The Regulation of Printing Inks in the European Union

I. Introduction

The European Commission (EC) has announced that it intends to work on a measure that will harmonize the regulation of printed food-contact materials in the European Union (EU), including, as a first priority, printed paper and paperboard. This announcement comes in the face of a years long effort in Germany, now on hold, to regulate printing inks on packaging materials, which is similar to a measure that has already been implemented by Switzerland (which is not a member of the EU). Most of the Member States have little or no regulations pertaining to these inks.

To understand better the possible direction in which the EU may be headed, we first provide below an overview of how food-contact printing inks are currently regulated in the EU. We also detail the main provisions of the Swiss Printing Inks Ordinance. Finally, given the potential influence the work of the German authorities could have on the direction that the EU could take, we highlight some of the main provisions of the draft German Printing Inks Ordinance.

II. Overview of the Regulation of Printing Inks in the EU

The regulation of printing inks on food-contact materials is not fully harmonized at the EU level. Under EU food-contact legislation, such printing inks must comply with the Framework Regulation (EC) No. 1935/2004 and the GMP (Good Manufacturing Practices) Regulation (EC) No. 2023/2006. Once this is established, food-contact printing inks may be placed on the market throughout the EU, subject to Member State legislation and the principle of mutual recognition.

The Framework Regulation, which regulates all food-contact materials placed on the EU market, establishes, among other provisions, a general safety requirement, and specifies that food-contact materials and articles must be manufactured in accordance with GMP so that they do not transfer their constituents to foodstuffs in quantities that could endanger human health or bring about an unacceptable change in the composition of the food or its organoleptic properties.

The GMP Regulation applies to all food-contact materials at all stages of production, apart from the manufacture of starting substances, and sets forth the general rules on GMP, such as the establishment of quality assurance and quality control systems and the adequate documentation of those systems. Specific requirements for printing inks applied on the non-food contact side of materials and articles are detailed in the Annex to the GMP Regulation. These requirements include, for example, a prohibition on unsafe levels of components of these inks transferring by set off or otherwise to the food-contact side.

While the EU has not established harmonized legislation specifically governing the use of printing inks as a category of food-contact materials, broad requirements for printing inks are included in the Regenerated Cellulose Directive, 2007/42/EC. More specifically, Article 5 prohibits contact between the printed surfaces of regenerated
cellulose film and food. Further, while printing ink components are not subject to the positive list requirement of the Plastics Regulation (EU) 10/2011, this regulation indirectly sets requirements for printing inks, as specific migration limits (SMLs) for components in the Plastics Regulation’s Union List apply to the final printed plastic article regardless of whether the component is a part of a printing ink. In other words, the migration of components from both the plastic substrate and the printing ink must be considered when determining whether an applicable restriction is met. Furthermore, since the Plastics Regulation imposes an overall migration limit (OML) of 10 mg/dm$^2$ (or 60 mg/kg in certain circumstances) from the final food contact article, any contribution from the printing inks must be considered when determining compliance with the OML.

Importantly, the principle of mutual recognition allows products to be placed on the market in an EU Member State when first lawfully manufactured or marketed in another Member State, even if the products do not fully comply with the specific technical requirements in the country of destination. Of course, under the principle of mutual recognition, business operators must otherwise comply with any applicable prior-authorization procedures, assuming such procedures are in line with the requirements of the Treaty on the Functioning of the EU.

III. National Printing Ink Requirements

A. The Swiss Printing Inks Ordinance

Although not an EU Member State, Switzerland is the only country in Europe that currently has legislation in place specifically regulating food packaging printing inks.[1] By way of background, Swiss Ordinance RS 817.023.21 establishes specific provisions for several types of food-contact materials and articles, including food packaging printing inks. At the outset, note that the Swiss Printing Inks Ordinance does not apply:

1) to printing inks directly in contact with food; 2) if migration of the ink substances to food is “impossible” (for example, in the case of printing inks on the outside of an aluminum can); and 3) if set off or transfer via a gas phase can be ruled out.

The positive list of components that may be used in printing inks pursuant to the Ordinance consists of substances listed in Annex 1 (Plastics) [2] and Annex 6 (Printing Inks). Annex 6 is comprised of positive lists for binders (monomers), colorants and pigments, solvents (including energy curing monomers), additives (which does not include those used in the preparation of pigments and aids to polymerization), and photoinitiators. The positive lists in Annex 6 are further divided into Part A (evaluated substances) and Part B (non-evaluated substances). The non-evaluated substances may only be used if no transfer to food occurs at a detection limit of 0.01 mg/kg. However, substances subject to the positive list requirement must be listed in either Part A or Part B (or in Annex 1) before they may be used in printing inks to be placed on the market in Switzerland.

The Swiss Printing Inks Ordinance does not require business operators to provide Declarations of Compliance for printing inks, although supporting documentation should be kept on file and made available to enforcement authorities upon request.

