IBFAN Action Pack

Related measures

Relevant EU measures

The Commission of the European Union (EU) has adopted two directives which reflect the provisions of the International Code of Marketing of Breastmilk Substitutes - one for the internal market and one for exports. In this section we describe the strengths and weaknesses of these directives and how they can be used to assist in implementation of the International Code.

Implementation of the *International Code* and Resolutions in EU Directives

After three votes in the European Parliament and over a decade of lobbying by IBFAN and many other NGOs, two European Directives on the marketing of baby milk and a Council Resolution were substantially strengthened and finally adopted in 1991 and 1992. All three proposals came into force in June 1994. Despite their weaknesses, they represent a major breakthrough in the protection of breastfeeding.

Of the 12 countries that have so far adopted laws incorporating them, 6 have banned advertising of infant formula to the public (see table inside).

The industry has attempted to convince people that the Directives are now the 'standard' which replaces the *International Code*. Since it seems likely that many European countries outside the European Union (EU) will adopt laws that are in line with these Directives it's important that we all understand their strengths and weaknesses.

NB: There is nothing in the European Directives (or in any law) which prevents companies from voluntarily marketing their products according to the *International Code* (and subsequent resolutions). This is called for in Article 11.3 of the *International Code.* There is also very little in the Directive (apart from a few labelling specifications) which prevents member states from implementing the whole *International Code* as law if they choose.

In this section the following EU measures are examined:

- Commission Directive on infant formulae and follow-on formulae (91/321/EEC) (for the internal market) amended 1997 (94/4/EEC)
- Council Directive on infant formula and follow-on formulae intended for export to third countries (92/52/EEC)
- A Council Resolution on the marketing of breastmilk substitutes in third countries by Community-based manufacturers (92/C 172/01)

Commission Directive on infant formulae and follow-on formulae: (91/321/EEC) (for the internal market)

STRENGTHS:

- **Endorsement of the *International Code:*** In the introductory paragraphs the Directive states: *"Whereas in an effort to provide better protection for the health of infants, the rules of ....this directive should be in conformity with the principles and the aim of the International Code."* This is vital and should help to ensure that the Directive is interpreted and used for the protection of breastfeeding rather than for the expansion of the European baby milk market.

- **Labels: (Article 7)** For infant formula: baby pictures are banned and the labels must state that breastfeeding is superior and that the product is used only on the advice of independent health professionals. For infant formula and follow-on formula: warnings of health hazards are mandatory and claims such as *"humanised"* and *"maternalised"* are banned.

- **Advertising: (Article 8.1)** This contains a discretionary clause which allows member states to restrict or prohibit all advertising of infant formula. Denmark, France, Luxembourg, The Netherlands and Spain have banned advertising of infant formula to the public. There is nothing in the Directive which states that advertising of follow-on milks may be permitted, so advertisements for these products could be banned too. Batch numbers and language are covered by other food laws.

- **Point of sale advertising and samples** of infant formula are banned.

- **Samples and gifts. (Articles 8.2 and 8.3)** Manufacturers and distributors of infant formula are prohibited from giving free or low-priced products, samples or any other promotional gifts to the general public either directly or indirectly. Strictly interpreted this includes complementary food and follow-on milk samples and any gift from an infant formula manufacturer. Luxembourg has used this Article to ban samples and point of sale advertising of follow-on milks.

- **Free and low-cost supplies of infant formula (Art. 8.3 and 9.4)** The Directive is contradictory on the question of free and low-cost supplies. Article 8.3 bans manufacturers from giving free or low-priced products - directly or indirectly. But Article 9.3 opens a loophole, referring to conditions which must apply if donations are made (i.e. if a country decides to permit them, they must only be for babies who *"have to be fed"* on infant formula. At one stage the European Commission removed the words *"have to be fed"* and it seemed likely that the Directive would allow free supplies for all babies who *"are bottlefed."* Because of IBFAN lobbying and the support of Parliamentarians, and UK, The Netherlands and Danish Governments, the words *"have to be fed"* were returned at the last minute.

