

## **VdMi member information on the Publication of the 21<sup>st</sup> Ordinance amending the Consumer Goods Ordinance (German “Printing Ink Ordinance”)**

### **Introduction / Background:**

The so-called German Printing Ink Ordinance was published in the Federal Law Gazette (*Bundesgesetzblatt*) on 7 December 2021 as the 21<sup>st</sup> Ordinance to amend the Consumer Goods Ordinance (Bedarfsgegenständeverordnung) and entered into force (Federal Law Gazette I 2021 p. 5068 (No. 82))<sup>1</sup> one day after promulgation, i.e. on 8 December 2021.

The regulation was thus launched on a national basis, although the EU Commission was already active at European level. From the point of view of the entire food packaging industry, which previously voiced massive criticism of this project, there is no need for this regulation.

This national regulation is detrimental to the internal market and does not contribute to a uniform level of consumer protection in Europe. Only a harmonised European solution would be useful and would serve the protection goals, namely consumer protection in Europe.

In the course of working on the EU legislation for printed food contact materials, the EU Commission identified fundamental deficits in the existing legal framework, which were to be examined as part of a broad-based evaluation. Due to the changed schedule at European level, the German regulation initiative was taken up again in 2020 and completed in 2021.

There are transitional periods of up to 4 years for the relevant provisions of the German Printing Ink Ordinance, so that essential parts of the ordinance only apply from 1 January 2026.

### **Key aspects of the German Printing Ink Ordinance at a glance:**

From the point of view of the entire food packaging industry there is no need for this regulation.

This national regulation came into force on 8 December 2021.

The incompleteness of the positive lists was also recognised by the German legislator, which is why a corresponding transitional period was set.

For the authorisation of a new substance (inclusion in Table 1), the procedure is not clearly defined.

The relevant provisions of the German Printing Ink Ordinance will only apply from 1 January 2026.

There is currently no basis for creating or requesting confirmations of compliance with the requirements of the new national printing ink regulation.

<sup>1</sup> [Bundesgesetzblatt \(bgbl.de\)](https://www.bgbl.de)

## Key provisions of the regulation

### Scope of application

Although the term "German Printing Ink Ordinance" has become established, the ordinance does not regulate printing inks, but printed food contact materials ("commodities"), that are in direct or indirect contact with food and where a transfer of substances from the printing ink layer to the food cannot be ruled out.

- The primary addressee is therefore the commercial manufacturer of printed food contact materials. The regulation applies to both food contact materials where the printing ink is in direct contact with the food (so-called internal printing) and those where the printing ink is applied to the side facing away from the food (so-called external printing). In addition, such printed food contact materials are included that can have foreseeable contact with the food but were not actually intended for this purpose (foreseeable short-term contact). The German Printing Ink Ordinance differs significantly from the Swiss Printing Ink Ordinance<sup>2</sup>, which only covers the outside printing of food contact materials.
- There are also discrepancies in indirect food contact between the German and Swiss Printing Ink Ordinance, some substances have a different SML, the Swiss List A is not identical to Table 1, so different limit values apply.

### Substances for printing inks

- The core of the German Ordinance is a positive list of substances (Annex 14 Table 1), which may be used to produce printing inks for food contact materials. These substances on the positive list can be used for all types of printed consumer goods (internal printing, external printing, and foreseeable short-term contact). This must take place in compliance with the set restriction, specification and cleanliness requirements. If no purity requirements are specified, the substances must be of good technical quality regarding purity requirements (see § 4, para. 5).
- Furthermore, there is a dynamic reference to the positive list of regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food. It should be noted that this reference only applies to substances that are listed without group restrictions and without restrictions and specifications. When restrictions are introduced for a substance in Regulation (EU) No 10/2011, it is automatically and immediately excluded for printing inks for food contact materials in direct contact with food.
- For the printing of food contact materials where the printing inks are in direct contact with the foodstuff, only those printing inks may be used which are fully composed of substances that are listed in the positive list (Annex 14, Table 1) or are covered by the dynamic reference to Regulation (EU) No 10/2011.
- In the case of food contact materials where the printing inks come into direct contact with food during normal, foreseeable use, although they are not intended for this purpose (e.g. printed napkins), the printing inks used may additionally contain the pigments listed in Table 2; however, this only applies until 1 January 2027.
- For the printing of food contact materials and articles where the printing ink is not in direct contact with foodstuff (so-called external printing), substances other than those covered

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<sup>2</sup> [SR 817.023.21 - Verordnung des EDI vom 16. Dezember 2016 über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen \(Bedarfsgegenstandsverordnung\) \(admin.ch\)](#)

in the positive list or according to the dynamic reference to the Union list of Regulation (EU) No 10/2011 may also be used in the printing ink. These other substances must not be classified as CMR under chemical legislation (CLP Regulation); in addition, a migration must not be detectable (i.e. < 10 ppb, detection limit).