Swiss Ordinance RS 817.023.21 will be repealed and replaced on May 1, 2017 by a new Ordinance on materials and articles intended to come into contact with foodstuffs (the new Swiss Ordinance).[3] With respect to the section
on printing inks, the Swiss Federal Food Safety and Veterinary Office (FSVO) has apparently removed some substances from the Part B list that the authorities have deemed carcinogenic, mutagenic, or toxic to reproduction (CMRs), and also transferred certain substances from Part B to the Part A list (following completion of a favorable evaluation). That said, the new Swiss Ordinance rules out the inclusion of substances in the Part B list that are CMRs and substances that can be detected at levels of 0.01 mg/kg and above.

Further, the new Ordinance defines nanoform substances as substances deliberately engineered to nanoform (i.e., the definition does not encompass substances naturally occurring in nanoform). Substances deliberately engineered to nanoform may be used if they are listed as such in the applicable Annexes (Plastics or Printing inks). Colorants and pigments in nanoform may also be used provided that no migration of nanoparticles to foodstuffs occurs.

Noteworthy, though, is the fact that the new Swiss Ordinance will apply a transitional period of four years from May 1, 2017 to the composition, labeling, and advertising of food-contact materials falling within its scope (subject to limited exceptions).[4] In other words, food-contact materials and articles complying with the current Swiss compositional, labeling, and advertising requirements may continue to be placed on the Swiss market until May 1, 2021, and may be provided to consumers even after the expiration of the transitional period until the exhaustion of stocks.

Although the new Swiss Ordinance will introduce a Declaration of Compliance requirement for several types of materials and articles, no such provision will apply to printing inks. That said, certain printed materials such as printed plastic materials and articles will be subject to a declaration of compliance requirement as of May 1, 2017.

**Petitioning for listings of printing ink components for food packaging in Switzerland**

The Swiss and German authorities have been, and continue to, informally collaborate on printing ink matters, even in the wake of the Germans’ announcement that its draft Ordinance is “on hold.” With respect to updates to the Swiss printing ink positive list (or draft positive list in the case of Germany), if a business operator sought listing of a component in the Part A lists (evaluated substances) of the Swiss Printing Inks Ordinance, a petition had to be submitted in parallel to both the Swiss Federal Food Safety and Veterinary Office (FSVO) and the German Institute of Risk Assessment (BfR). We understand that this informal (but required) practice is expected to continue in the foreseeable future, with the BfR and Swiss FVSO meeting twice yearly to jointly evaluate petitions for components of printing inks, even though work on the draft German Printing Inks Ordinance has been temporarily halted.

The Swiss Printing Inks Ordinance outlines that the following data should be included in a petition for a food contact printing ink:

- information regarding the toxicology of the substance;
- the nature and concentration of the substance migrating to the foodstuffs or to the food simulants;
- the trace analysis methods used in relation to the substance; and
- the technical necessity for using the substance.
The new Swiss Ordinance will align the data requirements more closely with those of the European Food Safety Authority’s Note for Guidance for Petitioners;[5] thus, as of May 1, 2017, submissions for all food contact materials will require:

- the identity of the substance;
- the chemical and chemical properties of the substance;
- the intended use of the substance;
- authorizations applicable to the substance;
- the migration of the substance (residual concentration in the material or article, nature and concentration of the components that may migrate, analytical methods); and
- the toxicity of the substance, as well as its impurities and degradation products.

B. The Draft German Printing Inks Ordinance

As highlighted earlier, Germany has suspended its work on the so called “Draft Printing Inks Ordinance” (formally, the “Twenty-first Ordinance amending the Consumer Goods Ordinance”), given the EC’s announcement that it plans to develop a harmonized EU measure on printed food-contact materials and articles. The draft German text, though, remains relevant, given the expectation that it will serve as a starting point for the EC’s work. The draft German text was notified to the EC on July 5, 2016, and proposed to apply to printing inks and printing varnishes applied on both the food-contact and non-food-contact sides of food packaging. Varnishes other than printing varnishes were excluded from its scope, as were colorants to dye food-contact materials and articles, as well as decorative inks for ceramic food-contact materials and articles applied in a combustion process.

The Draft Printing Inks Ordinance included positive lists of monomers and other starting substances, colorants (pigments and dyes), solvents, additives, and photoinitiators that could be used in the manufacture of printing inks and varnishes. In addition, certain monomers and additives listed in the Plastics Regulation could also be used in printing inks, subject to any applicable limitations or specifications. Substances in nanoform had to be explicitly permitted for use in nanoform.