- Compositional guidelines are included for both follow-on milks and infant formulas. Contaminants are to be addressed *"at a later stage".*

- **Information to parents.(Article 9)** This article nearly mirrors Article 4.2 of the *International Code*. Member states are required to ensure that objective and consistent information is provided on infant feeding only on request and that this information does not refer to proprietary brands or use any pictures which may idealise the use of infant formulae. The *International Code* refers to pictures and text. In the UK the Government is setting up a Working Group to draw up guidelines for these materials - hopefully this will prevent this article being used as a channel for promotion.

WEAKNESSES:

- **Scope (Article 1):** The Directive has a very limited scope and applies only to infant formula and follow-on formula *"intended for use by infants in good health"* rather than the whole range products covered by the *International Code* (including all breastmilk substitutes, bottle-fed complementary foods, baby teas, bottles and teats etc). The manufacturers are now also claiming that the *International Code* only applies to infant formula and only to infants in good health. They use this to defend promotion and weak labelling of a whole range of specialised products for pre-term infants, allergic infants etc etc. The *International Code* makes no exception for such products. (See also the section below that refers to HA milks and new amendments to the directive.)

- **Follow-on formula**. The Directive's provisions regarding follow-on formula are very weak. The Directive has fewer compositional requirements for these unnecessary milks - they can contain high levels of glucose syrup, protein and salt and yet can be marketed and advertised for infants aged 4 months. This is despite the fact that Codex and most world health opinion says they should not be given before 6 months. Follow-on milks are allowed to carry pictures of infants and there is no requirement (as there is in the export directive) that they are packaged to avoid any risk of confusion with infant formula - so in many countries they carry the same brand name as the formula. (For example, Nestlé's Nan 1 and Nan 2) This is very confusing and potentially harmful since it could lead mothers to give them to very young babies. It is also illogical that advertising restrictions should apply only to infant formula (which have some uses) and not to follow-on milks - which have yet to be proved useful at all.

- **Labels (Article 7)** The Directive allows 6 nutrient content claims. As a consequence a *"sucrose free"* claim can be made on products that may contain a high level of glucose syrup. Also allowed are claims such as *"low sodium"* and *"iron enriched"* and a statement that the products can be used on the advice of an *"independent"* pharmacist. Since many pharmacies sell baby milk it is vital that the word independent is recognised. An amendment was passed in 1997 (96/4/EEC) permitting a nutrient function claim relating to allergies.

- **Free supplies (Art 9.4)** The restrictions apply only to infant formula and refer to the possibility of donations for babies who *"have to be fed"* on infant formula. It is important that member states use WHO and UNICEF's interpretation. According to WHO's former Director General, free supplies were only ever intended for orphanages and institutions where babies stay for an extended period, not for hospitals and maternities. A distinction must be made between state provision of milk for low-income mothers and company donations - which are spasmodic and unreliable. The free supplies issue has been discussed many times at World Health Assemblies and the conclusion is that companies should not donate free supplies to health care facilities. (Resolution WHA47.5)

- **Advertising (Article 8)** Advertising of infant formula is restricted - but not the advertising of follow-on milks, other breastmilk substitutes or bottles and teats. Member states can also choose to allow advertising in *"publications specialising in baby care and scientific publications."* Such publications are regularly exported from the EU.

- The marketing of bottles and teats and other products covered by the scope of the Code are not addressed. The European Commission promised to do this in a later Directive.

- Marketing to health workers and their responsibilities (gifts and sponsorship of conferences mentioned in Article 7 of the WHO Code) is left out completely and must be dealt with by national governments.

The state of implementation of the EU Internal Directive is given in the chart overleaf.

