

Pursuant to Articles 50 and 51 of the Chemicals Act (Official Gazette, Nos 110/03 – official consolidated text, 47/04 – ZdZPZ, 61/06 – ZBioP, 16/08, 9/11, 83/12 – ZFfS-1 and 95/24 – ZFfS-1AUl....) the Government of the Republic of Slovenia issues the following

## **REGULATION**

### **on the restriction of certain substances in childcare articles**

#### GENERAL PROVISIONS

##### **Article 1**

##### **(Subject matter)**

In order to address serious or irreversible consequences for children's health, this Regulation limits the content of substances classified as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B (hereinafter: CMR 1A/1B substances) in childcare articles.

##### **Article 2**

##### **(Information procedure and clause)**

(1) This Regulation is issued subject to an information procedure in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L No 241 of 17. 9. 2015, pg. 1).

(2) The provisions of this Regulation shall not apply to products which, in accordance with national legislation that ensures an equivalent level of protection of the public interest as defined in the legislation of the Republic of Slovenia, are:

- legally produced or marketed in other Member States of the European Union and Turkey, or
- produced in the countries of the European Free Trade Association (EFTA), which are also signatories to the Agreement on the European Economic Area.

(3) This Regulation shall be implemented in accordance with Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (OJ L No 91 of 29. 3. 2019, pg. 1).

### **Article 3**

#### **(Definitions)**

The terms used in this Regulation have the following meaning:

- a) **Childcare articles** are products intended to facilitate the sitting, sleeping, relaxation, hygiene, feeding, sucking, transport or protection of children up to the age of 14.
- b) **A homogeneous material** is a material of uniform composition or a combination of materials that cannot be mechanically separated or disassembled.
- c) **CMR 1A/1B substances** are the substances classified as carcinogenic, mutagenic or toxic for reproduction in groups 1A and 1B, listed in Annex VI of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008. No 1) last amended by Regulation (EU) 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L 2865 of 20. 11. 2024; hereinafter: CLP).

### **Article 4**

#### **(Restriction of substances)**

(1) Child care products placed on the market in the Republic of Slovenia must not contain CMR 1A/1B substances in a concentration higher than 0.001 % (w/w) in any homogeneous material.

(2) If stricter limit values are specified for individual substances or groups of substances in other regulations or standards, the stricter limit values shall apply.

### **Article 5**

#### **(Exemptions)**

The restrictions referred to in the preceding Article shall not apply to:

- a) used childcare articles;
- b) parts of childcare articles that are completely inaccessible to children, even in the case of inhalation;
- c) toys;
- d) food contact articles;
- e) batteries;

- f) products, which are medical devices and regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117 of 5. 5. 2017);
- g) articles or materials that are subject to stricter specific EU regulations (e.g. materials in contact with food, biocidal products), provided that these regulations guarantee the same or higher level of protection for children.

## **Article 6**

### **(Obligations of producers and importers)**

The producer or importer of products must establish internal production control procedures or authorise a third party to carry them out, and draw up technical documentation, including analyses of homogeneous materials, demonstrating the conformity of childcare products with the requirements of Article 3 of this Regulation.

## SUPERVISION AND ENFORCEMENT

### **Article 7**

#### **(Supervision)**

- (1) Supervision of the implementation of this Regulation shall be carried out by the Health Inspectorate of the Republic of Slovenia.
- (2) The powers and measures laid down in the act governing technical requirements for products and conformity assessment shall be used to supervise the implementation of this Regulation.
- (3) If the health inspector does not possess sufficient expertise or equipment to conduct the necessary inspection or testing referred to in the second indent of paragraph 2 of this Article, it shall entrust a qualified institution with carrying out such individual tasks in the framework of the inspection.

