PlasticsEurope
Association of Plastics Manufacturers

Food Contact Experts Group

May 2021

Interpretation of Regulation (EU) No. 2020/1245 (the 15th amendment of Regulation (EU) No. 10/2011)
(revision 1)

Aim of this document is to summarize the most important changes of the 15th amendment and to reflect the PlasticsEurope Food Contact Committee interpretation following the WEB meeting that took place between Food Contact representatives of DG Sante and PlasticsEurope members of the Food Contact Committee with a focus on Annex IV point 6 and Article 2.

Please note that this is a non-binding guidance document and that the legal responsibility for complying with the regulation (EU No. 2020/1245) lies with the business operator placing the product on the market.

SUMMARY OF RELEVANT EXTRACTS FROM THE 15th AMENDMENT

A. Extracts related to Annex IV point 6

Disclosure of identity and concentrations of substances listed in Annex II with a restriction and of substances for which genotoxicity cannot be ruled out and which could migrate at levels exceeding 0.00015 mg/kg.

Recital (6)
Article 10 of the Regulation sets out general requirements, which are laid down in Annex II. This Annex restricts the migration of certain elements from plastic materials and articles to food and food simulants. The elements for which these restrictions apply may be present in plastic materials and articles (provided that the requirements in Annex II are met), because:

- they have been intentionally used as an **additive or starting substance** included in Annex I
- their use is subject by a **derogation under Article 6.** They may even be present in the plastic as an impurity or other non-intentionally added substance. The migration limits set in point I of Annex II therefore also apply to the metals which are present in the plastic material or article on basis of Article 6(3)(a).

Recital (28)
Before an intermediate or final material can be placed on the market, the manufacturer of that material needs to assess whether it complies with Article 3 of the Framework Regulation and/or with Article 19 of the Regulation. Various and complementary approaches should be used in such assessment. A common and cost-efficient testing approach is to determine only the safety of substances that are present above a concentration of **10 ppb** by using migration testing with a food simulant. Substances that do not exceed this limit are then considered safe. However, the migration of substances at a level of 10 ppb can only be considered safe if their genotoxicity can be ruled out.

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Therefore, it should be communicated to downstream users of an intermediate or final material that it may contain substances of which the genotoxicity has not been ruled out. Producers of intermediate materials know that these substances can be present in their products as they use preparations that contain them, or should obtain that information from their suppliers.

Annex II (1)
Substances listed in Table 1 shall only be used in accordance with the compositional requirements set out in Chapter II of the Regulation. If Chapter II does not provide a basis for the authorised use of such a substance, that substance may only be present as an impurity subject to the restrictions specified in Table 1 below.

Annex IV (6)
Adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.
At intermediate stages, this information shall include the identification and the amount of substances in the intermediate material,
– that are subject to restrictions in Annex II; or,
– for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant.

B. Extracts related to Article 2

Transition time

Recital (38)
Plastic materials and articles complying with Regulation (EU) No 10/2011, as applicable before the date of the entry into force of this Regulation, and which were also placed on the market before that date, should be allowed to be placed on the market for two more years and remain on the market until the exhaustion of stocks. However, this long period should not be used to develop new materials and articles which had not yet been placed on the market at the time of entry into force of this regulation and are not yet compliant with it. Business operators may not be able to fully anticipate the entry into force of this Regulation when they would have been already planning to place such new materials on the market before the entry into force of this Regulation. Therefor it is appropriate to allow such placing on the market of new materials and articles based on the old rules for six months after the entry into force of this Regulation.

Article 2
Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, and which were first placed on the market before 23 March 2021 may continue to be placed on the market until 23 September 2022 and remain on the market until the exhaustion of stocks.

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INTERPRETATION/DISCUSSION

C. Interpretation Annex IV point 6:

Disclosure of identity and concentration of substances in the intermediate material (plastic granules) which are listed in Annex II of the regulation with a restriction (the Commission guidance on DoC includes in section 3.1 a definition of intermediate plastic materials[1])

- This requirement applies to Annex II listed substances with a restriction which are present in the plastic as part of Annex I listed substances (e.g. zinc/aluminium hydroxide) or as part of intentionally added substances which are derogated under Article 6 (e.g. metals in salts of authorized acids, phenols or alcohols; AP's, PPA's or colorants)

- This requirement also applies to Annex II listed substances with a restriction which are present in the plastic as NIAS (e.g. impurities)

- Disclosure of Annex II (and Annex I) listed substances which have a SML restriction is not mandatory if a business operator can confirm that the residual concentration in the plastic is so low that one tenth of the restriction is not exceeded on the basis of worst case calculation or modelling or migration (see paragraph 4.3.1 (6.(b)(iii)) of the Union Guidance[1] on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food) Customer should be informed about the presence of a non-disclosed substance.

- Disclosure in the DoC of Annex II listed metals with a restriction is only required for metals which are known or expected to be present in the plastic based on knowledge by the plastic producer and on information provided by raw materials suppliers.

Disclosure of the identity and concentration of substances in the intermediate material (plastic granules) for which genotoxicity has not been ruled out and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0.00015 mg/kg food or food simulant.

