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# ICDC LEGAL UPDATE

Jan 2008



## From ICDC's desk in Penang...

July to December 2007 in summary ...

Code Implementation Training Courses with UNICEF  
Regional offices:

- ❖ July – CEE-CIS in Albania (with IBFAN Europe)
- ❖ Aug. – East & Southern Africa in Mozambique
- ❖ Nov. – East Asia & Pacific in Malaysia with WHO

National monitoring training:

- ❖ July – Cambodia

Publications (one was enough !):

- ❖ *Breaking the Rules, Stretching the Rules 2007*  
It was a mammoth task –3,000 reports from 67 countries—checking, compiling, writing, editing, designing and proof-reading – to end with 150 pages, then print, distribute... and sell. (see [www.ibfan.org](http://www.ibfan.org))

As we start 2008, we thought it opportune to re-visit a most important Code event in 2007 – the decision of the Philippine Supreme Court upholding the right of the State to regulate marketing practices. It took a year to settle the highly publicised case.

The media hype in the Philippines was such that when the final decision first became public, it was touted as a victory for baby food companies because the total ban imposed on advertising of all products under the scope of the Milk Code was struck down. A careful analysis of the decision revealed that there is in fact much cause for celebration on the Code front. This issue of *Legal Update* is devoted solely to this landmark decision as it will no doubt be a persuasive legal precedent for Code implementation in all jurisdictions.

*Yeong Joo Kean & Annelies Allain*



## Pharmaceutical and Health Care Association of the Philippines vs. Health Secretary Francisco T. Duque III et al.

### Facts of the case/Chronology of events

In May 2006, the Revised Implementing Rules and Regulations (RIRR) were issued by the Department of Health (DOH) in the Philippines to restrict many marketing practices used to boost sales of breastmilk substitutes. The RIRR is a set of 'delegated' legislation issued by DOH to ensure the successful implementation of the 1986 Milk Code, the parent law which gives effect to the International Code of Marketing of Breastmilk Substitutes in the Philippines.

Apart from clamping down on marketing excesses of baby food companies, the RIRR also adopts internationally endorsed policies and recommendations such as the Global Strategy on Infant and Young Child Feeding and World Health Assembly resolutions (e.g. six months of exclusive breastfeeding; health and nutrition claims; risk of intrinsic contamination of powdered infant formula.)

The RIRR set off a chain of legal proceedings.

■ 27 June 2006 – a 31-page Petition to the Supreme Court in Manila to annul and set aside the RIRR was filed by the Pharmaceutical and Health Care Association of the Philippines (PHAP) whose members include Abbott Ross, Mead Johnson, Wyeth, AstraZeneca Pharmaceuticals, Bayer, Novartis, GlaxoSmithKline and Mercury Drug Corporation.

In the Petition, PHAP disputed the authority of the DOH to issue the RIRR and the validity of a number of its provisions. It also applied for a Temporary Restraining Order (TRO) to stop DOH from implementing the RIRR pending the outcome of the case.

■ 11 July 2006 – the Supreme Court said no to PHAP's application for the TRO.

■ 15 August 2006 – the Supreme Court, upon PHAP's application for a review, granted the TRO and effectively prevented DOH from implementing the RIRR.

### US pressure directly on Head of State

The reversal of the Supreme Court's ruling on the TRO came in just days after the President of the Philippines, Gloria Arroyo, received a letter from Thomas Donohue, the President of the US Chamber of Commerce. (See box on "Veiled Threats and Coercion")

■ 19 June 2007 – the Supreme Court heard oral arguments on the merits of the main case.

■ 9 October 2007 – Decision was delivered. The Supreme Court:

- a) Agreed partially with PHAP that parts of the RIRR relating to –
  - i) a total ban on advertising of all products under the scope of the Milk Code and
  - ii) administrative sanctions

exceeded the power conferred upon DOH by the Milk Code. Such measures could only be implemented if a law is passed to amend the Milk Code.

- b) Ruled in favour of DOH and lifted the TRO because other parts of the RIRR were consistent with the objective, purpose and intent of the Milk Code and constituted reasonable regulation of an industry whose activities affect public health and welfare.

### Veiled threats and coercion

When a matter is sub-judice\*, no one should comment on its merits as parties have a fundamental right to have justice administered by the courts free from outside coercion or interference. Nevertheless, direct pressure was being exerted by the U.S. Chamber of Commerce on the President of the Philippines to withdraw the RIRR. A carefully worded letter dated 11 August 2006 from the President of the US Chamber of Commerce, Thomas Donohue showed how.

Donohue warned President Arroyo of "the risk to the reputation of the Philippines as a stable and viable destination for investment" if she did not re-examine the RIRR. He also complained that the RIRR treats formula as a potential health hazard without scientific justification.



Thomas Donohue

The Donohue letter was widely seen as a flagrant attempt to undermine the independence of the judiciary and prompted a wave of protest both at the national and international level. It does seem more than coincidental that the Supreme Court granted a Temporary Restraining Order on DOH just four days after the letter was written.

