



Republic of the Philippines
 Supreme Court
 Manila

SUPREME COURT OF THE PHILIPPINES
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PHARMACEUTICAL and HEALTH
 CARE ASSOCIATION of the
 PHILIPPINES,

Petitioner,

G.R. NO. 173034

Present:

PUNO, *C.J.*
 QUISUMBING,
 YNARES-SANTIAGO,
 SANDOVAL-GUTIERREZ,
 CARPIO,
 AUSTRIA-MARTINEZ,
 CORONA,
 CARPIO-MORALES,
 AZCUNA,
 TINGA,
 CHICO-NAZARIO,
 GARCIA,
 VELASCO, JR.,
 NACHIURA, and
 REYES, *JJ.*

- versus -

HEALTH SECRETARY
 FRANCISCO T. DUQUE III;
 HEALTH UNDERSECRETARIES
 DR. ETHIELYN P. NIETO,
 DR. MARGARITA M. GALON,
 ATTY. ALEXANDER A. PADILLA,
 & DR. JADE F. DEL MUNDO; and
 ASSISTANT SECRETARIES
 DR. MARIO C. VILLAVARDE,
 DR. DAVID J. LOZADA, AND
 DR. NEMESIO T. GAKO,
 Respondents.

Promulgated:
 October 09, 2007

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DECISION

AUSTRIA-MARTINEZ, J.:

The Court and all parties involved are in agreement that the best nourishment for an infant is mother's milk. There is nothing greater than for a mother to nurture her beloved child straight from her bosom. The ideal is, of course, for each and every Filipino child to enjoy the unequalled benefits of breastmilk. But how should this end be attained?

Before the Court is a petition for *certiorari* under Rule 65 of the Rules of Court, seeking to nullify Administrative Order (A.O.) No. 2006-0012 entitled, *Revised Implementing Rules and Regulations of Executive Order No. 51, Otherwise Known as The "Milk Code," Relevant International Agreements, Penalizing Violations Thereof, and for Other Purposes* (RIRR). Petitioner posits that the RIRR is not valid as it contains provisions that are not constitutional and go beyond the law it is supposed to implement.

Named as respondents are the Health Secretary, Undersecretaries, and Assistant Secretaries of the Department of Health (DOH). For purposes of herein petition, the DOH is deemed impleaded as a co-respondent since respondents issued the questioned RIRR in their capacity as officials of said executive agency.¹

Executive Order No. 51 (Milk Code) was issued by President Corazon Aquino on October 28, 1986 by virtue of the legislative powers granted to the president under the Freedom Constitution. One of the preambular clauses of the Milk Code states that the law seeks to give effect to Article

¹ Section 11, Rule 3, 1997 Rules of Civil Procedure which provides:

Section 11. *Misjoinder and non-joinder of parties.* - Neither misjoinder nor non-joinder of parties is ground for dismissal of an action.

11² of the International Code of Marketing of Breastmilk Substitutes (ICMBS), a code adopted by the World Health Assembly (WHA) in 1981. From 1982 to 2006, the WHA adopted several Resolutions to the effect that breastfeeding should be supported, promoted and protected, hence, it should be ensured that nutrition and health claims are not permitted for breastmilk substitutes.

In 1990, the Philippines ratified the International Convention on the Rights of the Child. Article 24 of said instrument provides that State Parties should take appropriate measures to diminish infant and child mortality, and ensure that all segments of society, specially parents and children, are informed of the advantages of breastfeeding.

On May 15, 2006, the DOH issued herein assailed RIRR which was to take effect on July 7, 2006.

However, on June 28, 2006, petitioner, representing its members that are manufacturers of breastmilk substitutes, filed the present Petition for *Certiorari* and Prohibition with Prayer for the Issuance of a Temporary Restraining Order (TRO) or Writ of Preliminary Injunction.

The main issue raised in the petition is whether respondents officers of the DOH acted without or in excess of jurisdiction, or with grave abuse of discretion amounting to lack or excess of jurisdiction, and in violation of the provisions of the Constitution in promulgating the RIRR.³

² Article 11. Implementation and monitoring

11.1 Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures. For this purpose, governments should seek, when necessary, the cooperation of WHO, UNICEF and other agencies of the United Nations system. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aim of this Code should be publicly stated, and should apply on the same basis to all those involved in the manufacture and marketing of products within the scope of this Code.

On August 15, 2006, the Court issued a Resolution granting a TRO enjoining respondents from implementing the questioned RIRR.

After the Comment and Reply had been filed, the Court set the case for oral arguments on June 19, 2007. The Court issued an Advisory (Guidance for Oral Arguments) dated June 5, 2007, to wit:

The Court hereby sets the following issues:

1. Whether or not petitioner is a real party-in-interest;
2. Whether Administrative Order No. 2006-0012 or the Revised Implementing Rules and Regulations (RIRR) issued by the Department of Health (DOH) is not constitutional;
 - 2.1 Whether the RIRR is in accord with the provisions of Executive Order No. 51 (Milk Code);
 - 2.2 Whether pertinent international agreements¹ entered into by the Philippines are part of the law of the land and may be implemented by the DOH through the RIRR; If in the affirmative, whether the RIRR is in accord with the international agreements;
 - 2.3 Whether Sections 4, 5(w), 22, 32, 47, and 52 of the RIRR violate the due process clause and are in restraint of trade; and
 - 2.4 Whether Section 13 of the RIRR on Total Effect provides sufficient standards.

¹ (1) United Nations Convention on the Rights of the Child; (2) the WHO and Unicef "2002 Global Strategy on Infant and Young Child Feeding;" and (3) various World Health Assembly (WHA) Resolutions.

The parties filed their respective memoranda.

The petition is partly imbued with merit.

On the issue of petitioner's standing

With regard to the issue of whether petitioner may prosecute this case as the real party-in-interest, the Court adopts the view enunciated in *Executive Secretary v. Court of Appeals*,⁴ to wit:

The modern view is that an association has standing to complain of injuries to its members. This view fuses the legal identity of an association with that of its members. **An association has standing to file suit for its workers despite its lack of direct interest if its members are affected by the action. An organization has standing to assert the concerns of its constituents.**

x x x x

x x x We note that, under its Articles of Incorporation, the respondent was organized x x x to act as the representative of any individual, company, entity or association on matters related to the manpower recruitment industry, and to perform other acts and activities necessary to accomplish the purposes embodied therein. The respondent is, thus, the appropriate party to assert the rights of its members, because it and its members are in every practical sense identical. x x x The respondent [association] is but the medium through which its individual members seek to make more effective the expression of their voices and the redress of their grievances.⁵ (Emphasis supplied)

which was reasserted in *Purok Bagong Silang Association, Inc. v. Yuipco*,⁶ where the Court ruled that an association has the legal personality to represent its members because the results of the case will affect their vital interests.⁷

Herein petitioner's Amended Articles of Incorporation contains a similar provision just like in *Executive Secretary*, that the association is formed "to represent directly or through approved representatives the pharmaceutical and health care industry before the Philippine Government and any of its agencies, the medical professions and the general public."⁸ Thus, as an organization, petitioner definitely has an interest in fulfilling its avowed purpose of representing members who are part of the pharmaceutical and health care industry. Petitioner is duly authorized⁹ to take the appropriate course of action to bring to the attention of government agencies and the courts any grievance suffered by its members which are directly affected by the RIRR. Petitioner, which is mandated by its

⁵ Id. at 96-97.

⁶ G.R. No. 135092, May 4, 2006, 489 SCRA 382.

⁷ Id. at 396.

⁸ Annex "G", Petitioner's Memorandum dated July 19, 2007.

⁹

Amended Articles of Incorporation to represent the entire industry, would be remiss in its duties if it fails to act on governmental action that would affect any of its industry members, no matter how few or numerous they are. Hence, petitioner, whose legal identity is deemed fused with its members, should be considered as a real party-in-interest which stands to be benefited or injured by any judgment in the present action.

On the constitutionality of the provisions of the RIRR

First, the Court will determine if pertinent international instruments adverted to by respondents are part of the law of the land.

Petitioner assails the RIRR for allegedly going beyond the provisions of the Milk Code, thereby amending and expanding the coverage of said law. The defense of the DOH is that the RIRR implements not only the Milk Code but also various international instruments¹⁰ regarding infant and young child nutrition. It is respondents' position that said international instruments are deemed part of the law of the land and therefore the DOH may implement them through the RIRR.

The Court notes that the following international instruments invoked by respondents, namely: (1) The United Nations Convention on the Rights of the Child; (2) The International Covenant on Economic, Social and Cultural Rights; and (3) the Convention on the Elimination of All Forms of Discrimination Against Women, only provide in general terms that steps must be taken by State Parties to diminish infant and child mortality and inform society of the advantages of breastfeeding, ensure the health and well-being of families, and ensure that women are provided with services

¹⁰

a) The UN Convention on the Rights of the Child (CRC); b) the International Code of Marketing Breastmilk Substitutes (ICMBS); c) the International Covenant on Economic, Social

and nutrition in connection with pregnancy and lactation. Said instruments do not contain specific provisions regarding the use or marketing of breastmilk substitutes.

The international instruments that do have specific provisions regarding breastmilk substitutes are the ICMBS and various WHA Resolutions.

Under the 1987 Constitution, international law can become part of the sphere of domestic law either by **transformation** or **incorporation**.¹¹ The transformation method requires that an international law be transformed into a domestic law through a constitutional mechanism such as local legislation. The incorporation method applies when, by mere constitutional declaration, international law is deemed to have the force of domestic law.¹²

Treaties become part of the law of the land through **transformation** pursuant to Article VII, Section 21 of the Constitution which provides that “[n]o treaty or international agreement shall be valid and effective unless concurred in by at least two-thirds of all the members of the Senate.” Thus, treaties or conventional international law must go through a process prescribed by the Constitution for it to be transformed into municipal law that can be applied to domestic conflicts.¹³

The ICMBS and WHA Resolutions are not treaties as they have not been concurred in by at least two-thirds of all members of the Senate as required under Section 21, Article VII of the 1987 Constitution.

