



Comments to (12th) amendment of the plastics Regulation (10/2011)

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29 August 2018

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Substance no 1068: [3-(2,3-epoxypropoxy) propyl]trimethoxy silane

Evaluation of the substance migration potential is based on the assumption that a surface volume ratio of 6:1 is applicable in all application of various scenarios including storage, processing, tableware and kitchen utensils. However, more studies have evaluated that in several cases the surface area to mass ratio is higher than the conventional 6 dm²/kg. The given restrictions should therefore include a maximum surface to volume ratio of 6:1

As the substance has a genotoxic potential according to the EFSA evaluation DTU has moreover the following comments: Presence of a genotoxic substance in food is a health concern. A daily intake of a genotoxic substance (or substances) at a level of ≤ 0.15 $\mu\text{g}/\text{person}$ would in most cases equate into a low probability of adverse health effects. But "low probability" is not "no probability". Humans are exposed to a multitude of genotoxic substances at low levels and combined their effect is likely significant. Therefore, from a health perspective our exposure to these substances should be minimized, not expanded. Thus, genotoxic substances should not be intentionally added to food. As the substance has a genotoxic potential the given restrictions should include a restriction on migration corresponding to non-detectable (N.D).

The substance (although intended for repeated use articles) shall respect the migration limit of N.D. already in the first test due to the genotoxic potential of the substance and the comments given above.

Substance no 1059: Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate)

As given in the EFSA opinion thermolysis of the substance end group can lead to formation of the degradation products of crotonic acid ((E)-2-butenoic acid and (E)-2-hexenoic acids). Crotonic acid is listed in EU No10/2011 (substance no 467) with a SML of 0.05 mg/kg food. This SML of the substance degradation product should be referred to in the restriction of the substance to ensure that this SML is met at all temperature and time conditions of use.