Supreme Court ruling in the Philippines

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BABY MILK ACTION

IBFAN

Baby Milk Action is a non-profit organisation which aims to save lives and protect infant and young child health through independent controls on babyfood marketing.

We are a member of the International Baby Food Action Network (IBFAN), a network of over 200 citizens groups in more than 100 countries.

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Overview

The Supreme Court in the Philippines has lifted its Temporary Restraining Order on the Revised Implementing Rules and Regulations (RIRR) for the marketing of baby foods introduced by the Ministry of Health, meaning these now come into force.

The Court ruled the Department of Health had over stepped its powers in extending its right to control advertising to an outright ban on advertising. The right to control advertising empowers of an Inter Agency Committee to disapprove advertising and other marketing materials or require their revision prior to being made public and will provide substantial protection to the public if exercised. An outright ban will require changes to the primary legislation.

The Department of Health had also over stepped its powers in setting fines for breaking of the regulations.

In all other regards the Court found against the industry and for the Department of Health.

The Court considered whether the Department of Health had exceeded its powers by considering the industry's claims that the RIRR went beyond the primary legislation, Executive Order 51 (known as the Milk Code) in the areas set out below.

It also considered the argument that the RIRR was an unconstitutional obstacle to trade

Obstacle to trade – argument rejected

The industry argued: 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**" [emphasis as in original]

The Court concluded: "The framers of the constitution were well aware that trade must be subjected to some form of regulation for the public good. Public interest must be upheld over business interests."

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Coverage of products – scope covering products for older children upheld

The Court concluded: "Petitioner [the industry] is mistaken in its claim that the Milk Code's coverage is limited only to children 0-12 months old."

"Clearly, the 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. The law treats infant formula, bottle-fed complementary food, and breastmilk substitute as separate and distinct product categories." [emphasis as in original]

Therefore, the scope of the RIRR, covering all breastmilk substitutes, including products for children up to two years of age, was upheld.

Legitimacy of products – view of proper use upheld

The court concluded: "It is also incorrect for the petitioner [the industry] to say that the RIRR, unlike the Milk Code, does not recognize that breastmilk substitutes may be a proper and possible substitute for breastmilk."

"Hence, the RIRR, just like the Milk Code, also recognizes that in certain cases, the use of breastmilk substitutes may be proper."

The industry had tried to portray the RIRR as detrimental to babies fed on formula. Yet as the Court noted the RIRR states: "when medically indicated and only when necessary, the use of breastmilk substitutes **is proper** if based on complete and updated information." [emphasis as in original]

Labelling requirements and advertising regulations – right to regulate upheld

The Court stated: "Health is a legitimate subject matter for regulation by the DOH (and certain other administrative agencies) in exercise of police powers delegated to it. The sheer span of jurisprudence on that matter precludes the need to further discuss it."

Regarding the newer area of breastmilk substitutes the Court notes the Department of Health's mandate in this area including:

"When it comes to information regarding nutrition of infants and young children, however, the Milk Code specifically delegated to the Ministry of Health (hereinafter referred to as DOH) the power to ensure that there is adequate, consistent and objective information on breastfeeding and use of breastmilk substitutes, supplements and related products; and the power to **control** such information." [emphasis as in original]

"Further, DOH is authorized by the Milk Code to control the **content** of any information on breastmilk vis-à-vis breastmilk substitutes, supplement and related products, in the following manner [provisions on requirements for information for the public, health workers and on product labels]" [emphasis as in original].

"The DOH is also authorized to control the purpose of the information and to whom such information may be disseminated under Sections 6 through 9 of the Milk code to ensure that the information that would reach pregnant women, mothers of infants, and health

professionals and workers in the health care system is restricted to scientific and factual matters and shall not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding."

"It bears emphasis, however, that the DOH's power under the Milk Code to **control** information regarding breastmilk vis-à-vis breastmilk substitute **is not absolute** as the power to control does not encompass the power to absolutely prohibit the advertising, marketing, and promotion of breastmilk substitutes." [emphasis as in original]

This is the nub of the ruling on advertising. The DOH has the authority to regulate advertising to ensure it is scientific and factual and does not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding, but can't ban advertising outright.

If the DOH is able to exercise this power it could make a significant difference to infant health as currently advertising is not scientific and factual and consists almost entirely of idealizing claims implying formula feeding is equivalent or superior to breastfeeding.

Labelling provisions - right to specify warnings and ban claims upheld

The Court upheld the provisions in the RIRR regarding labelling, stating:

"[the RIRR sections] contain some labelling requirements, specifically: a) that there be a statement that there is no substitute to breastmilk; and b) that there be a statement that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately. [Another section] of the RIRR prohibits all health and nutrition claims for products within the scope of the Milk code, such as claims of increased emotional and intellectual abilities of the infant and young child."

"These requirements and limitations are consistent with the provisions of Section 8 of the Milk Code."

This is great news! It means the Department of Health can prohibit Nestlé's 'brain building blocks' claim on infant formula and advertisements showing formula-fed children giving violin concertos.

Specifically on the warning of risks form intrinsic contamination, the ruling states:

"The label of a product contains information about said product intended for the buyers thereof. The buyers of breastmilk substitutes are mothers of infants, and Section 26 of the RIRR merely adds a fair warning about the likelihood of pathogenic microorganisms being present in infant formula and other related products when these are prepared and used inappropriately.

"[The industry's] Petitioner's counsel has admitted during the hearing on June 19, 2007 that formula milk is prone to contaminations and there is as yet no technology that allows production of powdered infant formula that eliminates all forms of contamination.

"Ineluctably, the requirement under Section 26(f) of the RIRR for the label to contain the message regarding health hazards including the possibility of contamination with pathogenic micororganisms is in accordance with Section 5(b) of the Milk Code.

Powers with regard to regulating advertising - upheld

The outright ban of advertising of breastmilk substitutes and other products within the scope of the Milk Code was not supported by the Court, judging this to go beyond the Department of Health's powers to 'control' advertising.

The Court upheld the powers to control, citing the mechanism of the Inter-Agency Committee, which consists of:

- Minister of Health (Chair),
- Minister of Trade and Industry,
- Minster of Justice and
- Minister of Social Services and Development

or their duly authorized representatives.

This being the case, much of the advertising in the Philippines can be ruled illegal.

The Court quotes the power of the Committee as follows:

"The Committee shall have the following powers and functions:

"(1) To review and examine all advertising, promotion or other marketing materials, whether written, audio or visual, on products within the scope of this Code [which as stated previously includes milks for older children];

"(2) To approve or disapprove, delete objectionable portions from and prohibit the printing, publication, distribution, exhibition and broadcast of, all advertising promotion or other marketing [illegible on my copy]

"(3) To prescribe the internal and operational procedure for the exercise of its powers and functions as well as the performance of its duties and responsibilities; and

"(4) To promulgate such rules and regulations as are necessary or proper for the implementation of Section 6(a) of this Code."

The Court said the DOH had arrogated the powers of the Inter-Agency Committee to itself and gone to far in making an outright prohibition on advertising. However, it added:

"Thus, the DOH has the significant responsibility to translate into operational terms the standards set forth in section 5, 8, and 10 of the Milk Code, by which the IAC shall screen advertising, promotional, or other marketing materials."

The Court said the DOH was correct in stating in the RIRR:

"Promotion of products within the scope of this Code must be objective and should not equate or make the product appear to be as good or equal to breastmilk or breastfeeding in the advertising concept. It must not in any case undermine breastmilk or breastfeeding. The 'total effect' should not directly or indirectly suggest that buying their product would produce better individuals, or resulting in greater love, intelligence, ability, harmony or in any matter bring better health to the baby or other such exaggerated and unsubstantiated claim."

The Court rules:

"Such standards bind the IAC in formulating its rules and regulations on advertising, promotion, and marketing. Through that single provision, the DOH exercises control over the information content of advertising, promotional and marketing materials on breastmilk vis-à-vis breastmilk substitutes, supplements and other related products. It also sets a viable standard against which the IAC may screen such materials before they are made public."

Note, this can, in theory, provide a high level of protection, as screening is to take place before materials are made public.

Information for women distributed through the health care system – ban upheld

The Court states:

"Contrary to the petitioner's [industry's] claim, Section 22 of the RIRR does not prohibit the **giving of information <u>to health professionals</u> on scientific and factual matters**. What it prohibits is the involvement of the manufacturer and distributor of the products covered by the Code in activities for the promotion, education and production of Information, Education and Communication (IEC) materials regarding breastfeeding that are **intended for <u>women and children</u>**. Said provision cannot be construed to encompass even the **dissemination of information <u>to health professional</u>, as restricted** by the Milk Code." [emphasis as in original]

What this means, is the industry was attempting to claim a right to provide materials for women and children through the health care system by representing this as information for health workers. This argument was thrown out.

