Food contact materials: staying abreast of regulation changes

As many readers already know, the materials that come into contact with food (called 'food contact materials' or 'FCM') are heavily regulated around the world. Regulations ensure food products are not impacted by harmful chemicals, therefore creating safe consumption conditions for the general public.

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Regulators impose extra precautions in the selection of materials used by manufacturers with the intention of safeguarding food products. Food contact materials manufacturers must meet regulatory requirements applicable to their products, and be able to address the safety concern of the chemicals used in a food contact article to ensure brand integrity and consumer loyalty.

While the existence of these regulators ensure consumers' peace of mind, they can complicate manufacturing activities as the regulatory environment can be both challenging and prone to constant changes.

Governing bodies

Regulatory bodies vary by country, posing yet another challenge for manufacturers. While these agencies have the same goal, which is to safeguard the health and safety of consumers, the perception towards certain chemicals and additives can vary based on geography.

In the United States, the Food and Drug Administration (FDA) is responsible for the supervision of food safety. Any substance that may come into contact or become part of the end food product must be approved by the FDA, unless it is deemed as safe (GRAS).

Jumping over the pond to Europe, where the regulatory body is the European Commission (EC), the Framework Regulation, the Good Manufacturing Practice (GMP) and materials-specific measures are in place to minimise any potential health risks arising from FCMs.

Consumer protection is paramount.

The use of silicone in food transfer applications

Silicone is a great choice for food contact material manufacturers due to its flexible and tear resistance properties, but most importantly, for safety purposes.

Plasticisers usually used at a high level in food contact articles, among other additives, are not used in silicone tubing extrusion, thus reducing the risk of contamination of the food that passes through the tubing. However, silicone tubing must be cured prior to use; manufacturers have two choices: peroxide or platinum cured silicones.

Bis (2,4-dichlororbenzoyl) peroxide (CAS 133-14-2) is used frequently in the silicone products and has been positively listed in many food contact regulations cross the EU, US, and China. This substance is allowed for use as a crosslinking agent during the silicone curing stage. The limit of use is 0.2% (EU/China) and 1.5% (US) in the final products. The peroxide residual should not exceed 0.08% in the final product.

Tubing cured with peroxide is longer lasting, especially when used in pumping operations. The most important consideration for food manufacturers, however, is that the use of peroxide as a curing agent may result in residuals and breakdown products. These chemicals may potentially impact the quality of the food passing through the tube.

Platinum, the other curing agent, is not prone to extractables or other byproducts. The downside to platinum is its high cost when compared to peroxide curing.

Reclassification risks

The reclassification of Bis (2,4-dichlororbenzoyl) peroxide as 'Toxic for Reproduction, Category 1B' under the Global Harmonised system of Classification and Labelling of Chemicals (GHS) indicating reproductive toxicity of this substances will result in concerns over the safety of its use in FCMs.

In EU, the positive list in the material specific measures has not been revised in the light of current state of knowledge and in the context of CLP Regulation/REACH. Further, the FDA does not ban a cleared food contact substance or further restrict its permitted use unless the agency views the continued use of the substance as an imminent health threat.

In the short term, this reclassification may have minimal impact on the current status of food contact regulations in the US and EU. However, close monitoring of the current regulation may be necessary to stay abreast of potential changes.

What can be done?

Manufacturers can avoid regulatory-related disruptions by partnering up with a provider which actively tracks regulations and has the infra-structure for quick turnarounds in the case of a regulation change.

Saint-Gobain Performance Plastics' regulatory affairs expertise is maintained by a dedicated team of professionals that closely tracks this space and anticipates changes. Our team proactively adjusts product offerings to meet and comply with regulatory standards on behalf of our customers.

Suppliers and manufacturers can be assured that Saint-Gobain actively investigates and researches the latest standards and regulations, updating products to meet compliance. This is done through continuous evaluation and analysis of the regulatory environment, and the development and establishment of appropriate regulatory strategies and tactics.

Our regulatory groups are also kept updated with new regulatory changes by many external resources including law firms and research institutes specialised in food contact regulations. Saint-Gobain supports and follows compliance work performed by functions according to procedures and checklists. ■