¹¹

Joaquin G. Bernas, S.J., Constitutional Structure and Powers of Government (Notes and Cases)
Part I (2005)

However, the ICMBS which was adopted by the WHA in 1981 had been 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 ICMBS *per se*.

The Milk Code is almost a verbatim reproduction of the ICMBS, but it is well to emphasize at this point that the Code did not adopt the provision in the **ICMBS absolutely prohibiting advertising** or other forms of promotion to the general public of products within the scope of the ICMBS. 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).**

On the other hand, Section 2, Article II of the 1987 Constitution, to wit:

SECTION 2. The Philippines renounces war as an instrument of national policy, *adopts the generally accepted principles of international law as part of the law of the land* and adheres to the policy of peace, equality, justice, freedom, cooperation and amity with all nations. (Emphasis supplied)

embodies the **incorporation** method.¹⁴

In *Mijares v. Ranada*,¹⁵ the Court held thus:

[G]enerally accepted principles of international law, by virtue of the incorporation clause of the Constitution, form part of the laws of the land even if they do not derive from treaty obligations. The **classical formulation in international law sees those customary rules accepted as binding result from the combination [of] two elements: the established, widespread, and consistent practice on the part of States; and a psychological element known as the *opinion juris sive necessitates* (opinion as to law or necessity). Implicit in the latter element is a belief that the practice in question is rendered obligatory by the existence of a rule of law requiring it.**¹⁶ (Emphasis supplied)

¹⁴

According to Fr. Bernas, the Austrian Constitution (Art. 9) and the Constitution of the Federal Republic of Germany (Art. 25) also use the incorporation method.

“Generally accepted principles of international law” refers to norms of general or customary international law which are binding on all states,¹⁷ *i.e.*, renunciation of war as an instrument of national policy, the principle of sovereign immunity,¹⁸ a person's right to life, liberty and due process,¹⁹ and *pacta sunt servanda*,²⁰ among others. The concept of “generally accepted principles of law” has also been depicted in this wise:

Some legal scholars and judges look upon certain “general principles of law” as a primary source of international law because **they have the “character of jus rationale” and are “valid through all kinds of human societies.”** (Judge Tanaka in his dissenting opinion in the 1966 South West Africa Case, 1966 I.C.J. 296). O'Connell holds that certain principles are part of international law because **they are “basic to legal systems generally” and hence part of the *jus gentium*.** These principles, he believes, are established by a process of reasoning based on the common identity of all legal systems. If there should be doubt or disagreement, one must look to state practice and determine whether the municipal law principle provides a just and acceptable solution. x x x²¹ (Emphasis supplied)

Fr. Joaquin G. Bernas defines customary international law as follows:

Custom or customary international law means “a general and consistent practice of states followed by them from a sense of legal obligation [*opinio juris*].” (Restatement) **This statement contains the two basic elements of custom: the *material factor*, that is, how states behave, and the *psychological or subjective factor*, that is, why they behave the way they do.**

x x x x

The initial factor for determining the existence of custom is the actual behavior of states. This includes several elements: duration, consistency, and generality of the practice of states.

The required duration can be either short or long. x x x

x x x x

Duration therefore is not the most important element. More important is the consistency and the generality of the practice. x x x

¹⁷ Merlin M. Magallona, Fundamentals of Public International Law, 2005 Ed., p. 526.
¹⁸ *Id.* at 525.

¹⁹ *Government of Hong Kong Special Administrative Region v. Olalia*, G.R. No. 153675, April 19, 2007.

²⁰ *Tañada v. Angara* 338 Phil 546, 507 (1007)

X X X X

Once the existence of state practice has been established, it becomes necessary to determine why states behave the way they do. Do states behave the way they do because **they consider it obligatory** to behave thus or **do they do it only as a matter of courtesy?** *Opinio juris, or the belief that a certain form of behavior is obligatory, is what makes practice an international rule.* Without it, practice is not law.²² (Underscoring and Emphasis supplied)

Clearly, customary international law is deemed incorporated into our domestic system.²³

WHA Resolutions have not been embodied in any local legislation. Have they attained the status of customary law and should they then be deemed incorporated as part of the law of the land?

The World Health Organization (WHO) is one of the international specialized agencies allied with the United Nations (UN) by virtue of Article 57,²⁴ in relation to Article 63²⁵ of the UN Charter. Under the 1946 WHO Constitution, it is the WHA which determines the policies of the WHO,²⁶ and has the power to adopt regulations concerning “advertising and labeling of biological, pharmaceutical and similar products moving in international commerce,”²⁷ and to “make recommendations to members with respect to

²² Supra note 13, at 10-13.

²³ *Minucher v. Court of Appeals*, 445 Phil. 250, 269 (2003).

²⁴ Article 57. The various specialized agencies, established by intergovernmental agreement and having wide international responsibilities, as defined in their basic instruments, in economic, social, cultural, educational, health, and related fields, shall be brought into relationship with the United Nations in accordance with the provisions of Article 63.

Such agencies thus brought into relationship with the United Nations are hereinafter referred to as specialized agencies.

²⁵ Article 63. The Economic and Social Council may enter into agreements with any of the agencies referred to in Article 57, defining the terms on which the agency concerned shall be brought into relationship with the United Nations. Such agreements shall be subject to approval by the General Assembly.

It may coordinate the activities of the specialized agencies through consultation with and recommendations to such agencies and through recommendations to the General Assembly and to the Members of the United Nations.

²⁶ Article 18. The *functions* of the Health Assembly shall be: (a) *to determine the policies of the Organization* x x x. (Emphasis supplied)

²⁷ Article 21. *The Health Assembly shall have authority to adopt regulations concerning:* x x x

any matter within the competence of the Organization.”²⁸ The legal effect of its regulations, as opposed to recommendations, is quite different.

Regulations, along with conventions and agreements, duly adopted by the WHA **bind member states** thus:

Article 19. The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such **conventions or agreements**, which **shall come into force for each Member when accepted by it in accordance with its constitutional processes**.

Article 20. **Each Member undertakes that it will**, within eighteen months after the adoption by the Health Assembly of a convention or agreement, **take action relative to the acceptance of such convention or agreement**. Each Member shall notify the Director-General of the action taken, and if it does not accept such convention or agreement within the time limit, it will furnish a statement of the reasons for non-acceptance. In case of acceptance, each Member agrees to make an annual report to the Director-General in accordance with Chapter XIV.

Article 21. *The Health Assembly shall have authority to adopt regulations concerning:* (a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (b) nomenclatures with respect to diseases, causes of death and public health practices; (c) standards with respect to diagnostic procedures for international use; (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce; (e) *advertising and labeling of biological, pharmaceutical and similar products moving in international commerce*.

Article 22. *Regulations adopted pursuant to Article 21 shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice.* (Emphasis supplied)

On the other hand, under Article 23, recommendations of the WHA do not come into force for members, in the same way that conventions or agreements under Article 19 and regulations under Article 21 come into force. Article 23 of the WHO Constitution reads:

Article 23. The Health Assembly shall have *authority to make recommendations* to Members with respect to any matter within the competence of the Organization. (Emphasis supplied)

The absence of a provision in Article 23 of any mechanism by which the recommendation would come into force for member states is conspicuous.

The former Senior Legal Officer of WHO, Sami Shubber, stated that WHA recommendations are generally not binding, but they "carry moral and political weight, as they constitute the judgment on a health issue of the collective membership of the highest international body in the field of health."²⁹ Even the ICMBS itself was adopted as a mere recommendation, as WHA Resolution No. 34.22 states:

"The Thirty-Fourth World Health Assembly x x x adopts, **in the sense of Article 23 of the Constitution**, the International Code of Marketing of Breastmilk Substitutes annexed to the present resolution." (Emphasis supplied)

The Introduction to the ICMBS also reads as follows:

In January 1981, the Executive Board of the World Health Organization at its sixty-seventh session, considered the fourth draft of the code, endorsed it, and unanimously recommended to the Thirty-fourth World Health Assembly the text of a resolution by which **it would adopt the code in the form of a recommendation rather than a regulation.** x x x (Emphasis supplied)

The legal value of WHA Resolutions as recommendations is summarized in Article 62 of the WHO Constitution, to wit:

Art. 62. Each member shall report annually on the action taken with respect to recommendations made to it by the Organization, and with respect to conventions, agreements and regulations.

Apparently, the WHA Resolution adopting the ICMBS and subsequent WHA Resolutions urging member states to implement the ICMBS are merely recommendatory and legally non-binding. Thus, unlike what has been done with the ICMBS whereby the legislature enacted most of the provisions into law which is the Milk Code, the subsequent WHA Resolutions,³⁰ specifically providing for exclusive breastfeeding from 0-6

³⁰ In Resolution No. 34.22 (May 21, 1981), the WHA, acting under Article 23 of the WHO Constitution, adopted the ICBMS.

- (a) In Resolution No. 35.26 (May 1982), the WHA urged member states to implement the ICBMS as a "minimum requirement".
- (b) In Resolution No. 39.28 (May 16, 1986), the WHA requested the WHO Director General to direct the attention of member states to the fact that any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breastfeeding and therefore should neither be promoted nor encouraged for us by infants during this period.
- (c) In Resolution No. 43.3 (May 14, 1990), the WHA urged member states to protect and promote breastfeeding as an essential component of nutrition policies so as to enable infants to be exclusively breastfed during the first four to six months of life.
- (d) In Resolution No. 45.34 (May 14, 1992), the WHA urged member states to implement the targets of the Innocenti Declaration specifically, to give effect to the ICMBS.
- (e) In Resolution No. 46.7 (May 10, 1993), the WHA urged member states to strive to eliminate under-nutrition, malnutrition and nutritional deficiency among children.
- (f) In Resolution No. 47.5 (May 9, 1994), the WHA urged member states to ensure that there are no donations of supplies of breastmilk substitutes and other products covered by the ICMBS in any part of the health care system.
- (g) In Resolution No. 49.15 (May 25, 1996), the WHA urged member states to ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding.
- (h) In Resolution No. 54.2 (May 2002), the WHA, noting that "despite the fact that the International Code of Marketing of Breastmilk Substitutes and relevant subsequent World Health Assembly resolutions state that there should be no advertising or other forms of promotion of products within its scope, new modern communication methods including electronic means, are currently increasingly being used to promote such products; and conscious of the need for the Codex Alimentarius Commission to take the International Code and subsequent relevant Health Assembly resolutions into consideration in dealing with health claims in the development of food standards and guidelines x x x," urged member states to develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation.
- (i) In Resolution No. 55.25 (May 15, 2002), the WHA requested the

months, continued breastfeeding up to 24 months, and absolutely prohibiting advertisements and promotions of breastmilk substitutes, have not been adopted as a domestic law.

