Message 201

Communication from the Commission - TRIS/(2025) 1033

Directive (EU) 2015/1535

Notification: 2024/0610/AT

Forwarding of the response of the Member State notifying a draft (Austria) to comments (5.2) of Poland.

MSG: 20251033.EN

1. MSG 201 IND 2024 0610 AT EN 08-05-2025 07-04-2025 AT ANSWER 08-05-2025

2. Austria

3A. Bundesministerium für Wirtschaft, Energie und Tourismus
Abteilung II/8
A-1010 Wien, Stubenring 1
Telefon +43-1/71100-805436
E-Mail: not9834@bmwet.gv.at

3B. Bundesministerium für Arbeit, Soziales, Gesundheit, Pflege und Konsumentenschutz
Abteilung VI/A/5
A-1030 Wien, Radetzkystraße 2
Telefon +43-1/71100-644471
E-Mail: werner.pilz@gesundheitsministerium.gv.at; valerie.lugert@gesundheitsministerium.gv.at

4. 2024/0610/AT - X60M - Tobacco

5.

6. With reference to the notification (notif. No 2024/610/AT) and to the comments/observations submitted, Austria permits would like to make the following comments:

The notification project in question is based on the current state of science and technology and is intended – in the interests of legal certainty and legal clarity – to contribute to an exemplary and transparent presentation of the statutory prohibitions of certain substances (cf. Article 7(6) and Article 20(3)(c) of the TPD II) in order to simplify the application of national law.

In general, it should be noted that while it is correct that references to Regulation (EC) No 1272/2008 and Regulation (EC) No 1907/2006 can be inferred from the TPD II (cf. Article 5(2) of the TPD II), there is no provision in the TPD II according to which the classification of substances (cf. Articles 7(6) and 20(3)(c) of the TPD II) would have to be carried out exclusively in accordance with the aforementioned Regulations, so that, in Austria's legal view, comparable reference sources can also be used. This legal view is supported by practical access, as according to the data dictionary (explaining the reporting obligations), EU-CEG contains fields for classifications according to the CLP Regulation (#item 99-101) and additional fields for further toxicity studies (including CMR properties; #item 108 and 113). The reference in Article 5(2) of the TPD II and the explanations in the data dictionary therefore do not allow a substance to be classified with regard to its CMR properties exclusively in accordance with the CLP Regulation, so that the use of further/other reference sources is by no means to be considered incorrect.

With regard to the use of the MAK/BAT list (cf. 1.4 in the chapter 'Prohibited ingredients in nicotine-containing and

nicotine-free electronic cigarettes and refill containers' and 5.4 in the chapter 'Prohibited ingredients in tobacco products' of the notification project) in the present context, it should be noted that it is developed by a scientific panel of over 30 members with appropriate qualifications and experience in the field – the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK Commission). It is true that the MAK/BAT list contains values relating to occupational exposure to pollutants, but a basic assessment of a pollutant with regard to its carcinogenic, mutagenic or reprotoxic properties is carried out independently of this. These hazardous properties are inherent to the particular substance, regardless of its presence/concentration in the workplace or its consumption via a tobacco or related product. With regard to the classification of substances, only the respective substance properties and not limit values/risks are taken into account in the TPD II (cf. Article 7(6) and Article 20(3)(c) TPD II).

In order to take into account the comments/observations, which are largely consistent with regard to the substance glycerol, as well as to prevent any further barriers to trade, extensive analyses have been carried out using the submissions available in EU-CEG on tobacco products and electronic cigarettes/refill containers. On the basis of the results obtained, the notification project in question will be amended in such a way that substances classified by the MAK Commission as category 5 for carcinogenic effects and category C for teratogenic effects will be eliminated in the future (cf. 1.4. and 5.4. of the notification project in question). Furthermore, the reference to substances classified by the European Food Safety Authority (EFSA) as carcinogenic, mutagenic or reprotoxic will be deleted in its entirety (cf. 1.5. and 5.5. of the present notification project).

• point 1.4 and point 5.4 now read as follows:
'Substances which, according to the MAK and BAT values list (published by the Deutsche Forschungsgemeinschaft (DFG)), have been classified by the MAK Commission as having carcinogenic effects in categories 1, 2, or 4, as teratogenic effects in categories A or B, and as germ cell mutagenic effects in categories 1, 2, 3A, or 3B.'
• point 1.5. and point 5.5. are deleted in their entirety.

The amended draft, attached as 'other text', largely addresses the concerns expressed in the comments/observations, so that the notification project in question also contributes to the proper functioning of the internal market in addition to the protection of health.

**********

European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu