all products (both domestic and imported) in the same manner in law and in fact. The judge said: "In my view the manufacturers are playing on a 'level playing field'.... It is clear that is important 'to uphold the law of the land in the public interest bearing in mind the stability in our society'." Had the judge been persuaded on the European point, it would have prompted the baby food industry to take it to the UK government or the European Commission, putting the very legitimacy of the law in question.

The judge also rejected SMA's argument that it took all reasonable precautions to avoid perpetrating the

offence, noting in particular that the format of the article was changed after it had been approved for publication whereby the SMA logo was transposed to become more prominent than the statutory warning notice.

In arriving at a guilty verdict on all six summonses, the judge said that the company has deliberately "crossed the line" in an effort to advertise directly to a vulnerable section of society

SMA did not lodge an appeal against the decision.

The outcome was welcomed by breastfeeding organisations and pressure groups. Mike Brady of Baby Milk Action said "It's a stunning victory for infants and mothers in this country, which I believe sets an important precedent and a warning to other companies."

Wyeth is a member of the International Association of Infant Food Manufacturers, which time and again has professed its support for the International Code.

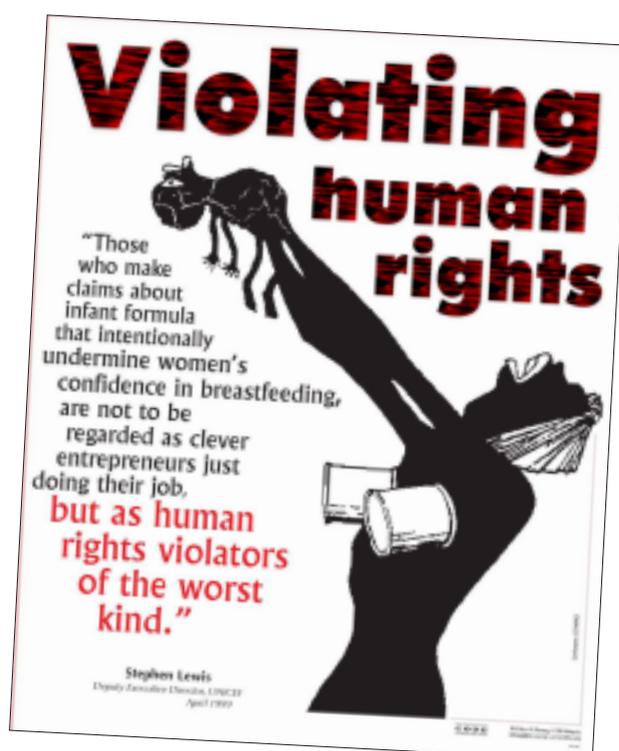
The name of its UK subsidiary, SMA Nutrition, seems to have been purposely crafted to promote various SMA branded formulae.



ICDC'S new human rights poster

The Humana and Wyeth/SMA cases underscore the need to adopt other platforms in our aim to protect infant health.

In October 2003, ICDC launched its new advocacy poster to give centre stage to human rights instruments which can be used to hold companies accountable for their behaviour.



UN committee gives the Code a boost

Through the efforts of IBFAN-GIFA, the UN Committee on the Rights of the Child receives shadow reports on the status of children from countries under review. Based on these, the Committee is calling on countries to implement the Code or to strengthen implementation. Recently, Pakistan was grilled on its poor infant mortality and malnutrition rates. The Committee also asked why industry was allowed to sit on the National Infant Feeding Board set up under the Pakistani Breastfeeding Promotion Ordinance. This approach should caution countries against conferring needless prominence to companies in the field of infant and young child nutrition.



Parliament adopts law in Azerbaijan

In June, ICDC received news that the Law of the Republic of Azerbaijan on Feeding Infants and Young Children had been adopted by Parliament. The law which implements a number of Code articles gives breastfeeding the emphasis it deserves by using a "rights" approach. The State guarantees the right to adequate food and nutrition and to information on breastfeeding. Milk companies are prohibited from disseminating information on breastmilk substitutes to mothers. Maternity benefits are provided to ensure support not only for pregnant women and breastfeeding mothers but also to wet-nurses. Health care facilities are required to implement "rooming-in" to facilitate the initiation of breastfeeding immediately after birth and are prohibited from receiving donations and gifts from anyone having commercial interests in the area of infant feeding. Most importantly, in a move which exceeds the minimum standards set by the International Code, all forms of corporate sponsorship to the medical profession are prohibited.

However, the law does not cover feeding bottles and teats. There are some irregularities with definitions which will give rise to ambiguities and difficulties in implementation. The types of promotion prohibited are limited to very few activities. Advertising in scientific publications is allowed. Even though confined to just scientific and factual matters, it blurs the thin line between information and promotion. There is no specific prohibition on supplies. Although the law provides for sanctions it is unclear which authority is in charge of overseeing implementation.

On the IBFAN-ICDC Scale, Azerbaijan's law is classified under category 2 – "many provisions law".



More countries moving on to six months in Europe

In the previous Update, we listed 69 countries which have government policies (expressed through legislation, decrees, official statements, directives and circulars to health workers) promoting exclusive breastfeeding for six months as recommended by World Health Assembly Resolution 54.2 (2001).

In May, the UK Government also adopted the six months policy. This was followed by Azerbaijan a month later in June. ICDC has also received confirmation that both Germany and the Netherlands earlier adopted a similar policy. This brings the total to 73.



Brazil on the cutting edge again

Brazil has a progressive and innovative record on the many ways one can protect breastfeeding. And now one of its cities continues the tradition by passing a law which gives all municipal workers 6 months maternity leave.

Florianapolis, capital of Santa Catarina, a state in the south of Brazil has the lowest infant mortality rate in the country: less than 10/1000. It intends to improve infant health even more by passing the law which enables all new mothers employed by the municipality to follow the WHO recommended duration of 6 months exclusive breastfeeding.

2003 in retrospect

Training sessions took place in Japan, Indonesia, China and Vietnam at the invitation of local groups and governments, mostly with support from UNICEF. In cooperation with IBFAN Africa and IBFAN Europe, regional training on Code monitoring was conducted in the Gambia (for participants from West African countries) and in Poland (for European IBFAN groups). The ICDC Director also participated at the IBFAN Asia Pacific Conference in Delhi.

ICDC held two well subscribed Code implementation courses, an international one in Penang with 28 participants from 15 countries and a regional one in Trinidad & Tobago for 30 participants from 15 Caribbean countries.

ICDC would like to thank David Clark of UNICEF Headquarters, Chessa Lutter of PAHO, The Informative Breastfeeding Service of Trinidad & Tobago, the UNICEF Caribbean Area Office and Jeanne Verster of South Africa for their wonderful contribution towards the above courses.

STOP PRESS • STOP PRESS

The Council of Ministers of Gabon (central Africa) adopted on 20 Nov 2003 a Decree on the Marketing of Breastmilk Substitutes. It is significant to note that the adoption was preceded by 11 years of debate over the text. ICDC has yet to receive the full text of the law.