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**Subject: Notification 2023/380/LU**

**Preliminary draft Grand-Ducal Regulation on materials and articles made of metal and alloys intended to come into contact with foodstuffs**

**Delivery of comments pursuant to Article 5(2) of Directive (EU) 2015/1535 of 9 September 2015**

Sir,

Within the framework of the notification procedure laid down by Directive (EU) 2015/1535<sup>1</sup>, the Luxembourgish authorities notified to the Commission on 20 June 2023 the “**Preliminary draft Grand-Ducal Regulation on materials and articles made of metal and alloys intended to come into contact with foodstuffs**” (hereafter “the notified draft”).

According to the notification message, the notified draft *lays down national requirements for materials that come into contact with foodstuffs, in order to achieve a high level of protection of public health.*

On 26 June 2023, the Commission sent a request for supplementary information to the Luxembourgish authorities inviting them to clarify certain aspects of Article 8 of the notified draft. The Luxembourgish authorities replied of 11 July 2023. The reply has been taken into account by the Commission.

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

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<sup>1</sup> 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.

Article 8 of the notified draft, titled “Mutual recognition” provides the following:

*The provisions of this Regulation, except those of Article 7, as well as the corresponding provisions applicable to the Kingdom of Belgium or the Kingdom of the Netherlands as derived from the Decision of the Benelux Committee of Ministers of 17 October 2022 M (2022) 12 on materials and articles made of metal and alloy intended to come into contact with foodstuffs, shall not apply to products lawfully manufactured or marketed in a Member State of the European Union not belonging to the Benelux or Turkey, or lawfully manufactured in an EFTA State party to the Agreement on the European Economic Area, unless mutual recognition cannot be applied pursuant to Articles 34 to 36 of the Treaty on the European Union.*

In its request for supplementary information, the Commission invited the Luxembourgish authorities to provide further clarifications on the practical application of the “exclusion” of Article 7 (conformity declaration) from the scope of the “mutual recognition mechanism”. The national authorities replied that *(i)n the absence of declaration(s) of conformity demonstrating the conformity of an assembly, a risk assessment shall be mandatory for users in the food industry in order to ensure that the release limits set out in the Annex to this draft Regulation are not exceeded. These assessments are mandatory throughout the production chain, with the exception of small and medium-sized enterprises (SMEs).*

Taking into account the reply of the Luxembourgish authorities the Commission understands that the declaration(s) of conformity provided for in Article 7 of the draft should be in any case submitted, otherwise a risk study shall be mandatory for all economic operators, with the exception of SMEs. Therefore, products that have been the subject of a declaration of conformity in accordance with Article 7 of the draft do not need to rely on the principle of mutual recognition, however, this makes the application of said principle conditional on additional rules.

Therefore, it follows from the reply of the national authorities to the request for supplementary information from the Commission that mutual recognition does not apply in case when the economic operator does not submit declaration(s) of conformity (except when it is a SME), as it must submit a risk study.

Furthermore, the Commission highlights the following phrase included in Article 8 of the notified draft: *unless mutual recognition cannot be applied pursuant to Articles 34 to 36 of the Treaty on the Functioning of the European Union*. The Commission asked the national authorities to specify what should be covered in cases where “recognition cannot be applied” under Articles 34 to 36 of the TFEU. The Luxembourgish authorities replied that *there are no specific reasons to include this provision apart from the reasons of clarification and precision, as set out in Article 7 “mutual recognition” of the draft Belgian Royal Decree on metal and alloy materials and articles intended to come into contact with foodstuffs* and noted that *this precision may be superfluous and can be withdrawn if necessary*.

The Commission kindly invited the national authorities to remove this phrase from the text of Article 8 of the notified draft in order to avoid misunderstandings as to the application of the mutual recognition principle.

Moreover, the Commission would like to recall that, according to recital 16 of Regulation (EU) 2019/515 on the mutual recognition of goods<sup>2</sup>, in order to raise awareness on the part of national authorities and economic operators of the principle of mutual recognition, Member States should consider providing for clear and unambiguous ‘single market clauses’ in their national technical rules with a view to facilitating the application of the principle.

The Commission notes that the Article 8 of the notified draft differs from the wording of the single market clause included in the Guidance on Regulation (EU) 2019/515<sup>3</sup>, which reads as follows:

*“Goods lawfully marketed in another Member State of the European Union or in Turkey, or originating and lawfully marketed in the Contracting Parties to the EEA Agreement are presumed to be compatible with these rules. The application of these rules is subject to Regulation (EU) 2019/515 of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State”.*

In order to ensure legal certainty and the correct application of the Regulation 2019/515 on the mutual recognition of goods, by avoiding exceptions not provided for in the Regulation and phrases that may be source of misunderstandings, the national authorities are invited to replace Article 8 of the draft by a single market clause, whose wording is consistent with the Commission suggestion as included above.

The Luxembourgish authorities are invited to take these comments into account.

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

Kerstin Jorna  
Director-General

Directorate-General for Internal  
Market, Industry, Entrepreneurship  
and SMEs

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<sup>2</sup> 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 (Text with EEA relevance.), OJ L 91, 29.3.2019, p. 1.

<sup>3</sup> Guidance document for the application of 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.