

Resolution MS No 583/2008

Having regard to item no 2002-2041/08-3 on the records of the Ministry of Health, and

whereas:

Children, as developing organisms, are particularly vulnerable to chemicals with the specific properties in question (toxic to reproduction and/or endocrine disrupting). The exposure of children to any sources of emission of these substances which can be avoided in practice, and especially articles which children may put in their mouths, should be reduced as much as possible, guaranteeing the maximum level of protection regardless of the age of the children concerned.

Within this conceptual framework by means of Resolution No 978 of 9 December 1999 the former Ministry of Health and Social Action restricted the possibility of children interacting with elements containing various compounds in the phthalate family constituting a potential or proven risk to their health.

That decision has subsequently been ratified and developed in Ministerial Resolutions No 438 of 30 April 2001, No 324 of 31 May 2002, No 180 of 24 February 2004 and No 243 of 10 March 2006 because there are still reasons for banning the manufacture, import, export, marketing or free distribution of certain childcare articles and toys for children under the age of THREE (3) to put in their mouths which are manufactured with: Di-(2-ethyl hexyl) phthalate (DEHP) CAS No 117-81-7, Di-iso-nonyl phthalate (DINP), CAS No 28553-12-0, di-n-octyl phthalate (DNOP or DOP), CAS No 117-84-0, diisodecyl phthalate (DIDP), CAS No 26761-40-0, butylbenzyl phthalate (BBP), CAS No 85-68-7 and dibutylphthalate (DBP), CAS No 84-74-2.

The conditions which underlay the abovementioned Resolutions still obtain, and were ratified by Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005, which restricts the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles) and was published in Official Journal No L 344 of 27 December 2005 pp. 0040 -0043.

The available scientific information and the evaluations of the toxicological hazard carried out in the European Union permit DEHP, DBP and BBP to be defined as reprotoxic substances (classified within the CMR --carcinogenic, mutagenic and toxic to reproduction -- category of substances).

Scientific information relating to DINP, DIDP and DNCP is inexistent or debated, but given children's unforeseeable behaviour and the problem of precisely determining the daily intake of a specific substance, their representing a potential hazard cannot be ruled out if they are used in toys and childcare articles which, by definition, are manufactured for children and which these may put in their mouths.

Exposure to DEHP, DBP and BBP from toys can be avoided; it is not clear that their use in toys is necessary or beneficial to children and it may possibly represent the greatest proportion of children's total exposure to these chemicals from all known sources (the environment, air in closed spaces, food, etc.) that can be controlled by specific measures.

Depending on the protocol of the observation study of children putting toys in their mouths, children have been shown to put objects in their mouths for times ranging between a few minutes (United States Consumer Product Safety Commission) and more than six hours (United Kingdom DTI study and Japanese reports), which reinforces the

doubts as to what is the worst case in terms of the time taken before children put a toy in their mouth and the need for an appropriate level of caution in the conclusions regarding exposure to phthalates from toys.

Uncertainties in the evaluation of exposure to these phthalates, such as how often children will put them in their mouths, the probable presence of more than one phthalate in toys, additional exposures via foods and air and skin contact with these, demand that precautionary considerations be taken into account and restrictions therefore be set for the use of these phthalates in toys and childcare articles and on the marketing of these articles.

Given the different levels of scientific evidence and for reasons of proportionality the restrictions for DINP, DIDP and DNOP should be less severe than those proposed for DEHP, DBP and BBP.

There are alternative substances (such as citrates and adipates) which can be used as plasticisers in toys and childcare articles. The European Union Scientific Committee on Toxicity, Ecotoxicity and the Environment has evaluated the safety studies of these and concluded, in an opinion of 8 June 2004, that there was no reason for concern regarding the use of acetyl tri-Butyl Citrate (ATBC) as a plasticiser in toys and childcare articles which small children may put in their mouths.

It falls to the State to determine the essential safety requirements to be met by products that are freely sold and/or widely used and to guarantee the population that the substances used in manufacturing toys do not compromise their safety in foreseeable conditions of use.

This body of the State is responsible for adopting appropriate measures to protect the population's health in respect of any factor which is a health hazard.

Given that there are no restrictions on such products in the countries in the region and that trade between some of them directly crosses the territory of the Republic of Argentina, it is necessary to specify that the measures provided for herein shall not apply to goods arriving on the customs territory in direct transit to a foreign destination so as not to create obstacles to commercial relations between our neighbours.

The Directorate-General of Legal Affairs has taken the steps for which it is responsible.

Accordingly,

THE MINISTER OF HEALTH

HEREBY RESOLVES:

Article I – The manufacture, import, export, marketing or free distribution of childcare articles and toys manufactured with plasticised material containing concentrations in excess of 0.1% by mass of the following phthalates (or other CAS numbers containing the substance) shall be banned:

di(2-ethylhexyl)phthalate (DEHP) CAS No 117-81-7;

dibutylphthalate (DBP) CAS No 84-74-2;

butylbenzylphthalate (BBP) CAS No 85-68-7.

Article 2 – The manufacture, import, export, marketing or free distribution of childcare articles and toys which children may put in their mouths manufactured using plasticised material containing concentrations in excess of ZERO POINT ONE PER CENT (0.1%) by mass of the following phthalates (or other CAS numbers containing the substance) shall be banned:

Di-iso-nonyl phthalate (DINP) CAS No 28553-12-0 and 68515-48-0;

Diisodecyl phthalate (DIDP) CAS No 26761-40-0 and 68515-49-1;

di-n-octyl phthalate (DNOP) CAS No 117-84-0.

Article 3 – Whenever childcare articles and toys of flexible material clearly are not manufactured using the esters of phthalic acid named in the preceding articles enter the country a technical report prepared by the Plastics Industry Research and Technological Development Centre (CITIP - INTI) attesting to this fact must be submitted to the Directorate-General for Customs.

Article 4 -- This Resolution shall come into force on the date of its publication in the *Boletín Oficial* for those childcare articles and toys hitherto not covered by the equivalent provisions.

Article 5 – Goods arriving on the customs territory in direct transit to a foreign destination shall be excluded from the provisions of Articles 1, 2 and 3.

Article 6 – For the purposes of this Resolution a "childcare article" is defined as any product intended to facilitate children's sleep, relaxation, hygiene and feeding or nursing.

Article 7 – The National Programme for the Prevention and Control of Intoxications shall be responsible for requesting and evaluating any new information permitting the rules in force to be updated.

Article 8 – The measures laid down in Articles 1 and 2 shall not apply to goods arriving on the customs territory in direct transit to a foreign destination so as to avoid hampering commercial relations between the neighbouring countries.

Article 9 -- Resolutions No 978 of 9 December 1999, No 438 of 30 April 2001, No 324 of 31 May 2002, No 180 of 24 February 2004 and No 243 of 10 March 2006 of this Ministry are hereby repealed.

Article 10 -- To be communicated by authenticated copy of this Resolution to the Fair Trade Directorate of the Subsecretariat for Competition and Consumer Protection of the Ministry of Economic Affairs and Production and to the Directorate-General for Customs of the Federal Revenue Administration of the Ministry of Economic Affairs and Production for their information and adoption of the corresponding measures within the areas of their responsibilities.

Article 11 -- To be communicated, published and given to the National Directorate for the Official Register. Copy for archives. -- María G. Ocaña.