Independence of research – requirement for ethical clearance upheld

The industry had alleged that the Milk Code "permits milk manufacturers and distributors to extend assistance in research and in the continuing education of health professionals, while Sections 22 and 32 of the RIRR absolutely forbid the same."

The Court disagreed that the RIRR contained a prohibition, stating: "[Section of the RIRR] provide that **research assistance for health workers and researchers may be allowed upon approval of an ethics committee, and with certain disclosure requirements imposed on the milk company and on the recipient of the research award."** [emphasis as in original]

Independence in policy making – ban on company involvement upheld

The industry critcised the RIRR's prohibition of company "participation in any policy making body in relation to the advancement of breastfeeding."

The Court concluded: “It is entirely up to the DOH to decide which entities to call upon or allow to be part of policymaking bodies on breastfeeding. Therefore, the RIRR’s prohibition on milk companies’ participation in any policymaking body in relation to the advancement of breastfeeding is in accord with the Milk Code.

Donations – prohibition upheld

The Court states: “As to the RIRR’s prohibition on donations, said provisions are also consistent with the Milk Code. Section 6(f) of the Milk Code provides that dontations **may** be made by manufacturers and distributors of breastmilk **substitutes upon the request or with the approval of the DOH**. The law does not proscribe the refusal of donations. The Milk Code leaves it purely to the discretion of the DOH whether to request or accept such donations. The DOH then appropriately exercised its discretion through Section 51 of the RIRR which sets forth its policy not to request or approve donations from manufacturers and distributors of breastmilk substitutes.” [emphasis as in original]

The need for legislation to achieve and outright ban on advertising

The Chief Judge was guided by US Supreme Court decisions on the Freedom of Commercial Speech.

Of international measures, only the International Code of Marketing of Breastmilk Substitutes was deemed to have value in Philippines legislation through being “transformed into domestic law through local legislation, the Milk Code. Consequently, it is the Milk Code that has the force and effect of law in this jurisdiction and not the ICBMS per se.”

The ruling notes: “The Milk Code is almost a verbatim reproduction of the ICBMS, but it is well to emphasize at this point that the Code did not adopt the provision in the **ICBMS absolutely prohibiting advertising** or other forms of promotion to the gerneral public of products within the scope of the ICBMS. Instead, **the Milk Code expressly provides that advertising, promotion, or other marketing materials may be allowed if such materials are duly authorized and approved by the Inter-Agency Committee (IAC).”** [emphasis as in original]

While there is an argument that Resolutions of the World Health Assembly (including the International Code) have validity as ‘customary international law’, there is a problem if these are adopted as recommendations rather than regulations. The US put pressure on the Assembly to adopt the Code as a recommendation in 1981, but even then voted against it. This has serious repercussions as the Supreme Court ruling states:

“Apparently, the WHA Resolution adopting the ICBMS and subsequent WHA Resolutions urging member states to implement the ICBMS are merely recommendatory and legally non-binding. **Thus, unlike what has been done with the ICBMS whereby the legislature enacted most of the provisions into law which is the Milk Code, the subsequent WHA Resolutions, specifically providing fgor exclusive breastfeeding from 0-6 months, continued breastfeeding up to 24 months, and absolutely prohibiting advertisements and promotions of breastmilk substitutes, have not been adopted as a domestic law.**” [emphasis as in original].

Certain WHA Resolutions, such as on SARS, have been seen as 'soft law' having political weight as the need for action by states is significant. However, the ruling stresses there is no obligation to implement these.

The crucial decision from the Supreme Court regarding the powers of the authorities to introduce regulations implementing the Resolutions is as follows:

"Consequently, legislation is necessary to transform the provisions of the WHA Resolutions into domestic law. **The provisions of the WHA Resolutions cannot be considered as part of the law of the land that can be implemented by executive agencies without the need of a law enacted by the legislature."** [emphasis as in original]

The Court also considered (pg 17) whether the Department of Health could introduce an outright ban on advertising as part of the national health policy. The court concluded, however, "The national policy of protection, promotion and support of breastfeeding cannot automatically be equated with a total ban on advertising…"

What this means is that the RIRR introduced by the Department of Health must be within the provisions of the 1986 Milk Code implementing the International Code. The Court judges that to go beyond this requires additional legislation giving legal status to the WHA Resolutions (or any other provisions the government wishes to introduce) in national measures.

Even given this decision, under Article 11.3 companies are responsible for ensuring their practices are in compliance independently of government measures.