



EUROPEAN COMMISSION

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Minister Caspar Veldkamp
Minister for Foreign Affairs
Bezuidenhoutseweg 67
P.O. Box 20061
NL - 2500 EB The Hague

Subject: Notification No 2024/307/NL

**Draft Regulation of the Minister for Medical Care amending the
Commodities Act Regulation on packaging and consumer products**

**Delivery of comments pursuant to Article 5(2) of Directive (EU)
2015/1535**

Dear Sir,

Within the framework of the notification procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services ⁽¹⁾, on 6 June 2024 the Dutch authorities notified to the Commission the draft Regulation of the Minister for Medical Care amending the Commodities Act Regulation on packaging and consumer products (hereinafter, ‘the notified draft’).

According to the notification message, the notified draft concerns the implementation of the Decision of the Benelux Committee of Ministers on metal and alloy materials and articles intended to come into contact with foodstuffs (M (2022) 12). The draft Regulation ensures that, where necessary, the already existing requirements at national level are brought into line with that Decision.

The examination of the notified draft has prompted the Commission to issue the following comments.

At the outset, the notified draft appears to constitute a national specific measure in the meaning of Article 6 of Regulation (EC) No 1935/2004 on materials and articles intended

¹ (1) 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 241, 17.9.2015, p. 1.

to come into contact with food². As no specific measures have so far been adopted by the Commission in accordance with Article 5(1) of that Regulation for metals or alloys, which are listed in point 8 of Annex I to that Regulation as one of the groups of materials and articles that may be covered by such specific measures, Member States are, in accordance with Article 6 of that Regulation, allowed to maintain or adopt national provisions for this group of materials and articles provided they comply with the rules of the Treaty.

The notified draft in its Article I replaces Section 1 “*Description*” in Chapter IV of Part A of the Annex to the Commodities Act Regulation on packaging and consumer products, which also includes Section 1.2 being replaced as follows:

“1.2. This Chapter applies to packaging and consumer products made wholly or partly of metals or alloys, and whether or not coated”.

As the notified draft, in accordance with the wording of the cited provision, would also apply to materials and articles made partly of metals or alloys and such materials or articles or their parts could also be plastic materials and articles within the meaning of Article 3 of Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food³, the Dutch authorities are invited to ensure full and correct application of that Regulation to such materials and articles.

The notified draft amends also Section 4 of Chapter IV of Part A of the Annex to the Commodities Act Regulation on packaging and consumer products. Accordingly, in the table in section 4.3 a number of specific migration limits applicable to certain metals is provided.

In this regard, the Commission would like to remind that Commission Regulation (EU) 2020/1245⁴ amended Annex II to Regulation (EU) No 10/2011 by laying down specific migration limits for certain metals. Those specific migration limits are applicable to their migration into food from plastic materials and articles.

The specific migration limits for certain metals applicable to materials and articles made of metals or alloys set out in the notified draft differ from those set out for the same metals in Annex II to Regulation (EU) No 10/2011 as amended by Regulation (EU) 2020/1245, and are higher for some metals and lower for others.

The Dutch authorities are invited to consider applying to other materials the migration limits laid down in Regulation (EU) No 10/2011, as amended by Regulation (EU) 2020/1245, since, on the one hand, those limits were not established on the basis of the specifics of plastic materials only and, on the other hand, different limits make compliance difficult for business operators that use multiple materials, in particular when they use them in combination,

² Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338 13.11.2004, p. 4.

³ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ L 12, 15.1.2011, p. 1.

⁴ Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, OJ L 288, 3.9.2020, p. 1.

The Dutch authorities may also wish to take into account the use of large uncertainty factors in the toxicological risk assessment where the differences between different values are small, and the level of health protection where the limits provided by the notified draft are above the values set out in Annex II to Regulation (EU) No 10/2011.

For these reasons and to ensure the effective functioning of the internal market for the materials and articles concerned, as well as to move closer to the realisation of the principle of ‘one substance, one assessment’, the Dutch authorities are invited to consider aligning the migration limits for certain metals applicable to materials and articles made of metals or alloys as set out in the notified draft with those set out for the same metals in Annex II to Regulation (EU) No 10/2011 applicable to plastic materials and articles. The Commission invites the Dutch authorities to take into account the above comments.

The Commission furthermore recalls that once the definitive text has been adopted, it must be communicated to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

Yours faithfully,

For the Commission

Sandra GALLINA
Directorate-General for Health and
Food Safety