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Plastics Regulation (EU) 10/2011 and the 15th Amendment

In January 2011, the European Union (EU) published Regulation (EU) 10/2011 to regulate food contact plastic materials and articles. It repealed Directive 2002/72/EC and its amendments, the specific directives for migration testing and the vinyl chloride Directive from 2011 May 1.

(EU) 10/2011 specifies the scope of application, the definition of key terms, principles in the manufacturing and placing on the market of plastic food contact materials, general requirements on overall and specific migration testing and information on food simulants and conditions to be used in the testing programs. (EU) 10/2011 also lists the substances that are authorized may be intentionally used in the manufacture of plastic materials and articles in the form of a positive list, so called "Union list". The Union list contains monomers or other starting substances, additives excluding colorants, polymer production aids excluding solvents, macromolecules obtained from microbial fermentation, and it totals 885 authorized substances.

On September 3, 2020, the European Union published Regulation (EU) No 2020/1245 to amend (EU) 10/2011. This 15th amendment adds new substances to the Union list, in addition to introducing several substantive changes to Annexes I, II, IV, and V to the Plastics Regulation. Some significant changes are listed below:



Annex II specific migration limits:

The new regulation provides specific migration limits (SMLs) for 24 elements.

Revised the SML of primary aromatic amine (PAA):

Each PAA listed in entry 43 of REACH Annex XVII shall not migrate from plastic materials and articles into food or food simulant, detection limit shall be 0.002 mg/kg, while the sum of PAAs not listed in REACH shall be ≤ 0.01 mg/kg.

Food packaging is one of the most challenging applications for colorants. All food contact materials and articles containing colorants must comply with the relevant regulations (such as the US FDA, EU 10/2011, China GB9685-2016, etc.), Trust Chem is committed to providing customers with colorant products that meet compliance requirements, and has been following up relevant laws and regulations to ensure continuous regulations compliance.