A Move to Mandatory: Japan Finalizes its Positive List for “Synthetic Resins”

Saturday, May 9, 2020

Japan’s Ministry of Health, Labour and Welfare (MHLW) published a notice (Notification No. 196 of 2020), officially requiring approval of substances used in “synthetic resins” for food-contact articles. This Notification was accompanied by the long-awaited final version of its Positive List (PL) of substances used to produce food-contact utensils, containers, and packaging (UCP).[1]

The notice was published on April 28, 2020 and the PL System is scheduled to take effect on June 1, 2020. However, the Japanese authorities have provided a 5-year grace period, which will allow unlisted substances used in synthetic resins that are manufactured/sold in Japan prior to the effective date to continue to be sold in Japan until May 31, 2025.

Structure

The final version of the PL includes the lists of permitted substances shown below.

- Table 1(1) – Base Polymers (Plastics)
The structure of these lists has remained consistent with prior drafts of the PL System that have been released by MHLW since last year. Unlike prior versions, however, the final PL does not contain English chemical names or CAS Registry Numbers. Rather, for each substance, the PL provides the Japanese chemical name, the permitted food types, maximum use temperature, relevant resin group, and other applicable restrictions.

Notably, MHLW has assigned each base polymer to one of seven “resin groups,” and the scope of additive clearances have been defined in relation to these groups. For example, polyethylene terephthalate (PET) polymers are classified into Resin Group 3, meaning that additives permitted in that resin group may be added to PET polymers subject to other applicable limitations.

Ongoing Review

In addition to the substances included in the “final” PL, the Ministry has released an updated List of substances under continued evaluation. These substances, which were nominated for inclusion on the list by companies which use or manufacture them, may be added to the list when next revised, which is expected in March 2021. In the meantime, MHLW may approach the nominating company to confirm/support the content of their submission (e.g., substance identity, intended uses, restrictions, etc.). Likewise, industry may continue to nominate additional substances for listing, which will be reviewed in order of receipt.

Functional Barrier

Pursuant to the Food Sanitation Act (as amended), unlisted substances not used in direct contact with food may still be permitted if they do not migrate to food in a quantity exceeding a level determined by MHLW as unlikely to be harmful to human health. MHLW Notification No. 195 sets this quantity at a threshold of 0.01 mg/kg in food provided that the substance is not genotoxic based on available information or the results of genotoxicity testing.

Accordingly, substances that are not listed in the PL may nonetheless be used in food packaging applications if they do not directly contact food, migration does not exceed 0.01 mg/kg (i.e., 10 ppb), and they are not genotoxic. Thus, while the functional barrier concept may offer some flexibility to the use of uncleared substances, its application must be carefully assessed on a case-by-case basis.

Path Forward

The swift compilation and finalization of the PL System for “synthetic resins”
represents an impressive achievement by the Japanese regulators. Some questions remain, including the fate of chemicals included on the list of substances under continued evaluation, which should be resolved in the next iteration of the PL System. Japan’s formal submission procedures for new substances have yet to be released, but are expected in the coming months.

Perhaps more importantly, MHLW plans to expand the PL System to cover other food-contact materials in the coming years. In the meantime, Japan’s traditional regulatory scheme and the voluntary standards that relate to these applications remain in effect.

[1] Notification No. 196 of 2020 was promulgated pursuant to Japan’s Food Sanitation Act. The Notification and the accompanying guidance documents provided (in Japanese) on the MHLW website.

[2] Drafts of the PL System were released in 2018 and, ultimately, notified to the WTO in August 2019. Additional information on these prior drafts is available.

[3] Reference tables of the English chemical names and CAS Registry Numbers of listed substances are separately published on the same MHLW website as referenced in Footnote 1.

[4] The List of substances under continued evaluation includes 1,497 resins, 110 minor monomers, and 1,751 additives. It is available on the MHLW website.

[5] See information on Japan’s data requirements for such substances


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