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German Printing Ink Ordinance (GIO) National Regulation for Printing Inks for FCM

TÜV Rheinland LGA Products - Information

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In December 2021, the 21st Ordinance amending the Consumer Goods Ordinance was published in the German Federal Official Journal and entered into force. It will be applicable and mandatory after a 4 year transition period from January 1st, 2026.

The aim of the Ordinance is to protect consumers' health by regulating the migration of potentially hazardous substances into foodstuff. It regulates printing inks with intentional and foreseeable direct and indirect food contact through a positive list of substances and respective migration limits.

As there is currently no harmonized measure in the European Union that regulates printing inks, according to the Framework Regulation 1935/2004, member states can introduce individual regulations. Some European countries already have certain measures on printing inks in place, however, by far the most comprehensive Regulation until now was the Swiss Printing Ink Ordinance. This Ordinance has been the reference for safe printing inks even globally since 2010. It remains to be seen if the GIO will become equally relevant.

SCOPE

The GIO covers printing inks to be printed on food contact materials where migration into the food can occur. It applies to indirect food contact with printing on the outside. But the direct food contact where the printing may come in direct contact with food is also included. Inks for printing on food itself are not in scope, neither does it apply to inks behind an absolute barrier, where migration is excluded (e.g. glass, thick aluminum). Preparations for the coloring of food contact materials and articles and also decorative colors for food contact articles made of ceramics or glass, which are applied in a firing process are not in scope of the Ordinance. In the scope of this ordinance, transient food contact applications, where the print may come into direct contact with food during normal or foreseeable use, such as printed napkins or kitchen towels, are considered direct food contact applications. Consistent with EU Plastics Regulation, unintentionally added substances (NIAS) must be evaluated in accordance with internationally recognized scientific principles on risk assessment.

CONTENT

Composition: Printing inks must be composed of allowed substances only (positive list principle). These allowed substances are listed in Annex 14 of the Consumer Goods Ordinance; additionally, substances listed in the Plastics Regulation (EU) No. 10/2011 may be used. For printing inks that are not intended to come into direct contact with food, other substances may also be used under certain restrictions: a) they are not "CMR substances" (carcinogenic, mutagenic or toxic to reproduction); b) they are not nanomaterials; c) they do not migrate into food above 10 ppb, that is 0.01 mg/kg food (nanomaterials must not be detectable at all, no threshold).



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Migration: Similar to the Plastics Regulation (EU) No 10/2011, specific migration limits per substance must not be exceeded. These limits are provided in Annex 14, column 6 (specific restrictions) or 7 (group restrictions), if no amount is specified, the Overall Migration Limit (OML) of 60 mg/kg food simulant applies.

Additionally, there are restrictions for the migration of metals and primary aromatic amines.

COMPARISON TO THE SWISS ORDINANCE 817.023.21 (SWISS ORDINANCE)

The Swiss ordinance 817.023.21 regulates printing inks for food contact materials. With a positive list for evaluated substances (~1000) and another one for unevaluated substances (~5000) as well as a huge number of specific migration limits based on thorough toxicological evaluation, this ordinance has been the reference for printing ink manufacturers worldwide. Despite this being a national regulation, most of the producers of food packaging and printed food contact materials have committed to follow the Swiss Ordinance, and many ink manufacturers have been producing their inks according to these rules for many years.

In comparison with the new German Ink Ordinance, there is a lot of overlap. However, there are also relevant differences, which need to be considered:

	Plastics Regulation (EU) No 10/2011	Swiss Ordinance 817.023.21	German Printing Ink Ordinance
Scope	Plastic food contact materials and articles	Printing inks for indirect food contact	Printing inks for direct, indirect and foreseeable food contact
Positive List	Positive list for plastics (applicable migration limits must not be exceeded by printed plastics)	Positive list with evaluated substances and not evaluated substances (10 ppb limit applies)	Positive list for direct food contact, for indirect contact other substances are allowed under certain conditions
DoC Requirement	yes	no	no

It is to be mentioned that the positive lists of the Swiss ordinance and the German Ordinance are very similar, however, they are not identical. Therefore, substances allowed under Swiss Regulations may not be permitted under German Law and vice versa.

IMPACT ON INDUSTRY

The German Ink Ordinance is a national Regulation and therefore it will be applicable directly only in Germany after the transition period of four years, i.e. from January 1st, 2026. Similar to the Swiss Ordinance, it may also become a reference for brand owners worldwide, and potentially also for a European measure on printing inks or printed food contact materials.

Due to the slight but relevant deviations from the long established Swiss Ordinance, German manufacturers for printed food packaging and printed food contact materials in general should ensure that the printing inks on their materials are fit to comply with the German Ink ordinance requirements once they become applicable.



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To do so, a two-step approach may be helpful: 1) ask your printing ink manufacturer for a confirmation that the inks are compliant in their formulation to the positive list of the German Ink Ordinance (a typical document can be a "Statement of Composition (SoC)") and 2) confirm that the migration limits of the migrateable substances are not exceeded by suitable specific migration testing and NIAS screening.

Note, however, that the positive list is expected to be further updated and additional substances may be added within the next four years. Therefore, many ink manufacturers are not yet able to issue a final confirmation.

Further information on current legal changes can also be found on our homepage at www.tuv.com/regulations-and-standards/en/.

Info box: For additional information about REACH Services please see https://www.tuv.com/world/en/reach.html

Further technical information can be obtained from:

TÜV Rheinland LGA Products GmbH
Technical Competence Center Softlines
Dr. Ansgar Wennemer
Wennemer@de.tuv.com
Am Grauen Stein 29
51105 Köln

Steffen Tuemptner

Steffen.Tuemptner@de.tuv.com

Alboinstr. 56

12103 Berlin

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