In addition, an interview with the Health Secretary, Francisco T. Duque revealed that certain officials from the US State Department and the US Embassy approached him and his staff asking for old provisions to be reinstated so that baby food companies could continue business as usual.



Francisco Duque

*"The threats were veiled. They were subliminal messages. And there have been some very influential people telling us that you might not be looking into the economic implications, if these guys close their operations and move out of the country. That might lead to unemployment blah, blah."*

- Health Secretary, Francisco T. Duque III in an interview with Philippine Center for Investigative Journalism, 4 August 2006

Full text of interview available at <http://pcij.org/blog/wp-docs/PCIJInterviewDuque.pdf>

\*Latin for "under a judge".



Saying it with umbrellas: Mothers display their disappointment over the Supreme Court's decision to temporarily suspend the RIRR

### Public protest

There were public demonstrations in Manila and when the local media blocked coverage, international articles and petitions highlighted the heavy-handed foreign interference in the judiciary. Would the case have been resolved differently if there had not been widespread national and international public protests? This is the multi-million dollar question but the huge public outcry has certainly given the Code a high profile. PHAP's legal action has resulted in a backlash which has dented the reputation of its baby food company members.

# Dissecting the Decision

Legal Update now looks at the 53-page Supreme Court Decision from a legal perspective focusing on areas which may have a bearing on Code implementation world wide.

## Where DOH lost

The one issue contended by PHAP that had any merit was that the RIRR went beyond the provisions of the Milk Code by amending and expanding the coverage of the law. In its defence, DOH argued that the RIRR implements not only the Milk Code but various international instruments regarding infant and young child feeding. DOH lost its argument on the following grounds:

### a. Incorporation of WHA resolutions

Although the Philippine Constitution allows for adoption of international treaties by incorporation (concurring by at least 2/3 of the Senate), the International Code and subsequent resolutions are not treaties but recommendations. While the International Code had been transformed into domestic law through the Milk Code, subsequent WHA resolutions (such as the recommendation for six months of exclusive breastfeeding) had not. The DOH did not prove that compliance with these resolutions by Member States is obligatory in nature or that they are customary international law that may be deemed part of the law of the land. Thus, they cannot be considered as part of the law of the Philippines that can be implemented by executive agencies, such as DOH.

\* International law that derives from the practice of States in their mutual relations and is accepted as legally binding. This is one of the principal building blocks of the international legal system.

### b. Ultra vires\*

Although the Milk Code is almost a verbatim reproduction of the International Code, it did not adopt one provision (Art 5.1) that absolutely prohibits advertising or other forms of promotion. The Milk Code expressly provides that advertising, promotion and other marketing materials may be allowed if such materials are duly authorised and approved by an interagency committee so the total ban on advertising in the RIRR is *ultra vires* vis-à-vis the Milk Code. In other words, the subsidiary legislation went beyond the primary law which should never happen.

Furthermore, the Supreme Court held that DOH exceeded its authority by providing for administrative fines and sanctions as the Milk Code does not grant DOH the authority to fix or impose administrative fines. DOH however is not left without means of enforcement because the Milk Code authorises DOH to “cause the prosecution of the violators of this Code and other pertinent laws on products covered by this Code.” The Milk Code also provides for penalties upon conviction.

\*Latin for “beyond the power”.

## Where DOH won

PHAP invoked many legal arguments to attack other provisions of the RIRR but failed in many respects. Only the rulings which are relevant to Code implementation are highlighted here.

### a. Extension of coverage in RIRR to “young children”

The Supreme Court, noting that the definition of “breastmilk substitutes” in Section 4(a) of the Milk Code (in *pari materia*\* with the definition of “breastmilk substitute” in the International Code) lacks reference to any particular age group, ruled that PHAP is wrong in its allegations that the Milk Code refers only to “infants” (i.e. 0-12 months). Coverage of the Milk Code is not dependent on the age of the child but on the kind of product being marketed to the public. Since breastmilk substitutes may also be intended for children of more than 12 months of age, the Milk Code, by regulating breastmilk substitutes, intends to protect and promote the nutrition of young children over the age of 12 months.

\* Latin for “in the same matter or in conjunction”.

### b. Labelling requirements were ruled valid, specifically:

- i) that there be a statement that there is no substitute for breastmilk;
- ii) that there be a statement that infant formula may contain pathogenic microorganisms and must be prepared and used appropriately; and
- iii) that all health and nutrition claims be prohibited.

The Supreme Court ruled that these requirements are consistent with Section 8(b) of the Milk Code (in *pari materia* with Article 7.2 of the International Code) which provides that information to health workers be restricted to scientific and factual matters and shall not create a belief that bottle feeding is equivalent or superior to breastfeeding. The Supreme Court dismissed possible arguments that Section 8(b) refers only to information to health workers, not to containers and labels. Such restrictive application of the provision would result in the absurd situation in which companies are forbidden to claim to health workers that their products are substitutes or equivalents of breastmilk and yet be allowed to display precisely this message on product labels.