## PENAL PROVISIONS

### **Article 8**

#### **(Infringements)**

(1) A fine of 3 000 to 40 000 EUR shall be imposed for an infringement on any legal person which, in conducting a commercial activity as a producer or importer of products:

- a) places on the market a childcare article containing CMR 1A/1B substances in a concentration equal to or greater than 0.001% by weight (10 mg/kg) in any homogeneous material (Article 4(1) of this Regulation);
- b) fails to provide technical documentation demonstrating the conformity of the product, including analyses of homogeneous materials (Article 6(1) of this Regulation).

(2) A fine of 2 000 to 15 000 EUR shall be imposed for an infringement on the entrepreneur or individual who independently carries out a commercial activity and in connection with the pursuit of his/her activity as a producer or importer commits the infringement referred to in the preceding paragraph.

(3) A fine of 1 200 to 4 000 EUR shall be imposed for an infringement on the responsible person of the legal entity or of the entrepreneur which, as a producer, importer or authorised representative in the Republic of Slovenia, commits the infringement referred to in paragraph 1 of this Article.

## TRANSITIONAL AND FINAL PROVISIONS

### **Article 9**

#### **(Transitional period)**

(1) For substances classified as CMR category 1A/1B in accordance with Annex VI to CLP after the entry into force of this Regulation, the provisions of Article 4 of this Regulation shall apply 12 months after the entry into force of the classification of each substance.

(2) No later than one year after the entry into force of this Regulation, the Chemicals Office of the Republic of Slovenia shall assess the justification, implementation and effects of the temporary measures set out in this Regulation and propose to the Government of the Republic of Slovenia their repeal, extension or the introduction of additional restrictions.

**Article 10**

**(Entry into force)**

This Decree shall enter into force on the 15th day following its publication in the Official Gazette of the Republic of Slovenia.

No.  
Ljubljana, on the  
Slovenia  
EVA

Government of the Republic of

dr. Robert Golob  
President

## Justification

Exposure to hazardous chemicals in early childhood represents one of the most pressing public health challenges of modern times. Children, due to their physiological characteristics – such as an immature immune system, faster breathing, thinner skin and greater relative body mass – and because of behavioural patterns that involve intense physical contact with products and frequent exposure to the oral route, absorb substances from the environment much more frequently and intensively than adults. They are therefore particularly at risk from the possible presence of hazardous chemicals in childcare articles.

The latest analysis by the European Chemicals Agency (ECHA) from 2023 provides extensive evidence that many materials used in the manufacture of childcare articles (e.g. plastics, textiles, foam, coatings, wood composites) may contain substances classified as carcinogenic, mutagenic or toxic to reproduction in categories 1A or 1B (CMR 1A/1B). Among the most commonly identified are heavy metals (lead, cobalt, cadmium), phthalates, formaldehyde, bisphenol A, aromatic amines, organophosphate flame retardants, and various substances that arise as impurities or residues from the manufacturing process. Such substances can be released from products and migrate into the air, saliva or onto the skin, which can lead to inhalation, oral or dermal exposure of children.

Since it is **not possible to establish a safe threshold of exposure** for genotoxic carcinogens, the protection of children from such substances is necessary. While these substances are already banned in toys, childcare articles – including seats, beds, prams, textiles, feeding, bathing and general care accessories – **have not yet been comprehensively regulated** with regard to their CMR 1A/1B substances content.

In view of the geographical, environmental and health characteristics of the Slovenian territory, as **defined in Article 50 of the Chemicals Act**, and the fact that these products are permanently present in the daily life of children, there are **reasonable grounds for concern** that the presence of CMR 1A/1B substances in childcare articles could lead to serious or irreversible health consequences. This justifies the introduction **of a provisional measure**, which the Government may adopt **even before definitive scientific evidence becomes available**, in accordance with the precautionary principle.

At the same time, **Article 51 of the Chemicals Act** lays down the obligation of the Government to review such a measure within one year at the latest, ensuring that the measure is flexible and proportionate in the light of new scientific knowledge.

On this basis, it is proposed to adopt the following **temporary Regulation** introducing a strict restriction of CMR 1A/1B substances in childcare articles, thus ensuring a high level of health protection for the most vulnerable population.