- The manufacturer of the intermediate material (plastic granules) should communicate in the DoC genotoxic substances present in the plastic granules at levels that could give rise to a migration from the final article exceeding 0.00015 mg/kg food or food simulant under specific conditions of use. Based on the information provided, the downstream user has to check if the migration limit for his application and conditions of use could be exceeded. It should be considered that the concentration of genotoxic substances in the intermediate material might drop during further processing by the downstream user e.g. volatile substances
  (remark: a formula for the calculation of worst-case migration is included in section 2.2.1.1 of the Plastics Europe guidance document on Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under Article 19 of Commission Regulation (EU) No10/2011 of 14 January 2011 on plastic materials and articles intended to come into

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contact with food[2]*. In order to meet the migration limit of 0.00015 mg/kg for a worst case scenario with 100% migration, the concentration level of the genotoxic substance in a* ***100 micron film*** *with* ***density 0.91*** *should not exceed 0.026 mg/kg!*)

- Genotoxic substances are e. g. described in section 3.5.1.2 of the CLP Regulation (EC) No 1272/2008[3] as agents which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non- physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.

  Genotoxic substances include substances classified as Mutagenic Cat 1+2 in accordance with the criteria set out in sections 3.5. of Annex I to Regulation (EC) No 1272/2008 or which do have a structural alert on genotoxicity based on QSAR analysis

As it is difficult to exactly state what is meant with genotoxicity the FCE group has asked toxicological experts how to get the information on genotoxic substances ready in a proper way. This should be performed by expert judgement.

The suggestion is to use a tiered approach as the following:

- Check if there is a harmonized CLP classification for mutagenicity within the EU.
- Check if there is a classification for mutagenicity in other international agencies.
- Check the EU REACH registration proposed by the lead registrant.
- Conduct literature research and refer to the JRC database[4] of genotoxic and carcinogenic substances.
- Run a QSAR analysis to check if there is a structural alert on genotoxicity using a tool such as ToxTree*
- Judgement of available information by an expert using weight of scientific evidence.

**Note: The use of ToxTree alone is not sufficient to rule out genotoxicity/mutagenicity. According to EFSA TTC guidance, a statistical system (e.g. CASE Ultra) is also necessary*

The requirement only applies to genotoxic substances (IAS/NIAS) originating from an intentional use for which the intermediate material producer knows that they can be present in their products (either by chemistry, literature or by analyses) or have obtained information from their suppliers. All NIAS in the intermediate material have to be assessed subject to Article 19 including their potential for genotoxicity.

- The requirement does not apply to genotoxic substances that have been evaluated by EFSA or national food safety authorities and are authorized for use in food contact plastics in the regulation (EC) No 10/2011 or according to national food contact law. These substances are subject to the restrictions laid down in the regulations. Genotoxic impurities in evaluated substances are in scope.

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D. Interpretation Article 2:

Recital 38

The interpretation of the PlasticsEurope Food Contact Committee of Recital 38 is, that existing plastic materials and articles already on the EU market before 23 September 2020, may continue to be placed on the market until 23 September 2022 and remain on the market until the exhaustion of stocks. After that date, the product should comply with Regulation (EU) No. 2020/1245. New plastic materials and articles can still be placed on the market according to the old rules until 23 March 2021 until the exhaustion of stocks. After 23 March 2021 new products should comply with the new Regulation (EU) No 2020/1245.

However, it has to be noted that the text of Recital (38) is not in line with Article 2, but it should be noted that Article 2 is the legal text.

Article 2

The interpretation of the PlasticsEurope Food Contact Committee of Article 2 is, that plastic materials and articles that are already on the EU market before 23 March 2021, may continue to be placed on the market until 23 September 2022 and remain on the market until the exhaustion of stocks.

Date product placed for the first time on the market	Compliance
Before 23 September 2020 (existing products)	Allowed to be placed on the market until 23 September 2022 according to the old rules before the publication of Regulation 2020/1245 and can remain on the market until the exhaustion of stocks. After 23 September 2022 the product needs to comply with Regulation 2020/1245
Between 23 September 2020 and 23 March 2021 (new products)	Allowed to be placed on the market until 23 September 2022 according to the old rules before the publication of Regulation 2020/1245 and can remain on the market until the exhaustion of stocks. After 23 September 2022 the product needs to comply with Regulation 2020/1245
After March 2021 (new products)	Product needs to comply with Regulation 2020/1245

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References:

1.Commission Guidance on DoC (section 3.1 and 4.3.1)
https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_reg_en.pdf

2.PlasticsEurope guidance document on the risk assessment of NIAS
https://www.plasticseurope.org/en/focus-areas/health-and-safety/food-contact

3. CLP Regulation (EC) 2282/2008 (section 3.5.1.2 + Annex VI table 3.1)
https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1507632416158&uri=CELEX:02008R1272-20170601

4.JRC data base mutagenic and carcinogenic substances
https://ec.europa.eu/jrc/en/publication/eurl-ecvam-genotoxicity-and-carcinogenicity-database-substances-eliciting-negative-results-ames-test

EFSA-Guidance on harmonized methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals, 20. February 2019:
doi: 10.2903/j.efsa.2019.5634

EFSA-Opinion: Clarification of some aspects related to genotoxicity assessemnt, 16 November 2017:
doi: 10.2903/j.efsa.2017.5113

EFSA-Guidance for submission for food additive evaluations:
EFSA Journal 2012;10(7):2760

WHO Hazard Identification and Characterization (2nd edition 2020): Section 4.5 Genotoxicity

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