Action by EU Member States to translate the Commission Directive on infant formulae and follow-on formulae (91/321/EEC) into national legislation. *Member states were required to bring into force laws which* ***permitted trade complying*** *with the Directive by 1 December 1992 and to* ***prohibit trade which does not comply*** *by 1 June 1994.*

Country	Date of Law	Adverts for infant formula (scientific and factual)	Free samples of infant formula	Free and low-cost supplies of infant formula	Adverts and samples for follow-on milks	Display of logos in health care system	Other comments
Luxembourg	13/12/93	**Specifically forbidden for the public** allowed only for health workers	**Forbidden**	**Forbidden** *except for babies who have to be fed artificially*	**Samples forbidden** permission must be sought to distribute information material on these products	**Permitted**	
Spain	20/11/92 composition aspects revised 4/2/98	**Allowed only for health workers** in child care and scientific publications	**Forbidden**	**Forbidden** *except for etc...*	**Permitted**	**Permitted**	Health Ministry confirmed in a letter that the publications referred to were not magazines for the public
France	4/6/94	**Forbidden for the public** allowed for health workers	**Forbidden**	**Forbidden** *except for etc...*	**Permitted**	**Permitted**	Anti-corruption law forbids bribery of health workers by companies. Companies pay hospitals directly to use their milks.
Denmark	8/7/93	**Forbidden for the public** allowed for health workers	**Forbidden**	**Forbidden** *except for etc...*	**Permitted**	**Permitted**	Danish Decree cover more products than infant formulas
Netherlands	24/9/93	**Forbidden for the public** allowed for health workers	**Forbidden**	**Forbidden** *except for etc...*	**Permitted**	**Permitted**	

Chart prepared by Baby Milk Action July 1998

Country	Date of Law	Adverts for infant formula (scientific and factual)	Free samples of infant formula	Free and low-cost supplies of infant formula	Adverts and samples for follow-on milks	Display of logos in health care system	Other comments
Belgium	5/1/94	**Forbidden for the public** allowed for health workers	**Forbidden** (5.1.5.2; 5.1.5.3)	**Forbidden** *except for etc...*	**Permitted**	**Permitted** and common in health care system	
UK	1/3/95	**Allowed for the public** in health care system, for health workers in trade journals & on labels	**Forbidden**	**Forbidden** *except for etc...*	**Permitted** with some restrictions	**Permitted** and common in health care system	Guidelines clarify the law and define good practice
Greece	9/8/93	**Allowed for the public** and health workers	**Forbidden**	**Forbidden** *except for etc...*	**Permitted**	**Permitted** and common throughout health care system	Only Pharmacists sell formula (Industry tried to sue Government)
Portugal		**Allowed for the public** and health workers	**Forbidden**	**Forbidden** *except for etc...*	**Permitted**	**Permitted**	
Germany	10/10/95	**Allowed for the public** and health workers (3.3)	**Forbidden** (3.2.7)	**Forbidden** *except for etc...*	**Permitted**	**Permitted**	The German law is weaker than the directive in places
Ireland	3/1/95	**Allowed for the public** and health workers	**Forbidden** only at point of sale and through health care system	**Forbidden** *except for etc...* Minister still to set guidelines	**Permitted** and common	Not referred to	The Irish law is weaker than the EU Directive.
Italy	6/4/94	**Allowed for the public** and health workers	**Forbidden**	**Forbidden** *except for etc...*	**Permitted**	**Permitted**	
Finland	pending	Newly joined - very high breastfeeding rates - no promotion allowed by voluntary agreement					
Austria	pending	Newly joined - very low breastfeeding rates					
Sweden	pending	The *International Code* has been in effect as a voluntary measure in Sweden since 1983. **The draft Swedish law is very strong and covers all breastmilk substitutes and bottles, teats and dummies**					

Implications of the EU internal market directive for countries outside the EU

The European Union is seen by many as a model to be followed for other free trade areas. In addition, the Union is expanding as other countries in Europe apply for membership.

