

# Regulatory Newsletter

This newsletter is intended to provide an information update on important regulatory issues and developments of interest to Sun Chemical customers.



## Food packaging and contact applications

### Germany

On April 29, 2020, the German Federal Ministry of Food and Agriculture (BMEL) presented a new draft of the 21st Ordinance amending the German Consumer Goods Ordinance, otherwise known as the [German Printing Ink Ordinance](#) ("Druckfarbenverordnung").

Germany notified the European Commission of a draft of this Printing Ink Ordinance in 2016. Eight European Union (EU) member states expressed their concerns in the form of detailed opinions, and two member states and the EU Commission submitted comments. In response to these objections, the Commission stated that it intended to adopt EU legislation on printed food contact materials and invited Germany to postpone its national measure.



In the course of this work, the Commission identified potential deficiencies in the existing regulatory framework (the Framework Regulation (EU) No. 1935/2004), which need to be considered before work on new material-specific measures can be continued.

Due to the changed timetable at the European level, the BMEL has now taken up its original initiative for a national regulation and presented a new draft of the ordinance. However, this draft is essentially identical to the draft previously notified in 2016.

The Food Federation Germany, in consultation with the German Ink Manufacturers Association (VdL), has expressed its incomprehension for this new initiative by the BMEL. In the [opinion of the VdL](#), only a harmonized European regulation for printed food contact materials makes sense. The printing ink industry supports the European Commission in its efforts to achieve a consistent European regulation and is advocating to give the European legislative process the time it needs.

working for you.

The proposed German positive list of substances only comprises a small proportion of substances required for producing printed food contact materials, compared to the Swiss Packaging Inks Ordinance and ink manufacturers' raw materials portfolios, for example, and the guidance for inclusion of substances on the list is considered to be unworkable.

In consequence, and also considering the unresolved objections to the previously notified draft, the VdL has [indicated](#) that it is premature to request confirmations of compliance with this latest draft of the German Printing Ink Ordinance.

**German Federal Institute for Risk Assessment**

The German Federal Institute for Risk Assessment (BfR) has published updated versions of several of their recommendations on food contact materials. While not legally binding, these BfR recommendations are widely respected and used by the industry throughout the European Union, and represent the current state of the scientific and technical knowledge for the conditions under which consumer goods made of polymeric materials meet the requirements of the German Food and Feed Code. A full list of the changes can be found in the [summary document](#) (in German).

**European Union**

The final report on [the evaluation of the EU food contact materials legislation](#) was published on July 1, 2020. The evaluation by the consultancy *Ecorys* focused on five criteria provided by the current legislation, namely effectiveness, efficiency, relevance, coherence and EU added-value, and will serve as input in the development of a [Commission Staff Working Document](#). Work on the postponed printed food contact materials measure is not expected to commence until after this study is finished.

The report makes several important conclusions, such as:

1. The persistence of national requirements for non-harmonized substances creates a burden for companies, especially small and medium-size enterprises.
2. Resources allocated to risk assessment, risk management and enforcement are insufficient.
3. There are particular concerns regarding the feasibility of establishing positive lists for all material groups. Resources are lacking and the costs could be prohibitively high.
4. An estimation that between 7,000 and 9,000 substances would need to be assessed, representing total costs above €256 million for the public sector and up to €5 billion for industry.
5. It would take between 140 and 360 years to perform all the necessary risk assessments with the current resources available at the European Food Safety Authority (EFSA).
6. It is very unlikely that it will be possible to establish positive lists of authorized substances for all food contact materials (FCM).
7. There is a need for a legislative framework that stimulates innovation along the entire food supply chain.



The European Printing Ink Association (EuPIA) and the Printing Ink Joint Industry Task Force (PIJITF) will continue to work with the European Commission to ensure that [new legislation](#) addresses these issues, while being workable and protecting consumer safety.

BfR Recommendation	Material	Update
XXXVI	Food contact papers, cardboard and paperboard	New slimicides, preservatives, coating agents; new migration limits for slimicides and aluminum; new purity requirements for fillers
XXXVI/1	Cooking paper, hot filter papers and filter layers	New preservatives and antimicrobial agents; new migration limit for aluminum
XXXVI/2	Paper, cardboard and paperboard for baking	New preservatives and antimicrobial agents; new migration limit for aluminum
XIV	Polymer dispersions	Expanded list of monomers; new preservative
III	Polyethylene	Updates to catalyst residues
XXV	Hard paraffins, microcrystalline waxes and mixtures thereof with waxes, resins and plastics	New requirements for natural waxes



The forthcoming [15th Amendment to the EU Plastics Regulation](#) (EU) No. 10/2011 will introduce new restrictions on plastic food contact materials. In particular, there are changes to Annex II, which covers metals and primary aromatic amines and some changes to testing conditions for repeated-use articles and overall migration limit (OML) compliance.