### NIAS and No Limit Substances

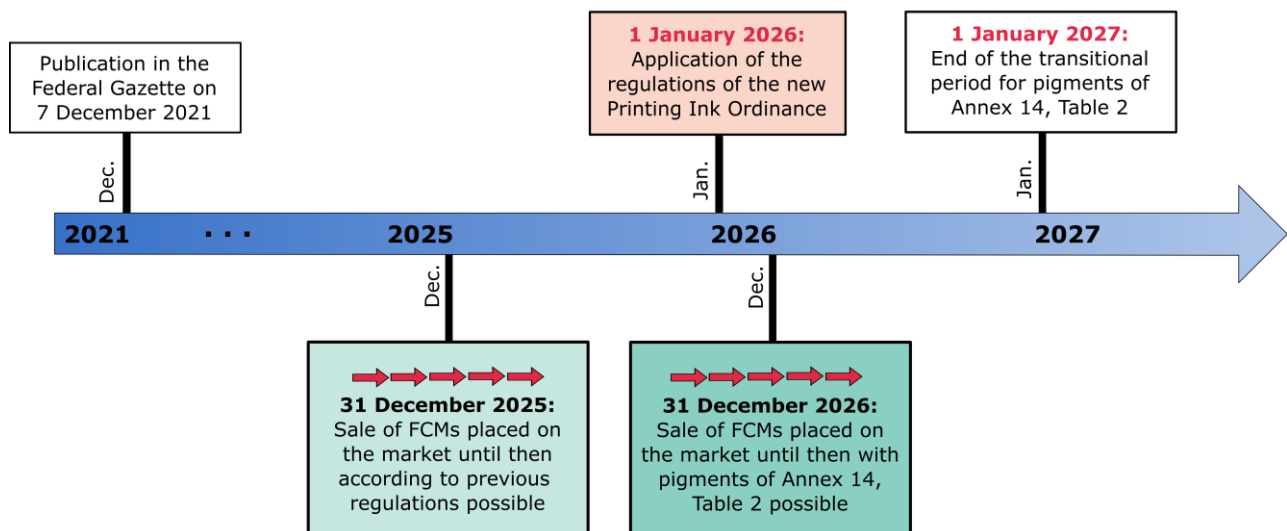
- For the purposes of the ordinance, "use" is defined as the planned use of substances for the manufacture of printing inks, i.e. it refers to intentionally added substances. Unintentionally added substances (NIAS) must be evaluated in accordance with internationally recognised scientific principles of risk assessment, as required by EU legislation.
- In the positive list, specific migration limits, group limits or restrictions are partially specified, which must be complied with. If no migration limit or other restrictions are defined, the global migration limit of 60 milligrams per kilogram of the foodstuff applies.

### Conformity

- Compliance with the migration limit values depends not only on the composition of the printing ink, but also on various factors such as the layer thickness, the packaging geometry or the packaging material and is therefore subject to the compliance work of the manufacturer of the final food contact material.
- The regulation does not contain any specifications regarding the transfer of information within the supply chain, close cooperation between the various players within the supply chain is crucial. There are already established concepts available, such as the "Statement of Composition".

### Transitional periods

#### Application and transitional periods of the German Printing Ink Ordinance of 2 December 2021



- A transitional period of 4 years (31 December 2025) is provided for the sale of printed food contact materials that do not comply with the German Printing Ink Ordinance. For printed food contact materials containing substances listed in Table 2 of Annex 14, a sales period of 5 years (until 31 December 2026) is foreseen.

### **Inclusion and assessment process**

- In order to be able to use pigments and fillers that are listed in Annex 14 Table 2 after 31 December 2026 in printing inks for so-called short-term printing or for internal printing, these substances must be included in the positive list (Annex 14 Table 1). For this purpose, an evaluation dossier must be submitted to the BfR (*German Federal Institute for Risk Assessment*).
- In 2020 the VdMi submitted evaluation dossiers for three pigments to the BfR. In 2021, one pigment was added to Table 1 and two pigments moved from Table 2 to Table 1.
- We also requested the inclusion of five further pigments in Table 2. The BfR confirmed that the pigments would be included in Table 2 in the next revision of the regulation. In the meantime, information about the inclusion of these five pigments can be found on the BfR<sup>3</sup> homepage (in German only).
- In 2021 an evaluation dossier for a Table 2 pigment was submitted. The assessment by the BfR has been delayed and is still pending.
- It is still possible to submit dossiers for missing pigments to the BfR; however, according to our experience the evaluation process takes a very long time. We see this as a significant obstacle, the evaluation of the dossiers is the bottleneck in the process, because only very few, in our estimation a maximum of 4 – 5 dossiers per year, are evaluated at the BfR. This national evaluation is an obstacle for the industry.

### **There is still the prospect of a European regulation**

According to numerous industry associations involved in the entire food packaging chain, only a European regulation can meet the requirements of the European internal market and ensure a uniform level of consumer protection. This view is also shared by the Bundesrat. In an accompanying resolution, the Bundesrat calls on the Federal Government to support the Commission in its review of the EU legal framework "*and to strongly advocate the development of a uniform European regulation*".

We welcome the resolution adopted by the federal states. In principle, the German Federal Government also recognises the priority of a European regulation. An extension of the transitional period is envisaged should the EU commission present a corresponding measure on printed food contact materials within this period. An EU-wide harmonised assessment practice (BfR, EFSA) is of considerable importance, especially for the raw materials, such as pigments and fillers, which are used in printing ink for the printing of food contact materials.

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<sup>3</sup> [BMEL - Lebensmittelverpackungen - Lebensmittelverpackungen und andere Lebensmittelbedarfsgegenstände](#)

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*The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e. g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e. g. silica), carbon black, ceramic and glass colours, food colourants, artists' and school paints, masterbatches and products for applied photocatalysis.*

*The VdMi is listed in the Lobbying Register for the Representation of Special Interests vis-à-vis the German Bundestag and the Federal Government (Lobbyregister des Deutschen Bundestags, number R000760) as well as in the Transparency Register of the EU Commission (number 388728111714-79).*