Companies have presented the EC Directive as a standard to be implemented elsewhere. They have also suggested to European states that their applications for membership will be affected if they implement legislation which is stronger than an EC Directive.

This is not the case. IBFAN has taken legal advice on this issue and understands that the true situation is as follows:

- If a country decides to introduce measures stronger than the EC Directive (e.g. the *International Code* and Resolutions in their entirety) this is unlikely to amount to a breach of the Treaty of Rome, the agreement which set up the European Union. A legal case (know as the Keck case of 1993) has already tested this situation in another area of legislation.

In addition:

- Labels are considered as part of the intrinsic character of the product itself. Restrictions can only be made on products in order to *"protect health and life of humans."*

- Restrictions pertaining to advertising are regarded as extrinsic to the product and could, therefore, be imposed without establishing reasons so long as the restrictions apply equally to all manufacturers (both domestic and foreign).

- Governments which have ratified the Conventions of the Rights of the Child (all countries except the United States and Somalia) have certain obligations to protect infant health. Article 24 of the Convention calls for parents to *"have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding..."* The Committee overseeing the Convention has indicated that implementation of the *International Code* and Resolutions is an appropriate step for governments to take to fulfil their obligations. IBFAN groups should make their governments aware of this (see section on Related International Instruments).

Council Directive on infant formulae and follow-on formulae intended for export to third countries (92/52/EEC)

It is not possible for the EU to control the activities of its companies by law when they operate in countries outside of the union since this would infringe on the sovereign rights of those countries. However it is possible for EU legislation to cover the labelling and composition of exports from member states. The Council Directive on infant formulae and follow-on formulae intended for export to third countries (the Export Directive) implements some of the elements of the *International Code* and Resolutions, but is limited in its scope. Complaints about violations of the Export Directive should be reported to the government of the country concerned. (See the section: Reporting Violations Using EU Measures).

Strengths:

- **Labels.** Exports of both follow-on formula and infant formula must contain all the information specified in the Internal Market Directive. In addition they have to be labelled in an appropriate language and in such a way as to avoid any risk of confusion between infant formula and follow-on formula.

- **Composition.** The composition of exports of follow-on formula and infant formula must comply with EU standards or the applicable world standards established by Codex Alimentarius.

Weaknesses:

- The Export Directive applies only to the composition and labelling of baby milks not to the marketing in third countries. Follow-on milks are allowed to be exported labelled as suitable from 4 months. It is not clear whether anything can be done about the export of magazines which contain advertisements or the export of tins labelled as *"samples".*

A Council Resolution on the marketing of breastmilk substitutes in third countries by Community-based manufacturers (92/C 172/01)

In an effort to ensure that the marketing activities of European Community-based manufacturers is of the highest standard, a Council Resolution was passed at the same time which recommended that companies market their products in conformity with the *International Code* whenever they are outside the EU. This Resolution covers much more than labels and composition and could be very useful in stopping free supplies, samples, advertising etc in countries that have not yet adopted the *International Code* as law. Complaints about violations of the Council Resolution should be reported to the EU delegation based in the country concerned. (See the section: Reporting Violations Using EU Measures).

Strengths:

- Recognises the *International Code* as the ideal model for all countries outside the EU. (Initially the Commission wanted this to refer only to *"developing countries"*) It gives people outside the EU the opportunity to report complaints about any activities of European Community-based manufacturers which are not in line with the *International Code.* When the Resolution was adopted it was stated that NGOs (not just government officials) could bring complaints to the attention of EU delegates. The Commission is to report back to the EU every two years. If used properly this could be a powerful tool.

Weaknesses

- The Commission has made no attempt to facilitate the process and to ensure that reporting is encouraged. Because the EU is such an important trading partner it could be difficult for NGOs and governments in third countries to complain openly to European delegates.

The section Reporting Violations Using EU Measures explains how to report violations using the EU Export Directive and Council Resolution