It is propounded that WHA Resolutions may constitute “soft law” or non-binding norms, principles and practices that influence state behavior.³¹

“Soft law” does not fall into any of the categories of international law set forth in Article 38, Chapter III of the 1946 Statute of the International Court of Justice.³² It is, however, an expression of non-binding norms, principles, and practices that influence state behavior.³³ Certain declarations and resolutions of the UN General Assembly fall under this category.³⁴ The most notable is the UN Declaration of Human Rights, which this Court has enforced in various cases, specifically, *Government of Hongkong Special Administrative Region v. Olalia*,³⁵ *Mejoff v. Director of Prisons*,³⁶ *Mijares v. Rañada*³⁷ and *Shangri-la International Hotel Management, Ltd. v. Developers Group of Companies, Inc.*³⁸

The World Intellectual Property Organization (WIPO), a specialized agency attached to the UN with the mandate to promote and protect

ICBMS.

(j) In Resolution No. 58.32 (May 25, 2005), the WHA urged member states to continue to protect and promote exclusive breastfeeding for six months.

(k) In Resolution No. 59.21 (May 27, 2006), the WHA reiterated its support for the Global strategy for Infant and Young Child Feeding.

³¹
³²

David Fidler, *supra* note 29.

Article 38. 1. The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply: a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting states; b) international custom, as evidence of a general practice accepted as law; c) the general principles of law recognized by civilized nations; d) subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

³³

Supra note 29.

³⁴

Louis Henkin, et al., *International Law, Cases and Materials*, 2nd Ed., *supra* note 21, at 114-136.

³⁵

Supra note 19.

³⁶

90 Phil. 70 (1951)

intellectual property worldwide, has resorted to soft law as a rapid means of norm creation, in order "to reflect and respond to the changing needs and demands of its constituents."³⁹ Other international organizations which have resorted to soft law include the International Labor Organization and the Food and Agriculture Organization (in the form of the *Codex Alimentarius*).⁴⁰

WHO has resorted to soft law. This was most evident at the time of the Severe Acute Respiratory Syndrome (SARS) and Avian flu outbreaks.

Although the IHR Resolution does not create new international law binding on WHO member states, it provides an excellent example of the power of "soft law" in international relations. International lawyers typically distinguish binding rules of international law-"hard law"-from non-binding norms, principles, and practices that influence state behavior-"soft law." WHO has during its existence generated many soft law norms, creating a "soft law regime" in international governance for public health.

The "soft law" SARS and IHR Resolutions represent significant steps in laying the political groundwork for improved international cooperation on infectious diseases. These resolutions clearly define WHO member states' normative duty to cooperate fully with other countries and with WHO in connection with infectious disease surveillance and response to outbreaks.

This duty is neither binding nor enforceable, but, in the wake of the SARS epidemic, the duty is powerful politically for two reasons. First, the SARS outbreak has taught the lesson that participating in, and enhancing, international cooperation on infectious disease controls is in a country's self-interest x x x if this warning is heeded, the "soft law" in the SARS and IHR Resolution could inform the development of general and consistent state practice on infectious disease surveillance and outbreak response, perhaps crystallizing eventually into customary international law on infectious disease prevention and control.⁴¹

In the Philippines, the executive department implemented certain measures recommended by WHO to address the outbreaks of SARS and

³⁹

Edward Kwakwa, Some Comments on Rulemaking at the World Intellectual Property Organization, www.law.duke.edu/shell/cite; September 13, 2007, 12:33, citing the 1999 WIPO Resolution Concerning Provisions on the Protection of Well-Known Marks, 2000 WIPO Recommendation Concerning Trademark Licenses, and 2001 WIPO Recommendation Concerning Provisions on the Protection of Marks and other Industrial Property Rights in Signs on the

Avian flu by issuing Executive Order (E.O.) No. 201 on April 26, 2003 and E.O. No. 280 on February 2, 2004, delegating to various departments broad powers to close down schools/establishments, conduct health surveillance and monitoring, and ban importation of poultry and agricultural products.

It must be emphasized that even under such an international emergency, the duty of a state to implement the IHR Resolution was still considered not binding or enforceable, although said resolutions had great political influence.

As previously discussed, for an international rule to be considered as customary law, it must be established that such rule is being followed by states because they **consider it obligatory** to comply with such rules (*opinio juris*). Respondents have not presented any evidence to prove that the WHA Resolutions, although signed by most of the member states, were in fact enforced or practiced by at least a majority of the member states; neither have respondents proven that any compliance by member states with said WHA Resolutions was obligatory in nature.

Respondents failed to establish that the provisions of pertinent WHA Resolutions are customary international law that may be deemed part of the law of the land.

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.**

Second, the Court will determine whether the DOH may implement the provisions of the WHA Resolutions.

under the Revised Administrative Code even in the absence of a domestic law.

Section 3, Chapter 1, Title IX of the Revised Administrative Code of 1987 provides that the DOH shall **define the national health policy** and implement a national health plan within the framework of the government's general policies and plans, and **issue orders and regulations concerning the implementation of established health policies.**

It is crucial to ascertain whether the absolute prohibition on advertising and other forms of promotion of breastmilk substitutes provided in some WHA Resolutions has been adopted as part of the national health policy.

Respondents submit that the national policy on infant and young child feeding is embodied in A.O. No. 2005-0014, dated May 23, 2005. Basically, the Administrative Order declared the following policy guidelines: (1) ideal breastfeeding practices, such as early initiation of breastfeeding, exclusive breastfeeding for the first six months, extended breastfeeding up to two years and beyond; (2) appropriate complementary feeding, which is to start at age six months; (3) micronutrient supplementation; (4) universal salt iodization; (5) the exercise of other feeding options; and (6) feeding in exceptionally difficult circumstances. Indeed, the primacy of breastfeeding for children is emphasized as a national health policy. **However, nowhere in A.O. No. 2005-0014 is it declared that as part of such health policy, the advertisement or promotion of breastmilk substitutes should be absolutely prohibited.**

The national policy of protection, promotion and support of breastfeeding cannot automatically be equated with a total ban on advertising for breastmilk substitutes.

In view of the enactment of the Milk Code which does not contain a total ban on the advertising and promotion of breastmilk substitutes, but instead, specifically creates an IAC which will regulate said advertising and promotion, it follows that a total ban policy could be implemented only **pursuant to a law** amending the Milk Code passed by the constitutionally authorized branch of government, the legislature.

Thus, only the provisions of the Milk Code, but **not those of subsequent WHA Resolutions**, can be validly implemented by the DOH through the subject RIRR.

Third, the Court will now determine whether the provisions of the RIRR are in accordance with those of the Milk Code.

In support of its claim that the RIRR is inconsistent with the Milk Code, petitioner alleges the following:

1. The Milk Code limits its coverage to children 0-12 months old, but the RIRR extended its coverage to “young children” or those from ages two years old and beyond:

MILK CODE	RIRR
<p>WHEREAS, in order to ensure that safe and adequate nutrition <u>for infants</u> is provided, there is a need to protect and promote breastfeeding and to inform the public about the proper use of breastmilk substitutes and supplements and related products through adequate, consistent and objective information and appropriate regulation of the marketing and distribution of the said substitutes, supplements and related products;</p>	<p>Section 2. Purpose – These Revised Rules and Regulations are hereby promulgated to ensure the provision of safe and adequate nutrition <u>for infants and young children</u> by the promotion, protection and support of breastfeeding and by ensuring the proper use of breastmilk substitutes, breastmilk supplements and related products when these are medically indicated and only when necessary, on the basis of adequate information and through appropriate marketing and distribution.</p>
<p>SECTION 4(e). “Infant” means a person falling within the age bracket of <u>0-12 months</u>.</p>	<p>Section 5(ff). “Young Child” means a person from the age of <u>more than twelve (12) months</u> up to the age of three (3) years (36 months).</p>

2. The Milk Code recognizes that infant formula may be a proper and possible substitute for breastmilk in certain instances; but the RIRR provides “exclusive breastfeeding for infants from 0-6 months” and declares that “there is no substitute nor replacement for breastmilk”:

MILK CODE	RIRR
<p>WHEREAS, in order to ensure that safe and adequate nutrition for <u>infants</u> is provided, there is a need to protect and promote breastfeeding and to inform the public about the <u>proper use of breastmilk substitutes and supplements and related products</u> through adequate, consistent and objective information and appropriate regulation of the marketing and distribution of the said substitutes, supplements and related products;</p>	<p>Section 4. Declaration of Principles – The following are the underlying principles from which the revised rules and regulations are premised upon:</p> <p>a. <u>Exclusive breastfeeding is for infants from 0 to six (6) months.</u></p> <p>b. There is <u>no substitute or replacement for breastmilk.</u></p>

3. The Milk Code only regulates and does not impose unreasonable requirements for advertising and promotion; RIRR imposes an absolute ban on such activities for breastmilk substitutes intended for infants from 0-24 months old or beyond, and forbids the use of health and nutritional claims. Section 13 of the RIRR, which provides for a “total effect” in the promotion of products within the scope of the Code, is vague:

MILK CODE	RIRR
<p>SECTION 6. The General Public and Mothers. – (a) No advertising, promotion or other marketing materials, whether written, audio or visual, for <u>products within the scope of this Code</u> shall be printed, published, distributed, exhibited and broadcast <u>unless such materials are duly authorized and approved by an inter-agency committee</u> created herein pursuant to the applicable standards provided for in this Code.</p>	<p>Section 4. Declaration of Principles – The following are the underlying principles from which the revised rules and regulations are premised upon:</p> <p style="text-align: center;">x x x x</p> <p>f. <u>Advertising, promotions, or sponsor-ships of infant formula, breastmilk substitutes and other related products are prohibited.</u></p> <p>Section 11. Prohibited Practices –</p>

substitutes intended for infants and young children up to twenty-four (24) months, shall be allowed, because they tend to convey or give subliminal messages or impressions that undermine breastmilk and breastfeeding or otherwise exaggerate breastmilk substitutes and/or replacements, as well as related products covered within the scope of this Code.