The lanthanide metals—europium, gadolinium, lanthanum and terbium—are added with a group migration limit of 0.05 mg/kg food, and limits are set for several heavy-metal impurities.

Primary aromatic amines (PAAs), which are listed in entry 43 to Appendix 8 of Annex XVII to the REACH Regulation (EC) No. 1907/2006, are given a generic migration limit of detection of 0.002 mg/kg food or food simulant applied to each individual primary aromatic amine. The sum of other (not listed) PAAs shall not exceed 0.01 mg/kg in food or food simulant.

#### Switzerland

The Swiss Federal Food Safety and Veterinary Office (FSVO) has revised its [Ordinance on Food Contact Materials](#) (SR 817.023.21) to better align with some of the EU FCM legislation. The requirements for printing inks (Section 12) are unchanged, although some of the details have been moved to the general sections. [Annex 10](#), which includes the list of substances permitted to be used for the production of packaging inks, has been updated, with an expected transitional period of one year, although it may be delayed by the pandemic.



#### Denmark

Denmark has introduced a [national ban](#) on the use of fluorinated substances (PFAS) in paper and cardboard food contact materials as of July 1, 2020. Such substances are used to give grease and water resistance and have been found in several surveys of cardboard and paper packaging products.



Fluorinated substances can migrate into food and are considered to be persistent and bioaccumulative. The ban covers cardboard and paper FCMs which have been treated with organic fluorinated compounds.

However, PFASs are allowed if the product contains a barrier to stop them from migrating into food. Similarly, the use of recycled paper and board will be allowed only if any fluorinated content in the material is separated with a migration barrier. Companies wishing to place FCMs in the Danish market will need to communicate with the supply chain to establish the potential presence of such substances.

#### New York

The New York legislature has approved a measure to ban per- and polyfluoroalkyl substances (PFAS) from food packaging or packaging components intended for direct food contact which are comprised of paper, paperboard or other materials originally derived from plant fibers.



If signed into law, this legislation would make New York the first state in the U.S. to prohibit the entire substance class from food packaging without consideration of whether suitable substitute products are available. Washington and Maine have both adopted similar laws in recent years, however, those prohibitions are contingent on each state completing an alternatives analysis through which a safer option is identified.

#### BRC Global Standards

The revised BRC Global Standard for Packaging and Packaging Materials Issue 6, published in August 2019, came into force in February 2020. The new version of the standard includes changes to the hazard and risk analysis, a new environmental monitoring clause, introduction of corrective and preventive action, and scrapping the previous two-tier hygiene system in favor of a simpler risk-based approach.



The new standard focuses more on product quality and not just product safety. Consequently, hazard analysis risk assessment (HARA) will be used more broadly, not just to assess product safety risks, but also to determine quality hazards. This may result in quality control points even if the company does not have any critical control points.

There are specific requirements on corrective and preventive action (CAPA) related to root cause analysis and adopting a structured continuous improvement approach. This emphasizes the importance of addressing issues with the intent to remove the risk of recurrence and supporting continuous improvement. The changes are discussed in a [video](#) prepared by Campden BRI.

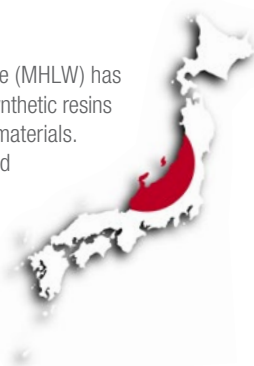
### Japan

Japan's Ministry of Health, Labour and Welfare (MHLW) has proposed a migration limit of 0.01 mg/kg for synthetic resins that are not approved for use in food contact materials.

These are defined as substances not included on the positive list, and the limit applies to utensils, containers and packaging listed under the Japanese Food Sanitation Act.

[The positive list](#) of synthetic resins comprises categories of polymers, monomers and additives used in synthetic resins, including thermoplastic and thermosetting resins.

The substances are divided into two groups: base polymers, including those for plastics, coatings or minor monomers, and additives.



