

## TÜV Rheinland LGA Products – Information

05/2020

### Japan added the positive list system for food contact materials

On 28<sup>th</sup> April 2020, Japan's Ministry of Health, Labour and Welfare (MHLW) published the MHLW Notification No. 196 of 2020 for amending the MHLW Notification No. 370 of 1959. A major change is to add the positive list system (i.e. only listed substances can be used for materials in contact with food). This move has the intention to utilize a more up to date and recognized compliance system in comparison with global food contact materials regulations.

However, the system itself is not 100% comparable to any existing positive list system and hence it is highly recommended to understand well and be prepared for this upcoming change when this amendment officially enters into force on 1<sup>st</sup> June 2020.

Please see below a list of noteworthy points related to this update.

Relating to the general framework, there is an amendment of Food Sanitation Act promulgated in June 2018, in which Article 18(3) is newly added and it describes:

- Scope of materials under this article (specified by the Cabinet Order, currently targeted material is synthetic resins, excluding rubber, hereafter "synthetic resins")
- Principal application of the positive list system of Japan
- "The quantity that is unlikely harm to human health" to be specified further by MHLW. Later, this level is specified at <0.01 mg/kg of food via the MHLW Notification No. 195 of 2020.

In response to the amendment of Food Sanitation Act, MHLW Notification No. 196 is published to support the application of the positive list system. It includes the following positive lists:

- Table 1(1) of Appendix table 1: Base polymers for plastics
- Table 1(2) of Appendix table 1: Base polymers for coatings
- Table 1(3) of Appendix table 1: Minor monomers (constitute less than 2% of the components of a base polymer) that can be used in base polymers
- Table 2 of Appendix table 1: Additives, coating agents, etc

Further details on the positive lists released by MHLW:

- Notably is that the positive list for plastic, coatings are on resin level, while the approval of minor monomers and additives are in substance level.
- Restrictions for each resin is stipulated in the positive list (e.g. applicable food type, applicable temperature)
- Synthetic resins in general have been categorized into 7 groups based on their material properties and consumption factor.
- The categorization of synthetic resins has an important role on the additive lists, in which additives are allowed to be used with maximum use level determined by each group.
- Scope of the positive list includes all substances that are intended to remain in the final product of synthetic resins, which is therefore mainly the starting resins and the additives. Substances that are not intended to remain in the final product of synthetic resins, should be managed according to conventional risk management method instead of the positive list.
- Substances used for coloring will still follow the existing requirements as approved colorants list in Appendix table 1 of MHLW Ordinance No. 23 of 1948 and/or as specified in MHLW Notification No. 370 of 1959 to be "not eluted or seeped out" into foodstuffs.

Further implications important to know:

It is important now to define the ingredients (for now applicable to synthetic resins only) to make sure all the substances are listed in the positive list and also to fulfil the restriction requirements (e.g. applicable food types, applicable temperature, maximum use level for additive). Substances that are not covered in the scope of the positive list system are managed by conventional risk management method.

As the new positive list system is an amendment to the existing food contact requirement, the existing approach of Japan compliance requirements are still valid and need to be applied, therefore testing according to MHLW Notification No. 370 of 1959 by an approved laboratory is still needed.

The Japanese food contact regulation has undergone a huge, impactful change and it is foreseeable this could impact many manufacturers and importers for the Japanese market. A 5-year transitional period is given to allow for products that are already on the market to achieve compliance. With the update above, TÜV Rheinland Group can support customers finding the right approach and testing for Japanese compliance requirements. Please feel free to contact your local TÜV Rheinland for further information.

Reference link:

[https://www.mhlw.go.jp/stf/newpage\\_05148.html](https://www.mhlw.go.jp/stf/newpage_05148.html)

**For further technical information, please contact us:**

TÜV Rheinland LGA Products GmbH  
Dr. Ansgar Wennemer  
Am Grauen Stein  
D-51105 Köln

Retail Technical Competence Center  
Tel. +49 221 806-2062  
Fax +49 221 806-2882  
Wennemer@de.tuv.com

**Disclaimer**

This newsletter contains only information of a general nature without concrete reference to specific natural or legal persons, objects or facts. This newsletter is not to be understood as legal advice and does not replace such advice in any case.

TÜV Rheinland LGA Products GmbH (TRLP) cannot guarantee that all formulations correspond exactly to the respective official versions. TRLP endeavours to ensure that the information provided is correct and up-to-date. Nevertheless, errors and ambiguities cannot be completely excluded. TRLP therefore accepts no liability whatsoever for the topicality, correctness, completeness or quality of the information provided.

Liability claims against TRLP relating to material or immaterial damage caused by the use or non-use of the information provided or by the use of incorrect or incomplete information are generally excluded.