The Draft Printing Inks Ordinance provided that substances other than those included in the positive list could also be used in the manufacture of printing inks not intended to come into direct contact with food, provided that certain conditions were met.[6] The draft also included a provisional list of pigments that could be used temporarily in direct contact with food, provided that they were not found to migrate to food using a detection limit of 0.01 mg/kg. Finally, it is noteworthy that a Declaration of Compliance requirement was dropped from an earlier version of the Ordinance.

IV. EC Weighs In

On November 24, 2016, soon before the German Ordinance extended standstill period was to expire,[7] the EC
announced its intention to “develop suitable legislation on printing inks as soon as possible” in response to a parliamentary question seeking input on the EC’s views on Regulation (EC) No 1935/2004’s protections against the transfer of substances from printing inks on cardboard food packaging. The EC indicated that such legislation could cover “other materials, particularly paper and board.”

The EC’s November 24, 2016 reply also followed the European Parliament’s October 6, 2016 Resolution on the implementation of the Food Contact Materials Regulation (EC) No 1935/2004 (2015/2259(INI)), putting pressure on the EC to focus on food contact materials that are not specifically regulated at the EU level, with priority given to, among other materials, printing inks.

The German announcement placing its work on hold – in the wake of the EC announcement -- is in keeping with Article 6.3 of Directive (EU) 2015/1535 (laying down a procedure for the provision of information in the field of technical regulations and of rules on information society services), which requires Member States to postpone adoption of a draft technical regulation for 12 months following the Commission’s receipt of the draft, if, within three months of that date, the Commission announces its intention to propose or adopt a directive, regulation or decision on the matter (although, strictly speaking, the Commission made this announcement after the expiration of the initial 3 month standstill period).

The draft EU harmonized measure was discussed on January 30, 2017, at both the working group on food materials of the toxicological safety section of the standing committee on plants, animals, food and feed (SC-PAFF) and the Technical Expert Group for food-contact materials. According to the summary of the SC-PAFF meeting, the draft EC measure will be developed in three phases:

Phase 1: Identify elements of a printing inks measure, using German Draft Printing Ink Ordinance and industry guidance as sources

Phase 2: Assess the feasibility and practicality of these elements, with particular focus on compliance and enforcement

Phase 3: Draft legislation[8]

According to the summary of the Technical Expert Group for food-contact materials meeting, the draft measure will apply to printing inks and printed substrates, although “the latter only as far as relevant for regulating printing inks.” Specifically, it “is not intended to establish new rules on the composition of the substrate as far as such rules are not necessary for addressing the printing”. Adoption is expected by mid-2018.

V. Conclusion

At the moment, the Swiss Printing Inks Ordinance is the most complete piece of national legislation in Europe regulating substances intended for use in printing inks that are not intended to come into direct contact with food. While currently the only legal standard of its kind in Europe, the Swiss Ordinance only directly impacts companies selling their products into Switzerland. Significant changes are on the horizon for manufacturers and users of printing inks and their components, though, as operators may soon be legally obligated to meet EU-wide requirements applicable to printing inks, if the EC follows through on its announced commitment to draft and
implement a harmonized EU measure on printed food contact materials and articles.

Authors

Catherine R. Nielsen, Partner, Keller and Heckman’s Food and Drug practice, contact +1 202-434-4140 or nielsen@khlaw.com. Hazel O’Keeffe, Counsel, Keller and Heckman’s Food and Drug practice, + 32 2 645 5076 or okeffe@khlaw.com.

[1] That said, certain EU Member States, such as the Netherlands, maintain national purity requirements for colorants used in all food contact materials.

[2] Annex 1 lists the monomers/starting substances, additives and polymer production aids that may be used in the manufacture of plastic materials and articles in Switzerland. Although the list of additives/polymer production aids is not yet a strict positive list for plastic materials and articles, the new Ordinance on materials and articles intended to come into contact with foodstuffs will make this a positive list.

[3] Although this Ordinance has not yet been published in the Swiss Official Journal (‘Recueil Officiel’), we understand that the version published on the FSVO’s website is the final adopted version, although minor editorial adjustments may be made.


[5] Note for Guidance for Petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorization (updated on July 30, 2008).

[6] For example, the unlisted substances could not be carcinogenic, mutagenic, or toxic to reproduction (‘CMRs’) and were not permitted to migrate to food at a detection limit of 0.01 mg/kg.

[7] Following notifications of draft technical regulations by Member States, the European Commission and the Member States have three months to issue comments or detailed opinions (i.e., object to) on the draft text. This period is known as the standstill period. (A standstill period can be extended - as was the case here - by three months if a detailed opinion is issued on a draft technical regulation, and during this period, the notifying Member State may not adopt the draft text. In the case at hand, numerous member states had issued detailed opinions or comments on the German Draft Printing Inks Ordinance, and given these, the standstill period (which had been set to expire on October 6, 2016), was extended to January 6, 2017.
See minutes of SC-PAFF meeting:

See minutes of Technical Exert Group on Food Contact Materials meeting: