



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Notification Number : 2019/0520/DK (Denmark)

Order on food contact materials and on provisions for penalties for breaches of related EU legislation

Date received : 23/10/2019

End of Standstill : 24/01/2020

Message

Message 002

Communication from the Commission - TRIS/(2019) 02944

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2019/0520/DK

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201902944.EN)

1. MSG 002 IND 2019 0520 DK EN 23-10-2019 DK NOTIF

2. DK

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4. 2019/0520/DK - C00A

5. Order on food contact materials and on provisions for penalties for breaches of related EU legislation

6. Food contact materials

7. - Regulation (EC) No 1935/2004 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.

8. The purpose of the Order is to ban the placement on the market of food contact material made of cardboard and paper if perfluoroalkyl and polyfluoroalkyl substances (PFAS) have been used.

The Order will however allow the placement on the market of food contact materials made of cardboard and paper where perfluoroalkyl and polyfluoroalkyl substances (PFAS) have been used, for example from inks or reused cardboard and paper, but only if a functional barrier is used in the material to prevent the substances migrating into the food.



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Previously translated content in the DRAFT document:

- Annex 1: The form can be found in English at the link below. However, the sequence is not identical.
https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_legis_additives-prov-list.pdf
- Annex 2: Appears in English in Annex II to Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.
- Annex 3: Appears in English in Annexes I and II to Commission Directive 2007/42/EC of 29 June 2007 on relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
- Annex 6: Appears in English in Annexes I and II to Council Directive 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs. However, the Danish text has an amended layout.

9. Perfluoroalkyl and polyfluoroalkyl substances (PFAS) can be used to make cardboard and paper food contact materials oil- and water-repellent. It is difficult to break down perfluoroalkyl and polyfluoroalkyl substances in the environment; some of them are retained in animals and people, and several of them are suspected of being carcinogenic, disruptive to hormones and damaging to the immune system. There are now alternatives to perfluoroalkyl and polyfluoroalkyl substances. For example, mechanical treatment of paper can make it stronger and more repellent, or a different surface layer can be added to the paper. In December 2018, EFSA published an enhanced risk assessment for two of the substances (PFOS and PFOA), in which the amount that we can absorb before harmful effects may arise was drastically reduced. Denmark's Technical University (DTU), the National Food Institute agrees with EFSA's enhanced risk assessment for the two fluorinated substances, and the Institute has previously (in 2017) made the assessment that it is also unlikely that data will be found in the coming decades that will make it possible to undertake detailed risk assessments for all perfluoroalkyl and polyfluoroalkyl substances. DTU also observes that on the basis of the knowledge that the Technical University currently has on the substances, there is a good basis for reducing the exposure of the population not just to PFOA but also to other compounds similar to fluorinated substances, since DTU expects that the other perfluoroalkyl and polyfluoroalkyl substances will display similar effects in people and animals. The Institute has also shown in experiments that fluorinated substances in cardboard and paper packaging can migrate into food. DTU expressed its concern about perfluorinated alkylcarboxylic acids (PFCA) and alkylsulfonic acids (PFSAs) in October 2019. They conclude that perfluorinated alkylcarboxylic acids (PFCA) with chain lengths from C4 up to at least C11 are able to activate the PPAR α receptor, which is a molecular mechanism that can among other things lead to damage to the reproductive system. Perfluorinated alkylsulfonic acids (PFSAs) with a chain length of C6 and C8 can affect the immune defence system and cause lung damage. DTU also states that PFCA and PFSAs are expected to cause cocktail effects and that account should therefore be taken of exposure to all PFCA and PFSAs in future risk assessments. It is not news that perfluoroalkyl and polyfluoroalkyl substances can have damaging characteristics. Before this proposal for a ban, Denmark has tried to use less invasive measures to reduce the exposure of the population to perfluoroalkyl and polyfluoroalkyl substances, including guidance to consumers and business, determination of an indicator value for unavoidable background level of total organic fluorine in paper and voluntary phasing out of the substances. But there are still food contact materials made of cardboard and paper on the Danish market with a content of perfluoroalkyl and polyfluoroalkyl substances, which suggests that perfluoroalkyl and polyfluoroalkyl substances have been used. These measures have therefore proved inadequate, for which reason the current ban is considered to be the only realistic measure that Denmark can take to protect Danish consumers against the migration of perfluoroalkyl and polyfluoroalkyl substances into food from food contact materials made of cardboard and paper. The Danish ban is targeted to reduce the risk of Danish consumers' exposure to perfluoroalkyl and polyfluoroalkyl substances from food contact materials made of cardboard and paper, by preventing the possibility of migration.

10. Limiting the marketing or use of a chemical substance, preparation or product

Reference(s) to the basic text(s): This draft Order will be issued pursuant to § 25, § 25a, § 49(1) and § 60(3) of the Food Act, cf. Consolidated Act No 999 of 2 July 2018.

The Foodstuffs Act is enclosed as a PDF file, in relation to which attention is drawn to the fact that the Act is an



administrative compilation of the original main Act from 2005 and a number of other amending Acts.

11. No

12. -

13. No

14. No

15. Yes

16. WTO aspect

Yes

SPS aspect

Yes

European Commission

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