Section 13. "Total Effect" - 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 manner bring better health to the baby or other such exaggerated and unsubstantiated claim.

Section 15. Content of Materials. - The following shall not be included in advertising, promotional and marketing materials:

a. Texts, pictures, illustrations or information which discourage or tend to undermine the benefits or superiority of breastfeeding or which idealize the use of breastmilk substitutes and milk supplements. In this connection, no pictures of babies and children together with their mothers, fathers, siblings, grandparents, other relatives or caregivers (or yayas) shall be used in any advertisements for infant formula and breastmilk supplements;

b. The term "humanized," "maternalized," "close to mother's milk" or similar words in describing breastmilk substitutes or milk supplements;

c. Pictures or texts that idealize the use of infant and milk formula.

Section 16. All health and nutrition claims for products within the scope of the Code

any phrase or words that connotes to increase emotional, intellectual abilities of the infant and young child and other like phrases shall not be allowed.

4. The RIRR imposes additional labeling requirements not found in the Milk Code:

MILK CODE	RIRR
<p>SECTION 10. Containers/Label. –</p> <p>(a) Containers and/or labels shall be designed to provide the necessary information about the appropriate use of the products, and in such a way as not to discourage breastfeeding.</p> <p>(b) Each container shall have a clear, conspicuous and easily readable and understandable message in Pilipino or English printed on it, or on a label, which message can not readily become separated from it, and which shall include the following points:</p> <ul style="list-style-type: none"> (i) the words “Important Notice” or their equivalent; (ii) a statement of the superiority of breastfeeding; (iii) a statement that the product shall be used only on the advice of a health worker as to the need for its use and the proper methods of use; and (iv) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation. 	<p>Section 26. Content – Each container/label shall contain such message, in both Filipino and English languages, and which message cannot be readily separated therefrom, relative the following points:</p> <ul style="list-style-type: none"> (a) The words or phrase “Important Notice” or “Government Warning” or their equivalent; (b) A statement of the superiority of breastfeeding; (c) <u>A statement that there is no substitute for breastmilk;</u> (d) A statement that the product shall be used only on the advice of a health worker as to the need for its use and the proper methods of use; (e) Instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation; and (f) <u>The health hazards of unnecessary or improper use of infant formula and other related products including information that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately.</u>

5. The Milk Code allows dissemination of information on infant formula to health professionals; the RIRR totally prohibits such activity:

MILK CODE	RIRR
<p>SECTION 7. Health Care System. –</p> <p>(b) No facility of the health care system</p>	<p>Section 22. No manufacturer, distributor,</p>

infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Section 8(b).

SECTION 8. Health Workers. -

(b) Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code shall be restricted to scientific and factual matters and such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. It shall also include the information specified in Section 5(b).

involved in any activity on breastfeeding promotion, education and production of Information, Education and Communication (IEC) materials on breastfeeding, holding of or participating as speakers in classes or seminars for women and children activities and to avoid the use of these venues to market their brands or company names.

SECTION 16. All health and nutrition claims for products within the scope of the Code are absolutely prohibited. For this purpose, any phrase or words that connotes to increase emotional, intellectual abilities of the infant and young child and other like phrases shall not be allowed.

6. The Milk Code permits milk manufacturers and distributors to extend assistance in research and continuing education of health professionals; RIRR absolutely forbids the same.

MILK CODE	RIRR
<p>SECTION 8. Health Workers – (e) Manufacturers and distributors of products within the scope of this Code <u>may assist in the research, scholarships and continuing education, of health professionals,</u> in accordance with the rules and regulations promulgated by the Ministry of Health.</p>	<p>Section 4. Declaration of Principles – The following are the underlying principles from which the revised rules and regulations are premised upon: i. Milk companies, and their representatives, <u>should not form part of any policymaking body or entity in relation to the advancement of breastfeeding.</u></p> <p>SECTION 22. No manufacturer, distributor, or representatives of products covered by the Code shall be allowed to conduct or be involved in <u>any activity on breastfeeding promotion, education and production of Information, Education and Communication (IEC) materials on breastfeeding, holding of or participating as speakers in classes or seminars for women and children activities</u> and to avoid the use of these venues to market their brands or company names.</p>
	<p>SECTION 32. Primary Responsibility of Health Workers - It is the primary responsibility of the health workers</p>

and appropriate infant and young child feeding. Part of this responsibility is to continuously update their knowledge and skills on breastfeeding. No assistance, support, logistics or training from milk companies shall be permitted.

7. The Milk Code regulates the giving of donations; RIRR absolutely prohibits it.

MILK CODE	RIRR
<p>SECTION 6. The General Public and Mothers. – (1) Nothing herein contained shall prevent donations from manufacturers and distributors of products within the scope of this Code upon request by or with the approval of the Ministry of Health.</p>	<p>Section 51. Donations Within the Scope of This Code - Donations of products, materials, defined and covered under the Milk Code and these implementing rules and regulations, shall be strictly prohibited.</p> <p>Section 52. Other Donations By Milk Companies Not Covered by this Code. - Donations of products, equipments, and the like, not otherwise falling within the scope of this Code or these Rules, given by milk companies and their agents, representatives, whether in kind or in cash, may only be coursed through the Inter Agency Committee (IAC), which shall determine whether such donation be accepted or otherwise.</p>

8. The RIRR provides for administrative sanctions not imposed by the Milk Code.

MILK CODE	RIRR
	<p>Section 46. Administrative Sanctions. – The following administrative sanctions shall be imposed upon any person, juridical or natural, found to have violated the provisions of the Code and its implementing Rules and Regulations:</p> <p>a) 1st violation – Warning;</p> <p>b) 2nd violation – Administrative fine of a minimum of Ten Thousand (₱10,000.00) to Fifty Thousand (₱50,000.00) Pesos, depending on the gravity and extent of the violation, including the recall of the</p>

a minimum of Sixty Thousand (₱60,000.00) to One Hundred Fifty Thousand (₱150,000.00) Pesos, depending on the gravity and extent of the violation, and in addition thereto, the recall of the offending product, and suspension of the Certificate of Product Registration (CPR);

d) 4th violation – Administrative Fine of a minimum of Two Hundred Thousand (₱200,000.00) to Five Hundred (₱500,000.00) Thousand Pesos, depending on the gravity and extent of the violation; and in addition thereto, the recall of the product, revocation of the CPR, suspension of the License to Operate (LTO) for one year;

c) 5th and succeeding repeated violations – Administrative Fine of One Million (₱1,000,000.00) Pesos, the recall of the offending product, cancellation of the CPR, revocation of the License to Operate (LTO) of the company concerned, including the blacklisting of the company to be furnished the Department of Budget and Management (DBM) and the Department of Trade and Industry (DTI);

f) An additional penalty of Two Thousand Five Hundred (₱2,500.00) Pesos per day shall be made for every day the violation continues after having received the order from the IAC or other such appropriate body, notifying and penalizing the company for the infraction.

For purposes of determining whether or not there is “repeated” violation, each product violation belonging or owned by a company, including those of their subsidiaries, are deemed to be violations of the concerned milk company and shall not be based on the specific violating product alone.

9. The RIRR provides for repeal of existing laws to the contrary.

The Court shall resolve the merits of the allegations of petitioner *seriatim*.

1. Petitioner is mistaken in its claim that the Milk Code's coverage is limited only to children 0-12 months old. Section 3 of the Milk Code states:

SECTION 3. *Scope of the Code* – The Code applies to the marketing, and practices related thereto, of the following products: breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.

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.

Section 4(h) of the Milk Code defines infant formula as “a breastmilk substitute x x x to satisfy the normal nutritional requirements of *infants up to between four to six months of age*, and adapted to their physiological characteristics”; while under Section 4(b), bottle-fed complementary food refers to “any food, whether manufactured or locally prepared, suitable as a complement to breastmilk or infant formula, when either becomes insufficient to satisfy the nutritional requirements of the *infant*.” An infant under Section 4(e) is a person falling within the age bracket 0-12 months. It is the nourishment of this group of infants or children aged 0-12 months that is sought to be promoted and protected by the Milk Code.

But there is another target group. Breastmilk substitute is defined under Section 4(a) as “any food being marketed or otherwise presented as a

purpose.” This section conspicuously lacks reference to any particular age-group of children. Hence, the provision of the Milk Code cannot be considered exclusive for children aged 0-12 months. In other words, breastmilk substitutes may also be intended for young children more than 12 months of age. Therefore, by regulating breastmilk substitutes, the Milk Code also intends to protect and promote the nourishment of children more than 12 months old.

Evidently, as long as what is being marketed falls within the scope of the Milk Code as provided in Section 3, then it can be subject to regulation pursuant to said law, even if the product is to be used by children aged over 12 months.

There is, therefore, nothing objectionable with Sections 2⁴² and 5(ff)⁴³ of the RIRR.

2. It is also incorrect for petitioner to say that the RIRR, unlike the Milk Code, does not recognize that breastmilk substitutes may be a proper and possible substitute for breastmilk.

The entirety of the RIRR, not merely truncated portions thereof, must be considered and construed together. As held in *De Luna v. Pascual*,⁴⁴ “[t]he particular words, clauses and phrases in the Rule should not be studied as detached and isolated expressions, but the whole and every part thereof must be considered in fixing the meaning of any of its parts and in order to produce a harmonious whole.”

⁴² Section 2. *Purpose* – These Revised Rules and Regulations are hereby promulgated to ensure the provision of safe and adequate nutrition for infants and young children by the promotion, protection and support of breastfeeding and by ensuring the proper use of breastmilk substitutes, breastmilk supplements and related products when these are medically indicated and only when necessary, on the basis of adequate information and through appropriate marketing and distribution. (Underscoring supplied)

⁴³ Section 5(ff) “Young Child”

Section 7 of the RIRR provides that “when medically indicated and only when necessary, **the use of breastmilk substitutes is proper** if based on complete and updated information.” Section 8 of the RIRR also states that information and educational materials should include information on the proper use of infant formula when the use thereof is needed.

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

3. The Court shall ascertain the merits of allegations 3⁴⁵ and 4⁴⁶ together as they are interlinked with each other.

To resolve the question of whether the labeling requirements and advertising regulations under the RIRR are valid, it is important to deal first with the nature, purpose, and depth of the regulatory powers of the DOH, as defined in general under the 1987 Administrative Code,⁴⁷ and as delegated in particular under the Milk Code.

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.⁴⁸ However, health information, particularly advertising materials on apparently non-toxic products like breastmilk substitutes and supplements, is a relatively new area for regulation by the DOH.⁴⁹

⁴⁵ See pp. 19-21.

⁴⁶ See p. 21.

⁴⁷ Executive Order No. 292, made effective on November 23, 1989 by Proclamation No. 495.

⁴⁸ *Jacobson v. Massachusetts*, 197 US 11 (1905); *Beltran v. Secretary of Health* G.R. No. 133640, November 25, 2005, 476 SCRA 168, 196; *St. Lukes's Medical Center Employees Association-AFW v. National Labor Relations Commission*, G.R. No. 162053, March 7, 2007; *Tablarin v. Gutierrez*, G.R. No. L-78164, July 31, 1987, 152 SCRA 730, 741; *Pollution Adjudication Board v. Court of Appeals*, G.R. No. 93891, March 11, 1991, 195 SCRA 112, 123-124; *Rivera v. Campbell*, 34 Phil. 348, 353-354 (1916); *Lorenzo v. Director of Health*, 50 Phil. 595, 597 (1927).

⁴⁹ As early as *People v. Pomar*, 46 Phil. 440, 445 (1924), we already noted that “*advancing civilization is bringing within the scope of police power of the state today things which*”

As early as the 1917 Revised Administrative Code of the Philippine Islands,⁵⁰ health information was already within the ambit of the regulatory powers of the predecessor of DOH.⁵¹ Section 938 thereof charged it with the duty to protect the health of the people, and vested it with such powers as “(g) the dissemination of hygienic information among the people and *especially the inculcation of knowledge as to the proper care of infants* and the methods of preventing and combating dangerous communicable diseases.”

Seventy years later, the 1987 Administrative Code tasked respondent DOH to carry out the state policy pronounced under Section 15, Article II of the 1987 Constitution, which is “to protect and promote the right to health of the people and *instill health consciousness* among them.”⁵² To that end, it was granted under Section 3 of the Administrative Code the power to “(6) propagate health information and *educate the population* on important health, medical and environmental matters which have health implications.”⁵³

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. These are expressly provided for in Sections 12 and 5(a), to wit:

SECTION 12. *Implementation and Monitoring* –

masses and of the government to look after and care for the interests of the individuals of the state, have brought within the police power of the state many questions for regulation which formerly were not so considered.”

⁵⁰ Act No. 2711, approved on March 10, 1917.

⁵¹ Known then as Public Health Service

x x x x

(b) The Ministry of Health shall be principally responsible for the implementation and enforcement of the provisions of this Code. For this purpose, the Ministry of Health shall have the following powers and functions:

(1) To promulgate such rules and regulations as are necessary or proper for the implementation of this Code and the accomplishment of its purposes and objectives.

x x x x

(4) To exercise such other powers and functions as may be necessary for or incidental to the attainment of the purposes and objectives of this Code.

SECTION 5. *Information and Education* –

(a) The government shall ensure that **objective and consistent** information is provided on infant feeding, for use by families and those involved in the field of infant nutrition. This responsibility shall cover the planning, provision, design and dissemination of information, and the *control* thereof, on infant nutrition. (Emphasis supplied)

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:

SECTION 5. x x x

(b) Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants, shall include clear information on all the following points: (1) the benefits and superiority of breastfeeding; (2) maternal nutrition, and the preparation for and maintenance of breastfeeding; (3) the negative effect on breastfeeding of introducing partial bottlefeeding; (4) the difficulty of reversing the decision not to breastfeed; and (5) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. *When such materials contain information about the use of infant formula, they shall include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breastmilk substitutes. Such materials shall not use any picture or text which may idealize the use of breastmilk substitutes.*

SECTION 8. *Health Workers* –

x x x x

(b) Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code shall be restricted to scientific and factual matters, and such information shall not imply or create a belief that bottlefeeding is equivalent or superior to breastfeeding. It shall also include the information specified in Section 5(b).

SECTION 10. *Containers/Label* –

(a) Containers and/or labels shall be designed to provide the necessary information about the appropriate use of the products, and in such a way as not to discourage breastfeeding.

x x x x

(d) The term “humanized,” “maternalized” or similar terms shall not be used. (Emphasis supplied)

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 Code⁵⁴ to ensure that the information that would reach

⁵⁴SECTION 6. *The General Public and Mothers* –

- (a) No advertising, promotion or other marketing materials, whether written, audio or visual, for products within the scope of this Code shall be printed, published, distributed, exhibited and broadcast unless such materials are duly authorized and approved by an inter-agency committee created herein pursuant to the applicable standards provided for in this Code.
- (b) Manufacturers and distributors shall not be permitted to give, directly or indirectly, samples and supplies of products within the scope of this Code or gifts of any sort to any member of the general public, including members of their families, to hospitals and other health institutions, as well as to personnel within the health care system, save as otherwise provided in this Code.
- (c) There shall be no point-of-sale advertising, giving of samples or any other promotion devices to induce sales directly to the consumers at the retail level, such as special displays, discount coupons, premiums, special sales, bonus and tie-in sales for the products within the scope of this Code. This provision shall not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.
- (d) Manufacturers and distributors shall not distribute to pregnant women or mothers of infants any gifts or articles or utensils which may promote the use of breastmilk substitutes or bottlefeeding, nor shall any other groups, institutions or individuals distribute such gifts, utensils or products to the general public and mothers.
- (e) Marketing personnel shall be prohibited from advertising or promoting in any other manner the products covered by this Code, either directly or indirectly, to pregnant women or with mother of infants, except as otherwise provided by this Code.
- (f) Nothing herein contained shall prevent donations from manufacturers and distributors or products within the scope of this Code upon request by or with the approval of the Ministry of Health.

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 bottlefeeding 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-a-vis* breastmilk substitutes is **not absolute** as the power to control does not encompass the power to absolutely prohibit the advertising, marketing, and promotion of breastmilk substitutes.

infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Section 8(b).

- (c) Facilities of the health care system shall not be used for the display of products within the scope of this Code, or for placards or posters concerning such products.
- (d) The use by the health care system of "professional service" representatives, "mothercraft nurses" or similar personnel, provided or paid for by manufacturers or distributors, shall not be permitted.
- (e) In health education classes for mothers and the general public, health workers and community workers shall emphasize the hazards and risks of the improper use of breastmilk substitutes particularly infant formula. Feeding with infant formula shall be demonstrated only to mothers who may not be able to breastfeed for medical or other legitimate reasons.

SECTION 8. *Health Workers* -

- (a) Health workers shall encourage and promote breastfeeding and shall make themselves familiar with objectives and consistent information on maternal and infant nutrition, and with their responsibilities under this Code.
- (b) Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code shall be restricted to scientific and factual matters and such information shall not imply or create a belief that bottlefeeding is equivalent or superior to breastfeeding. It shall also include the information specified in Section 5(b).
- (c) No financial or material inducements to promote products within the scope of this Code shall be offered by manufacturers or distributors to health workers or members of their families, nor shall these be accepted by the health workers or members of their families, except as otherwise provided in Section 8(e).
- (d) Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, shall not be provided to health workers except when necessary for the purpose of professional evaluation or research in accordance with the rules and regulations promulgated by the Ministry of Health. No health workers shall give samples of infant formula to pregnant women and mothers of infants or members of their families.
- (e) Manufacturers and distributors of products within the scope of this Code may assist in the research, scholarships and continuing education, of health professionals, in accordance with the rules and regulations promulgated by the Ministry of Health.

The following are the provisions of the Milk Code that unequivocally indicate that the control over information given to the DOH is not absolute and that absolute prohibition is not contemplated by the Code:

a) Section 2 which requires adequate information and appropriate marketing and distribution of breastmilk substitutes, to wit:

SECTION 2. *Aim of the Code* – The aim of the Code is to contribute to the provision of safe and adequate nutrition for infants by the protection and promotion of breastfeeding and by ensuring the proper use of breastmilk substitutes and breastmilk supplements when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

b) Section 3 which specifically states that the Code applies to the marketing of and practices related to breastmilk substitutes, including infant formula, and to information concerning their use;

c) Section 5(a) which provides that the government shall ensure that objective and consistent information is provided on infant feeding;

d) Section 5(b) which provides that written, audio or visual informational and educational materials shall not use any picture or text which may idealize the use of breastmilk substitutes and should include information on the health hazards of unnecessary or improper use of said product;

e) Section 6(a) in relation to Section 12(a) which creates and empowers the IAC to review and examine advertising, promotion, and other marketing materials;

f) Section 8(b) which states that milk companies may provide information to health professionals but such information should be restricted

bottlefeeding is equivalent or superior to breastfeeding; and

g) Section 10 which provides that containers or labels should not contain information that would discourage breastfeeding and idealize the use of infant formula.

It is in this context that the Court now examines the assailed provisions of the RIRR regarding labeling and advertising.

Sections 13⁵⁵ on “total effect” and 26⁵⁶ of Rule VII of the RIRR contain some labeling 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. Section 16⁵⁷ 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, to wit:

SECTION 8. *Health workers -*

x x x x

(b) Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code shall be **restricted to scientific and factual matters**, and such information **shall not** imply or create a belief that bottlefeeding is *equivalent* or **superior** to breastfeeding. It shall also include the information specified in Section 5.⁵⁸ (Emphasis supplied)

⁵⁵ See p. 20.

⁵⁶ See p. 21.

⁵⁷ SECTION 16. All health and nutrition claims for products within the scope of the Code are absolutely prohibited. For this purpose, any claim that...

and Section 10(d)⁵⁹ which bars the use on containers and labels of the terms “humanized,” “maternalized,” or similar terms.