The Supreme Court held that:

- ❖ PHAP’s contention that the RIRR, unlike the Milk Code, failed to recognise that breastmilk substitutes may be a legitimate replacement for breastmilk was deemed incorrect. Even though the RIRR contains a declaration that there is no substitute nor replacement for breastmilk, the Regulations must be considered in their entirety. The RIRR, just like the Milk Code, recognises that in certain cases, the use of breastmilk substitutes may be necessary as it contains provisions about the use of breastmilk substitutes when medically indicated. It also requires that materials include information on the proper use of infant formula when needed.



- ❖ The requirement to warn about intrinsic contamination is consistent with Section 5(b) of the Milk Code (in *pari materia* with Article 4.2 of the International Code regarding information and education) as it merely adds a fair warning about the likelihood of pathogenic microorganisms being present in products.

This ruling therefore affirmed the authority of DOH to control information regarding breastmilk substitutes.

**c. Ban on company involvement in activities for the promotion, education and production of IEC materials intended for women and children.**

The Supreme Court dismissed PHAP's argument that the provision is inconsistent with the Milk Code. The Milk Code allows for dissemination of scientific and factual information to health workers and this ban in the RIRR cannot be understood or interpreted to encompass the dissemination of information to the public.

**d. Ban on participating in policy making body.**

Since DOH is principally responsible for the implementation and enforcement of the Milk Code, the Supreme Court ruled that it is entirely up to DOH to decide which entities to call upon or allow to be part of policy making in relation to the 'advancement' and promotion of breastfeeding.

**e. Ban on sponsorship for training of health workers.**

PHAP's argument that this prohibition contravenes the Milk Code was overruled. It is within the prerogative\* given to DOH to ban such sponsorship as Section 8(e) of the Milk Code only says that manufacturers and distributors may assist in research, scholarships and continuing education of health professionals in accordance with existing rules and regulations.

\*Exclusive right or privilege.

**f. Restrictions on research assistance for health workers and researchers.**

Relying on the same Section 8(e) of the Milk Code, the Supreme Court held that limitations imposed by the RIRR for research assistance such as approval by an ethics committee and disclosure on the parts of sponsors and recipients are completely in accord with the Milk Code.

**g. Ban on donations**

PHAP's allegation that the RIRR contravenes the Milk Code by absolutely prohibiting donation of products and materials was rejected. Although Section 6(f) of the Milk Code provides that donations may be made by manufacturers and distributors upon the request and approval of the DOH, it does not proscribe the refusal of donations. The Supreme Court interpreted the Milk Code as leaving the matter purely to the discretion of

DOH whether to request or accept such donations. By banning donations, DOH appropriately exercised its discretion and the RIRR sets forth its policy not to request or approve donations.

**h. Restraint of Trade**

PHAP made a "catch-all" allegation that the RIRR is "unnecessary and oppressive and is offensive to the due process clause\* of the Constitution, insofar as the same is in restraint of trade".

The Supreme Court relied on an earlier case which stated that although the Philippine Constitution enshrines free enterprise, it nonetheless reserves to the government the power to intervene whenever necessary to promote general welfare. Free enterprise does not call for the removal of protective regulations and it must be clearly explained and proven by competent evidence just exactly how protective regulation would result in restraint of trade.

PHAP had failed to demonstrate how activities proscribed by the RIRR would unreasonably hamper the trade of breastmilk substitutes.

\*The due process clause in many jurisdictions prohibits governments from unfairly or arbitrarily depriving a person of life, liberty or property..

**Talking dollars but not sense**

In its submission to the Supreme Court, PHAP estimated the potential cost of complying with the RIRR at US\$192 million in a market that is said to be worth US\$400 million.

PHAP also claimed there is no proof that the milk industry is undermining the breastfeeding culture in the Philippines. It maintained that commercial infant formula used in the Philippines only has "a penetration rate of 7% of the potential use of infants" and that DOH's "consistent whinge that the marketing of breastmilk substitutes has become more aggressive, is utterly false".

In May 2007, while the case was still pending, Wyeth ran public events to woo mothers. At these events, banners promoted Bonakid growing-up milk but most who came were mothers with small babies. Pre-mixed infant formula was available for the young ones. Mothers received gift packs and were told they could exchange empty Bonna infant formula cans and boxes for prizes.

**Competing with breastfeeding**



**Beyond the Supreme Court Case**

The DOH is proceeding with plans to implement the Milk Code through the RIRR now that all barriers have been eliminated. As of January 2008, the baby food industry has been directed to submit all new labels and packaging materials for approval. The ruling will take effect in August 2008. DOH has also agreed to call on civil society to establish a monitoring system that will help to check compliance with the RIRR. Legal Update wishes them good luck.