

1. -----IND- 2009 0620 NL- EN- ----- 20091120 --- --- PROJET

Decree of the Minister for Health, Welfare and Sport of 2009, VGP/ [Nutrition, Health Protection and Prevention Department], laying down a policy regulation concerning standards to be enforced with regard to the safety of balloons

Date

The Minister for Health, Welfare and Sport,

Announces the following:

Nitrosamines are chemical substances, of which a number are classified according to Annex XVII of REACH¹, part 28, appendix 2, as 'category 2 carcinogenic substances'. These carcinogenic nitrosamines and nitrosatable compounds are not deliberately added to balloons. They arise in the course of time in the balloons, through the use of certain raw materials and under the influence of polluted air. These substances are released in the sucking on balloons and are taken up via the mouth.

People are also exposed to nitrosamines via other routes, including via food and drink products and tobacco smoke. There is thus cumulative exposure. The users of balloons are mainly children. Children form a vulnerable group where exposure to carcinogenic substances is concerned. The risks related thereto are not recognisable without warnings.

For these reasons I announced in 2006 that balloons present a particular danger in the sense of Article 3 of the Toys (Commodities Act) Decree. Balloons should not contain any carcinogenic substances to which children are exposed through use of these products intended for their use. In the Policy regulation regarding standards concerning the safety of balloons (*Beleidsregel inzake normen ten aanzien van veiligheid van ballonnen*)², it was stipulated that balloons are seen as a particular danger, if they contain levels of nitrosamines and nitrosatable compounds above 0.01 mg/kg rubber and 1 mg/kg rubber respectively. The particular danger resides in the fact that the release of and exposure to carcinogenic substances from balloons to the consumer are not recognisable and any health damage may be irreversible. These standards, according to the RIVM

¹ Regulation (EC) No. 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396).

² Government Gazette 28 March 2006, No. 62, p. 9.

(Dutch National Institute for Public Health and the Environment), provide sufficient protection to children. These standards are also seen as achievable for the manufacturers of balloons according to a practicability investigation by the VWA (Dutch Food and Consumer Product Safety Authority), which showed that an improvement can be seen in the quality of balloons on the Dutch market in 2004 compared to 2002 (Migration of Nitrosamines and N-nitrosatable substances from latex balloons, report No. NDO4o063/02, January 2005).

It was also agreed with the trade that a warning clause should appear on all balloon packaging on the Dutch market, to warn consumers not to blow balloons up by mouth, but instead use a balloon pump.

In the 2006 Policy regulation regarding standards with respect to the safety of balloons, I indicated that I had at that time raised the subject of balloons at European level, to argue that this subject should be included in the revision of the Toys Directive (Directive 88/378/EEC).

The European Commission requested the Scientific Committee on Consumer Products (SCCP) to advise it about nitrosamines and nitrosatable substances in balloons. On 18 December 2007, the SCCP³ advised that a limit value for nitrosamines in balloons is recommended, because it is possible via modern production techniques to minimise nitrosamine formation and thus the exposure to nitrosamines via balloons is largely avoidable.

The SCCP further concluded that the migration of 50 micrograms of nitrosamines per kilogram of rubber from balloons would cause a negligible exposure level for children, namely 13.5 nanograms of nitrosamine per day and would not contribute to a potential health risk.

Besides this, the SCCP recommended that the use of rubber accelerators which do not contribute to the formation of carcinogenic nitrosamines should be encouraged.

The policy regulation based on my decision in 2006 was necessary because no specific requirements for nitrosamines and nitrosatable compounds in balloons are included in the Toys (Commodities Act) Decree, by which the stipulations in the Toys Directive 88/378/EEC are implemented.

The new Directive from the European Parliament and the Council on the safety of toys⁴, prohibits, in Annex 2 (Particular Safety Requirements), Part III (Chemical Properties), point 8, the use of nitrosamines and nitrosatable substances in toys intended for children under 36 months and in other toys intended to be put into the mouth, if the migration of the substances is greater than or equal to 0.05 mg/kg for nitrosamines and 1 mg/kg for nitrosatable substances.

The European Parliament and Council thus stipulate requirements for nitrosamines and nitrosatable compounds. For nitrosamines, the requirement becomes less strict than was stipulated in my current 2006 policy regulation. The European requirement for nitrosatable compounds is equal to that in the policy regulation. The Directive contains no stipulation directed at the obligation to show a warning clause on the label. This warning clause is still considered necessary, because

³ SCCP/1132/07, Opinion on the presence and release of nitrosamines and nitrosatable compounds from rubber balloons, adopted at its 14th plenary of 18 December 2007.

⁴ Directive 2009/48/EC of the European Parliament and the Council of 18 June 2009 on the safety of toys (OJ L 170).

nitrosamines and nitrosatable compounds in balloons can also be formed after production, for example in stores or in the consumer's cupboard.

Given that the new European requirements for nitrosamines and nitrosatable compounds can guarantee sufficient safety for users, I consider it desirable to adopt these European requirements and to replace the 2006 policy regulation in order to abolish unnecessary trade restrictions.

Decrees:

Balloons are considered as a particular danger in the sense of Article 3 of the Toys (Commodities Act) Decree, if they contain levels of nitrosamines and nitrosatable compounds above 0.05 mg/kg for nitrosamines and 1 mg/kg for nitrosatable substances.

A warning clause should appear on all balloon packaging on the Dutch market, to warn consumers (and particularly children) not to blow balloons up by mouth, but instead use a balloon pump.

The VWA will enforce the nitrosamine and nitrosatable compound content in the balloons, as well as the warning clause on the labels.

As suitable warning clause is considered:

WARNING! FOR SAFETY REASONS, DO NOT PUT IN THE MOUTH, AND ONLY INFLATE WITH A BALLOON PUMP.

The text must be shown in a noticeable and clearly readable form on the packaging.

The text was composed at the time in consultation with the trades and businesses concerned. At the same time, it was agreed with the ROW (Regular Consultation on the Commodities Act)⁵ that implementation would be given to the criterion 'noticeable and clearly readable' by using the following starting points:

1. The warning clause must be separated from the other warnings by at least ½ a blank line.
2. In the warning clause, the phrases 'warning!' and 'do not put in the mouth' must be underlined.
3. The warning clause, in contrast to other warning clauses on the packaging of balloons, must be shown completely in capital letters, or with respect to the other warnings, must be shown completely in a larger font.

The Decree of the Minister for Health, Welfare and Sport of 23 March 2006, VGP/PSL 2667606, laying down a policy regulation concerning standards to be enforced with regard to the safety of balloons (Govt Gazette 62) is abolished.

The subject of this policy regulation was presented to the participants of the Regular Consultation on the Commodities Act (in Dutch, ROW). This consultation did not lead to any reaction concerning content.

The subject of this policy regulation was notified to the Commission of the European Communities pursuant to Article 8, paragraph 1 of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204). This

⁵ Representatives of entrepreneurs (industry and trade), of consumers, of Ministries (particularly of Health, Welfare and Sport, of Agriculture, Nature Management and Fisheries, and of Economic Affairs), of the Food and Consumer Product Safety Authority, and of Product and Commodity Boards participate in the ROW.

notification was necessary given that this policy regulation is a technical regulation in the sense of Directive 98/34/EC.

The Minister for Health,
Welfare and Sport,

Dr A. Klink