These provisions of the Milk Code expressly forbid information that would imply or create a belief that there is any milk product equivalent to breastmilk or which is humanized or maternalized, as such information would be inconsistent with the superiority of breastfeeding.

It may be argued that Section 8 of the Milk Code refers only to information given to health workers regarding breastmilk substitutes, not to containers and labels thereof. However, such restrictive application of Section 8(b) will result in the absurd situation in which milk companies and distributors are forbidden to claim to health workers that their products are substitutes or equivalents of breastmilk, and yet be allowed to display on the containers and labels of their products the exact opposite message. That askewed interpretation of the Milk Code is precisely what Section 5(a) thereof seeks to avoid by mandating that all information regarding breastmilk *vis-a-vis* breastmilk substitutes be *consistent*, at the same time giving the government control over planning, provision, design, and dissemination of information on infant feeding.

Thus, Section 26(c) of the RIRR which requires containers and labels to state that the product offered is not a substitute for breastmilk, is a reasonable means of enforcing Section 8(b) of the Milk Code and deterring circumvention of the protection and promotion of breastfeeding as embodied in Section 2⁶⁰ of the Milk Code.

⁵⁹ SECTION 10. *Containers/Label* –
x x x x

⁶⁰ (d) The term “humanized”, “maternalized” or similar terms shall not be used.
SECTION 2. *Aim of the Code* – The aim of the Code is to contribute to the provision of safe and

Section 26(f)⁶¹ of the RIRR is an equally reasonable labeling requirement. It implements Section 5(b) of the Milk Code which reads:

SECTION 5. x x x

x x x x

(b) Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants, shall include clear information on all the following points: x x x (5) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they shall include the social and financial implications of its use; *the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breastmilk substitutes*. Such materials shall not use any picture or text which may idealize the use of breastmilk substitutes. (Emphasis supplied)

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.

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.⁶²

Ineluctably, the requirement under Section 26(f) of the RIRR for the label to contain the message regarding health hazards including the

⁶¹ SECTION 26. *Content* – Each container/label shall contain such message, in both Filipino and English languages, and which message cannot be readily separated therefrom, relative the following points:

x x x x

(f) The health hazards of unnecessary or improper use of infant formula and other related products

possibility of contamination with pathogenic microorganisms is in accordance with Section 5(b) of the Milk Code.

The authority of DOH to control information regarding breastmilk *vis-a-vis* breastmilk substitutes and supplements and related products cannot be questioned. It is its intervention into the area of advertising, promotion, and marketing that is being assailed by petitioner.

In furtherance of Section 6(a) of the Milk Code, to wit:

SECTION 6. *The General Public and Mothers.* -

(a) No advertising, promotion or other marketing materials, whether written, audio or visual, for products within the scope of this Code shall be printed, published, distributed, exhibited and broadcast unless such materials are duly authorized and approved by an inter-agency committee created herein pursuant to the applicable standards provided for in this Code.

the Milk Code invested regulatory authority over advertising, promotional and marketing materials to an IAC, thus:

SECTION 12. *Implementation and Monitoring* -

(a) For purposes of Section 6(a) of this Code, an inter-agency committee composed of the following members is hereby created:

- Minister of Health ----- Chairman
- Minister of Trade and Industry ----- Member
- Minister of Justice ----- Member
- Minister of Social Services and Development ----- Member

The members may designate their duly authorized representative to every meeting of the Committee.

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;

(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

(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.**
x x x (Emphasis supplied)

However, Section 11 of the RIRR, to wit:

SECTION 11. *Prohibition* – No advertising, promotions, sponsorships, or marketing materials and activities for breastmilk substitutes intended for infants and young children up to twenty-four (24) months, shall be allowed, because they tend to convey or give subliminal messages or impressions that undermine breastmilk and breastfeeding or otherwise exaggerate breastmilk substitutes and/or replacements, as well as related products covered within the scope of this Code.

prohibits advertising, promotions, sponsorships or marketing materials and activities for breastmilk substitutes in line with the RIRR's declaration of principle under Section 4(f), to wit:

SECTION 4. *Declaration of Principles* –

x x x x

(f) Advertising, promotions, or sponsorships of infant formula, breastmilk substitutes and other related products are prohibited.

The DOH, through its co-respondents, evidently arrogated to itself not only the regulatory authority given to the IAC but also imposed absolute prohibition on advertising, promotion, and marketing.

Yet, oddly enough, Section 12 of the RIRR reiterated the requirement of the Milk Code in Section 6 thereof for prior approval by IAC of all advertising, marketing and promotional materials prior to dissemination.

Even respondents, through the OSG, acknowledged the authority of IAC, and repeatedly insisted, during the oral arguments on June 19, 2007, that the prohibition under Section 11 is not actually operational, *viz*:

SOLICITOR GENERAL DEVANADERA:

x x x x

x x x Now, the crux of the matter that is being questioned by Petitioner is whether or not there is an absolute prohibition on advertising making AO 2006-12 unconstitutional. We maintained that what AO 2006-12 provides is not an absolute prohibition because Section 11 while it states and it is entitled prohibition it states that no advertising, promotion, sponsorship or marketing materials and activities for breast milk substitutes intended for infants and young children up to 24 months shall be allowed because this is the standard they tend to convey or give subliminal messages or impression undermine that breastmilk or breastfeeding x x x.

We have to read Section 11 together with the other Sections because the other Section, Section 12, provides for the inter agency committee that is empowered to process and evaluate all the advertising and promotion materials.

x x x x

What AO 2006-12, what it does, it does not prohibit the sale and manufacture, it simply regulates the advertisement and the promotions of breastfeeding milk substitutes.

x x x x

Now, the prohibition on advertising, Your Honor, must be taken together with the provision on the Inter-Agency Committee that processes and evaluates because there may be some information dissemination that are straight forward information dissemination. What the AO 2006 is trying to prevent is any material that will undermine the practice of breastfeeding, Your Honor.

x x x x

ASSOCIATE JUSTICE SANTIAGO:

Madam Solicitor General, under the Milk Code, which body has authority or power to promulgate Rules and Regulations regarding the Advertising, Promotion and Marketing of Breastmilk Substitutes?

SOLICITOR GENERAL DEVANADERA:

Your Honor, please, it is provided that the Inter-Agency Committee, Your Honor.

x x x x

ASSOCIATE JUSTICE SANTIAGO:

x x x Don't you think that the Department of Health overstepped its rule making authority...

materials under Section 13 and 15 of the rules and regulations?

SOLICITOR GENERAL DEVANADERA:

Your Honor, please, first we would like to stress that there is no total absolute ban. Second, the Inter-Agency Committee is under the Department of Health, Your Honor.

x x x x

ASSOCIATE JUSTICE NAZARIO:

x x x Did I hear you correctly, Madam Solicitor, that there is no absolute ban on advertising of breastmilk substitutes in the Revised Rules?

SOLICITOR GENERAL DEVANADERA:

Yes, your Honor.

ASSOCIATE JUSTICE NAZARIO:

But, would you nevertheless agree that there is an absolute ban on advertising of breastmilk substitutes intended for children two (2) years old and younger?

SOLICITOR GENERAL DEVANADERA:

It's not an absolute ban, Your Honor, because we have the Inter-Agency Committee that can evaluate some advertising and promotional materials, subject to the standards that we have stated earlier, which are they should not undermine breastfeeding, Your Honor.

x x x x

x x x Section 11, while it is titled Prohibition, it must be taken in relation with the other Sections, particularly 12 and 13 and 15, Your Honor, because it is recognized that the Inter-Agency Committee has that power to evaluate promotional materials, Your Honor.

ASSOCIATE JUSTICE NAZARIO:

So in short, will you please clarify there's no absolute ban on advertisement regarding milk substitute regarding infants two (2) years below?

SOLICITOR GENERAL DEVANADERA:

We can proudly say that the general rule is that there is a prohibition, however, we take exceptions and standards have been set. One of which is that, the Inter-Agency Committee can allow if the advertising and promotions will not undermine breastmilk and

breastfeeding, Your Honor.⁶³

Sections 11 and 4(f) of the RIRR are clearly violative of the Milk Code.

However, although it is the IAC which is authorized to promulgate rules and regulations for the approval or rejection of advertising, promotional, or other marketing materials under Section 12(a) of the Milk Code, said provision must be related to Section 6 thereof which in turn provides that the rules and regulations must be "pursuant to the applicable standards provided for in this Code." Said standards are set forth in Sections 5(b), 8(b), and 10 of the Code, which, at the risk of being repetitious, and for easy reference, are quoted hereunder:

SECTION 5. *Information and Education* –

x x x x

(b) Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants, shall include clear information on all the following points: (1) the benefits and superiority of breastfeeding; (2) maternal nutrition, and the preparation for and maintenance of breastfeeding; (3) the negative effect on breastfeeding of introducing partial bottlefeeding; (4) the difficulty of reversing the decision not to breastfeed; and (5) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they shall include the social and financial implications of its use; the health hazards of inappropriate foods of feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breastmilk substitutes. Such materials shall not use any picture or text which may idealize the use of breastmilk substitutes.

x x x x

SECTION 8. *Health Workers*. –

x x x x

(b) Information provided by manufacturers and distributors to health professionals regarding products within the scope of this

Code shall be restricted to scientific and factual matters and such information shall not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding. It shall also include the information specified in Section 5(b).

x x x x

SECTION 10. *Containers/Label* –

(a) Containers and/or labels shall be designed to provide the necessary information about the appropriate use of the products, and in such a way as not to discourage breastfeeding.

(b) Each container shall have a clear, conspicuous and easily readable and understandable message in Pilipino or English printed on it, or on a label, which message can not readily become separated from it, and which shall include the following points:

- (i) the words “Important Notice” or their equivalent;
- (ii) a statement of the superiority of breastfeeding;
- (iii) a statement that the product shall be used only on the advice of a health worker as to the need for its use and the proper methods of use; and
- (iv) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation.

Section 12(b) of the Milk Code designates the DOH as the principal implementing agency for the enforcement of the provisions of the Code. In relation to such responsibility of the DOH, Section 5(a) of the Milk Code states that:

SECTION 5. *Information and Education* –

(a) The government shall ensure that **objective and consistent** information is provided on infant feeding, for use by families and those involved in the field of infant nutrition. This responsibility shall cover the planning, provision, design and dissemination of information, and the control thereof, on infant nutrition. (Emphasis supplied)

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

It is pursuant to such responsibility that the DOH correctly provided for Section 13 in the RIRR which reads as follows:

SECTION 13. "*Total Effect*" - 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 manner bring better health to the baby or other such exaggerated and unsubstantiated claim.

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-a-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.

In *Equi-Asia Placement, Inc. vs. Department of Foreign Affairs*,⁶⁴ the Court held:

x x x [T]his Court had, in the past, accepted as sufficient standards the following: "public interest," "justice and equity," "public convenience and welfare," and "simplicity, economy and welfare."⁶⁵

In this case, correct information as to infant feeding and nutrition is infused with public interest and welfare.

4. With regard to activities for dissemination of information to health professionals, the Court also finds that there is no inconsistency between the provisions of the Milk Code and the RIRR. Section 7(b)⁶⁶ of the Milk Code,

⁶⁴ G.R. No. 152214, September 19, 2006, 502 SCRA 295.

⁶⁵ Id. at 314.

⁶⁶ SECTION 7. *Health Care System* –
x x x x

in relation to Section 8(b)⁶⁷ of the same Code, allows dissemination of information to health professionals but such **information is restricted to scientific and factual matters.**

Contrary to petitioner's claim, Section 22 of the RIRR does not prohibit the **giving of information to health professionals 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 women and children.** Said provision cannot be construed to encompass even the **dissemination of information to health professionals, as restricted by the Milk Code.**

5. Next, petitioner alleges that Section 8(e)⁶⁸ of 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. Petitioner also assails Section 4(i)⁶⁹ of the RIRR prohibiting milk manufacturers' and distributors' participation in any policymaking body in relation to the advancement of breastfeeding.

Section 4(i) of the RIRR provides that milk companies and their representatives should not form part of any policymaking body or entity in

⁶⁷ dissemination of information to health professionals as provided in Section 8(b).

SECTION 8. *Health Workers.* -

x x x x

(b) Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code shall be restricted to scientific and factual matters and such information shall not imply or create a belief that bottlefeeding is equivalent or superior to breastfeeding. It shall also include the information specified in Section 5(b).

⁶⁸ SECTION 8. *Health Workers* -

x x x x

(e) Manufacturers and distributors of products within the scope of this Code may assist in the research, scholarships and continuing education, of health professionals, in accordance with the rules and regulations promulgated by the Ministry of Health.

⁶⁹ SECTION 4. *Declaration of Principles* - The following are the underlying principles from which the revised rules and regulations are premised upon:

x x x x

relation to the advancement of breastfeeding. The Court finds nothing in said provisions which contravenes the Milk Code. Note that under Section 12(b) of the Milk Code, it is **the DOH which shall be principally responsible** for the implementation and enforcement of the provisions of said Code. 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.

Petitioner is also mistaken in arguing that Section 22 of the RIRR prohibits milk companies from giving reasearch assistance and continuing education to health professionals. **Section 22⁷⁰ of the RIRR does not pertain to research assistance to or the continuing education of health professionals**; rather, it deals with breastfeeding promotion and **education for women and children**. Nothing in Section 22 of the RIRR prohibits milk companies from giving assistance for research or continuing education to health professionals; hence, petitioner's argument against this particular provision must be struck down.

It is Sections 9⁷¹ and 10⁷² of the RIRR which govern research assistance. Said sections 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**

⁷⁰ SECTION 22. No manufacturer, distributor, or representatives of products covered by the Code shall be allowed to conduct or be involved in any activity on breastfeeding promotion, education and production of Information, Education and Communication (IEC) materials on breastfeeding, holding of or participating as speakers in classes or seminars for women and children activities and to avoid the use of these venues to market their brands or company names.

⁷¹ SECTION 9. *Research, Ethics Committee, Purpose* - The DOH shall ensure that research conducted for public policy purposes, relating to infant and young child feeding should, at all times, be free from any commercial influence/bias; accordingly, the health worker or researcher involved in such must disclose any actual or potential conflict of interest with the company/person funding the research. In any event, such research and its findings shall be subjected to independent peer review. x x x.

⁷² SECTION 10. *Public Disclosure* - For transparency purposes, a disclosure and/or disclaimer of the sponsoring company should be done by the company itself health worker, researcher involved

the milk company and on the recipient of the research award.

The Milk Code endows the DOH with the power to determine how such research or educational assistance may be given by milk companies or under what conditions health workers may accept the assistance. Thus, Sections 9 and 10 of the RIRR imposing limitations on the kind of research done or extent of assistance given by milk companies are completely in accord with the Milk Code.

Petitioner complains that Section 32⁷³ of the RIRR prohibits milk companies from giving assistance, support, logistics or training to health workers. This provision is within the prerogative given to the DOH under Section 8(e)⁷⁴ of the Milk Code, which provides that manufacturers and distributors of breastmilk substitutes may assist in researches, scholarships and the continuing education, of health professionals in accordance with the rules and regulations promulgated by the Ministry of Health, now DOH.

6. 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 donations **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 51⁷⁵ of the RIRR which sets forth its policy not to request or approve donations from manufacturers and distributors of breastmilk substitutes.

⁷³ SECTION 32. *Primary Responsibility of Health Workers* – It is the primary responsibility of the health workers to promote, protect and support breastfeeding and appropriate infant and young child feeding. Part of this responsibility is to continuously update their knowledge and skills on breastfeeding. No assistance, support, logistics or training from milk companies shall be permitted.

⁷⁴ Supra note 68.

⁷⁵ SECTION 51. *Donations Within the Scope of This Code* – Donations of products, materials

It was within the discretion of the DOH when it provided in Section 52 of the RIRR that any donation from milk companies not covered by the Code should be coursed through the IAC which shall determine whether such donation should be accepted or refused. As reasoned out by respondents, the DOH is not mandated by the Milk Code to accept donations. For that matter, no person or entity can be forced to accept a donation. There is, therefore, no real inconsistency between the RIRR and the law because the Milk Code does not prohibit the DOH from refusing donations.

7. With regard to Section 46 of the RIRR providing for administrative sanctions that are not found in the Milk Code, the Court upholds petitioner's objection thereto.

Respondent's reliance on *Civil Aeronautics Board v. Philippine Air Lines, Inc.*⁷⁶ is misplaced. The glaring difference in said case and the present case before the Court is that, in the *Civil Aeronautics Board*, the Civil Aeronautics Administration (CAA) was **expressly granted by the law (R.A. No. 776) the power** to impose fines and civil penalties, while the Civil Aeronautics Board (CAB) was granted by the same law the power to review on appeal the order or decision of the CAA and to determine whether to impose, remit, mitigate, increase or compromise such fine and civil penalties. Thus, the Court upheld the CAB's Resolution imposing administrative fines.

In a more recent case, *Perez v. LPG Refillers Association of the Philippines, Inc.*,⁷⁷ the Court upheld the Department of Energy (DOE) Circular No. 2000-06-10 implementing *Batas Pambansa (B.P.) Blg. 33*. The circular provided for fines for the commission of prohibited acts. The Court found that nothing in the circular contravened the law because the DOE was

expressly authorized by B.P. *Blg.* 33 and R.A. No. 7638 to impose fines or penalties.

In the present case, neither the Milk Code nor the Revised Administrative Code grants the DOH the authority to fix or impose administrative fines. Thus, without any express grant of power to fix or impose such fines, the DOH cannot provide for those fines in the RIRR. In this regard, the DOH again exceeded its authority by providing for such fines or sanctions in Section 46 of the RIRR. Said provision is, therefore, null and void.

The DOH is not left without any means to enforce its rules and regulations. Section 12(b) (3) of the Milk Code authorizes the DOH to “cause the prosecution of the violators of this Code and other pertinent laws on products covered by this Code.” Section 13 of the Milk Code provides for the penalties to be imposed on violators of the provision of the Milk Code or the rules and regulations issued pursuant to it, to wit:

SECTION 13. *Sanctions* –

(a) Any person who violates the provisions of this Code **or the rules and regulations issued pursuant to this Code** shall, upon conviction, be punished by a penalty of two (2) months to one (1) year imprisonment or a fine of not less than One Thousand Pesos (₱1,000.00) nor more than Thirty Thousand Pesos (₱30,000.00) or both. Should the offense be committed by a juridical person, the chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefor, shall be penalized.

(b) Any license, permit or authority issued by any government agency to any health worker, distributor, manufacturer, or marketing firm or personnel for the practice of their profession or occupation, or for the pursuit of their business, may, upon recommendation of the Ministry of Health, be suspended or revoked in the event of repeated violations of this Code, or of the rules and regulations issued pursuant to this Code. (Emphasis supplied)

8. Petitioner’s claim that Section 57 of the RIRR repeals existing laws

Section 57 reads:

SECTION 57. *Repealing Clause* - All orders, issuances, and rules and regulations or parts thereof inconsistent with these revised rules and implementing regulations are hereby repealed or modified accordingly.

Section 57 of the RIRR does not provide for the repeal of laws but only orders, issuances and rules and regulations. Thus, said provision is valid as it is within the DOH's rule-making power.

An administrative agency like respondent possesses quasi-legislative or rule-making power or the power to make rules and regulations which results in delegated legislation that is within the confines of the granting statute and the Constitution, and subject to the doctrine of non-delegability and separability of powers.⁷⁸ Such express grant of rule-making power necessarily includes the power to amend, revise, alter, or repeal the same.⁷⁹ This is to allow administrative agencies flexibility in formulating and adjusting the details and manner by which they are to implement the provisions of a law,⁸⁰ in order to make it more responsive to the times. Hence, it is a standard provision in administrative rules that prior issuances of administrative agencies that are inconsistent therewith are declared repealed or modified.

In fine, only Sections 4(f), 11 and 46 are *ultra vires*, beyond the authority of the DOH to promulgate and in contravention of the Milk Code and, therefore, null and void. The rest of the provisions of the RIRR are in consonance with the Milk Code.

Lastly, petitioner makes a "catch-all" allegation that:

x x x [T]he questioned RIRR sought to be implemented by the Respondents is **unnecessary and oppressive, and is offensive to the due**

⁷⁸

Smart Communications, Inc. v. National Telecommunications Commission, 456 Phil. 145, 155-156 (2003)

process clause of the Constitution, insofar as the same is in restraint of trade and because a provision therein is inadequate to provide the public with a comprehensible basis to determine whether or not they have committed a violation.⁸¹ (Emphasis supplied)

Petitioner refers to Sections 4(f),⁸² 4(i),⁸³ 5(w),⁸⁴ 11,⁸⁵ 22,⁸⁶ 32,⁸⁷ 46,⁸⁸ and 52⁸⁹ as the provisions that suppress the trade of milk and, thus, violate the

⁸¹ Petitioner's Memorandum.

⁸² SECTION 4. *Declaration of Principles* – The following are the underlying principles from which the revised rules and regulations are premised upon:

x x x x

(f) Advertising, promotions, or sponsorships of infant formula, breastmilk substitutes and other related products are prohibited.

⁸³ SECTION 4. *Declaration of Principles* – x x x

(i) Milk companies, and their representatives, should not form part of any policymaking body or entity in relation to the advancement of breastfeeding.

⁸⁴ SECTION 5. x x x x (w) "Milk Company" shall refer to the owner, manufacturer, distributor, of infant formula, follow-up milk, milk formula, milk supplement, breastmilk substitute or replacement, or by any other description of such nature, including their representatives who promote or otherwise advance their commercial interests in marketing those products; x x x.

⁸⁵ SECTION 11. *Prohibition* – No advertising, promotions, sponsorships, or marketing materials and activities for breastmilk substitutes intended for infants and young children up to twenty-four (24) months, shall be allowed, because they tend to convey or give subliminal messages or impressions that undermine breastmilk and breastfeeding or otherwise exaggerate breastmilk substitutes and/or replacements, as well as related products covered within the scope of this Code.

⁸⁶ Supra note 70.

⁸⁷ Supra note 73.

⁸⁸ SECTION 46. *Administrative Sanctions*. – The following administrative sanctions shall be imposed upon any person, juridical or natural, found to have violated the provisions of the Code and its implementing Rules and Regulations:

a) 1st violation – Warning;

b) 2nd violation – Administrative fine of a minimum of Ten Thousand (₱10,000.00) to Fifty Thousand (₱50,000.00) Pesos, depending on the gravity and extent of the violation, including the recall of the offending product;

(c) 3rd violation – Administrative Fine of a minimum of Sixty Thousand (₱60,000.00) to One Hundred Fifty Thousand (₱150,000.00) Pesos, depending on the gravity and extent of the violation, and in addition thereto, the recall of the offending product, and suspension of the Certificate of Product Registration (CPR);

(d) 4th violation – Administrative Fine of a minimum of Two Hundred Thousand (₱200,000.00) to Five Hundred (₱500,000.00) Thousand Pesos, depending on the gravity and extent of the violation; and in addition thereto, the recall of the product, revocation of the CPR, suspension of the License to Operate (LTO) for one year;

(e) 5th and succeeding repeated violations – Administrative Fine of One Million (₱1,000,000.00) Pesos, the recall of the offending product, cancellation of the CPR, revocation of the License to Operate (LTO) of the company concerned, including the blacklisting of the company to be furnished the Department of Budget and Management (DBM) and the Department of Trade and Industry (DTI);

(f) An additional penalty of Two Thousand Five Hundred (₱2,500.00) Pesos per day shall be made for every day the violation continues after having received the order from the IAC or other such appropriate body, notifying and penalizing the company for the infraction.

For purposes of determining whether or not there is "repeated" violation, each product violation belonging or owned by a company, including those of their subsidiaries, are deemed to be violations of the concerned milk company and shall not be based on the specific violating product alone.

⁸⁹ SECTION 52. *Other Donations By Milk Companies Not Covered by this Code* - Donations of products, equipments, and the like, not otherwise falling within the scope of this Code or these Rules, given by...

due process clause of the Constitution.

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.⁹⁰ In *Pest Management Association of the Philippines v. Fertilizer and Pesticide Authority*,⁹¹ it was held thus:

x x x Furthermore, as held in *Association of Philippine Coconut Desiccators v. Philippine Coconut Authority*, **despite the fact that “our present Constitution enshrines free enterprise as a policy, it nonetheless reserves to the government the power to intervene whenever necessary to promote the general welfare.”** There can be no question that the unregulated use or proliferation of pesticides would be hazardous to our environment. Thus, in the aforesaid case, the Court declared that **“free enterprise does not call for removal of ‘protective regulations’.”** x x x **It must be clearly explained and proven by competent evidence just exactly how such protective regulation would result in the restraint of trade.** [Emphasis and underscoring supplied]

In this case, petitioner failed to show that the proscription of milk manufacturers’ participation in any policymaking body (Section 4(i)), classes and seminars for women and children (Section 22); the giving of assistance, support and logistics or training (Section 32); and the giving of donations (Section 52) would unreasonably hamper the trade of breastmilk substitutes. Petitioner has not established that the proscribed activities are indispensable to the trade of breastmilk substitutes. Petitioner failed to demonstrate that the aforementioned provisions of the RIRR are unreasonable and oppressive for being in restraint of trade.

Petitioner also failed to convince the Court that Section 5(w) of the RIRR is unreasonable and oppressive. Said section provides for the definition of the term “milk company,” to wit:

SECTION 5 x x x. (w) “Milk Company” shall refer to the owner, manufacturer, distributor of infant formula, follow-up milk, milk formula, milk supplement, breastmilk substitute or replacement, or by any other description of such nature, including their representatives who promote or

otherwise advance their commercial interests in marketing those products;

On the other hand, Section 4 of the Milk Code provides:

- (d) "Distributor" means a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code. A "primary distributor" is a manufacturer's sales agent, representative, national distributor or broker.

x x x x

- (j) "Manufacturer" means a corporation or other entity in the public or private sector engaged in the business or function (whether directly or indirectly or through an agent or an entity controlled by or under contract with it) of manufacturing a products within the scope of this Code.

Notably, the definition in the RIRR merely merged together under the term "milk company" the entities defined separately under the Milk Code as "distributor" and "manufacturer." The RIRR also enumerated in Section 5(w) the products manufactured or distributed by an entity that would qualify it as a "milk company," whereas in the Milk Code, what is used is the phrase "products within the scope of this Code." Those are the only differences between the definitions given in the Milk Code and the definition as re-stated in the RIRR.

Since all the regulatory provisions under the Milk Code apply equally to both manufacturers and distributors, the Court sees no harm in the RIRR providing for just one term to encompass both entities. The definition of "milk company" in the RIRR and the definitions of "distributor" and "manufacturer" provided for under the Milk Code are practically the same.

The Court is not convinced that the definition of "milk company" provided in the RIRR would bring about any change in the treatment or regulation of "distributors" and "manufacturers" of breastmilk substitutes,

Except Sections 4(f), 11 and 46, the rest of the provisions of the RIRR are in consonance with the objective, purpose and intent of the Milk Code, constituting reasonable regulation of an industry which affects public health and welfare and, as such, the rest of the RIRR do not constitute illegal restraint of trade nor are they violative of the due process clause of the Constitution.

WHEREFORE, the petition is **PARTIALLY GRANTED**. Sections 4(f), 11 and 46 of Administrative Order No. 2006-0012 dated May 12, 2006 are declared **NULL** and **VOID** for being *ultra vires*. The Department of Health and respondents are **PROHIBITED** from implementing said provisions.

The Temporary Restraining Order issued on August 15, 2006 is **LIFTED** insofar as the rest of the provisions of Administrative Order No. 2006-0012 is concerned.

SO ORDERED.


MA. ALICIA AUSTRIA-MARTINEZ
Associate Justice

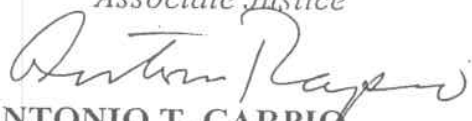
WE CONCUR:


REYNATO S. PUNO
Chief Justice


LEONARDO A. QUISUMBING
Associate Justice

(On Official Leave)
CONSUELO YNARES-SANTIAGO
Associate Justice


ANGELINA SANDOVAL-GUTIERREZ
Associate Justice


ANTONIO T. CARPIO
Associate Justice


RENATO C. CORONA
Associate Justice

(On Official Leave)
ADOLFO S. AZCUNA
Associate Justice

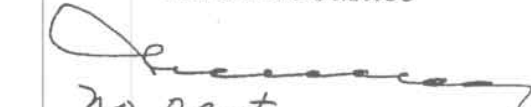

MINITA V. CHICO-NAZARIO
Associate Justice

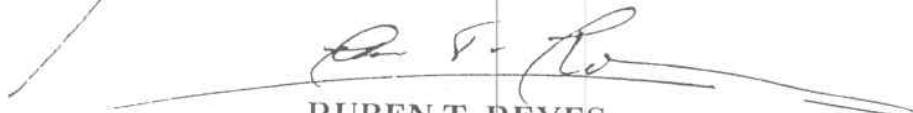

PRESBITERO J. VELASCO, JR.
Associate Justice


CONCHITA CARPIO-MORALES
Associate Justice


DANTE O. TINGA
Associate Justice

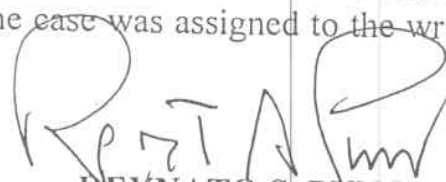

CANCIO C. GARCIA
Associate Justice


no part.
ANTONIO EDUARDO B. NACHURA
Associate Justice


RUBEN T. REYES
Associate Justice

CERTIFICATION

Pursuant to Section 13, Article VIII of the Constitution, it is hereby certified that the conclusions in the above Decision had been reached in consultation before the case was assigned to the writer of the opinion of the Court.


REYNATO S. PUNO
Chief Justice