### India

The Bureau of Indian Standards has issued a revised draft standard for printing ink for food packaging. The move comes as a precursor to implementing its recommendation of a ban on the use of toluene and certain plasticizers in printing inks.

The standard contains a code of practice for using ink for printing food packaging. It establishes guidelines on how food contact packaging and wrappings are to be used, specifying the responsibilities of the printers of packaging materials and the food industry packing their products. The revised standard covers:

1. external packaging (in addition to immediate food wrapping, such as transport packaging)
2. immediate food wrappings (wrapping material in direct contact with food)
3. print in direct food contact (the printed side is in direct contact with food)
4. disposables (plates, straws, napkins, etc., that might be used to wrap or hold food)

For printing inks in indirect contact with food, the code of practice lays out that the industry must ensure (as far as possible) that the printed surface does not come into immediate contact with food.

However, if the printed surface needs to be in direct contact with food, the printing ink used on the surface of printed films—or material inserted for dry granular food—should be formulated in such a way that there is no reasonable risk of migration of the print onto the food.



In the case of immediate food wrappings, the ink film applied on a wrapper needs to be extremely thin generally and the total quantity involved very small, reducing the risk of migration. However, as a precaution, inks shall be formulated with materials other than those known to be toxic according to the revised standards in the draft.

### South Korea

South Korea's Ministry of Food and Drug Safety (MFDS) has updated the country's food contact material standards. The use of recycled plastics, such as mechanically recycled resins, is now permitted in non-direct food packaging. This new requirement has been included in the standard under the provision that there is no risk of harmful substances migrating into food. The notice was published on May 29, 2020, and the revisions to the Standards and Specifications for Food Utensils, Containers and Packaging took effect immediately.



### Indonesia

Indonesia's National Agency of Drug and Food Control (BPOM) has issued an overarching food packaging regulation replacing the 2011 version. This new regulation is one of the most comprehensive on food contact materials and packaging in the Asia-Pacific region, and includes packaging made from both new and recycled materials.

Food producers must ensure that the packaging they use does not endanger human health. [The regulation](#) (in Indonesian) has several annexes containing chemical lists (in Indonesian with substance names also in English). The placement of a substance in a particular annex determines how it is regulated.

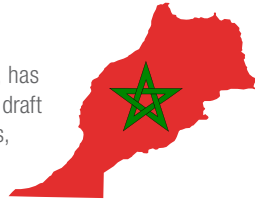
Annex I lists substances that are prohibited from use. Annex II lists substances that are permitted for use by technical function for particular applications, some with migration limits. Annex III lists the food contact materials (paper, plastic mono- and multilayers, resins, polymers, coatings, adhesives, ceramics, glass) and their total migration limits. Annex IV lists specifications for materials used as packaging for different types of food and beverages.

BPOM approval is required for any substance that is not listed in Annex II or III.



**Morocco**

Morocco's food safety authority, the ONSSA, has notified the World Trade Organization (WTO) of draft standards for groups of food contact materials, proposing migration limits for chemicals, including heavy metals. The list of material groups and, where applicable, the combinations of these materials in contact with primary products and food products likely to be subject to specific measures includes:



- Metals and alloys
- Paper and cardboard
- Ceramics
- Plastics
- Pigments and dyes in packaging
- Inks, coatings and varnishes for printing packaging intended for food contact
- Silicone elastomers and rubber
- Regenerated cellulose films

Article 17 relating to printing inks states that the printed side of the packaging of primary products and foodstuffs, whether or not it is lacquered, must not come into contact with foodstuffs. In the case of inks used on the reverse side of transparent packaging films, the only thing that satisfies the conditions concerning the packaging intended to be in contact with primary products and foodstuffs is where the prints are protected by a (flat) protective coating. It must effectively protect the food product and not flake.

Article 18 authorizes specific components of varnishes intended for the internal coating of food cans and as components of plastic materials used for the packaging of primary products and foodstuffs. Article 21 specifies that the pigments and colorings allowed in packaging placed in contact with primary products and foodstuffs must be of high purity, with limits on heavy-metal content, aromatic amines and benzo[a]pyrene.

**Brazil**

Brazil's health ministry has delayed the implementation of the positive list of additives allowed for use in food contact materials due to the international public health emergency caused by the coronavirus pandemic. The list, which aligns the country with a Mercosur technical regulation, was set to enter into force on June 1, 2020, but the date for compliance with the new rules has been extended to June 3, 2021.



For more information on these regulatory issues, please contact the Regulatory Affairs team in **North America**, **Latin America** or **Europe**.

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