



## POSITION PAPER

### Impact of a German Printing Ink Ordinance on the single European market for packaged foods and beverages

Communication from the Commission – TRIS/(2016) 02044

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#### Executive summary

Inks are essential to the ability of pre-packaged food and beverage business operators to fulfill their legal duties to inform the consumer regarding composition of the product being sold.

On 5 July 2016, the draft of a German Regulation on printing inks, notified by the Federal Government (21st amendment of the Consumer Goods Regulation), was published within the TRIS procedure (TRIS (2016) 02044). The planned national legislation specifies the composition and application of printing inks for food contact materials and articles. It is based on national specific approval and listing of individual printing ink components which are allowed to be used for printing materials such as food packaging and articles for short-term food contact. Due to the very broad scope the flow of goods like food in printed packaging will be severely impacted within German, European and international supply chains. The European Food Packaging Supply Chain and the Food Packaging Industry fear severe disturbance of the internal market and ask Member States and the European Commission to react.

European industry is concerned that the German proposal sets a precedent for the safety of food contact material. If there is a need for specific and detailed legislative control of food contact components this should be done at the level of the European Union and in a harmonized way. Industry takes steps to ensure its responsibility for “safe food and in safe packaging” is met, but also needs conditions suitable for innovation and functioning of the European Single Market.

The European Food Packaging Supply Chain is in favour of a European Regulation on printing inks, provided it is proportionate, relevant and practical, but it opposes firmly any such measure on a national level. The Framework Regulation (EC) No 1935/2004 forms the basis on which such measure should be developed on the community level. Furthermore it is the role of EFSA to estimate scientific reasons and assessments as basis for an additional measurement on printing inks. Moreover, a national, unilateral Regulation is in general against the European Single Market and creates clearly discrimination of companies within the supply chain and avoidable cost and marketing burdens.

Added to that industry sees the following main issues with the drafted German Regulation and requests Member States and Commission to intervene in the TRIS process with urgency:

- The positive list of substances in the notified version is yet incomplete and according to industries analysis, amongst others, this would result in severe limitations to the process of modern flexo printing technology which accounts for about half of the food packaging printings (in volume). Similar restrictions would have to be anticipated in the low migration UV printing segment. Market upheavals, significantly reduction or loss of packaging materials, and in so far risks for food safety and as well immense costs are foreseeable. Time schedule and transparency of a subsequent listing of materials are not compatible with Directive (EU) 2015/1535
- The regulation does not contain any mutual recognition clause; the German Government states that due to consumer protection there is no general application of the principles of mutual recognition in terms of products which are compliant with requirements of Article 3 of Regulation (EC) No 1935/2004 but not in detail with the German law. Active marketing of such products from other member states require the administrative measure of § 54 of the German Food and Feed Code. This means an individual assessment and product approval by the German Bundesinstitut für Lebensmittelsicherheit und Verbraucherschutz (BVL). Accordingly the single market and free movement is failed even for products which are considered as safe under the perspective of harmonized EU Regulation.

Printing inks are an essential component of the packaging of foods and beverages. Food and beverage producers are legally required to provide the consumer with information<sup>1</sup>. For example:

- regarding ingredients used;
- the presence of certain additives or preservatives;
- the allergen status of a food product;
- specific labeling may be mandated regarding healthier choices.

Information provided by printing on packs is used to deliver compliance to these requirements.

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<sup>1</sup> Food Information to Consumers Regulation 1169/2011; Food Additive Regulation 1333/2008; UK Traffic Lights system

Food producers and their suppliers are obliged to ensure that existing requirements regarding food safety and quality are met. For printed packaging this is defined by Article 3 of the Framework Regulation on Food Contact Materials 1935/2004 and the GMP Regulation for Food Contact Materials 2023/2006. Supplier assurance and sector specific guidance are utilized to ensure high standards of consumer safety are maintained. This approach is able to adapt quickly to innovation and minimizes cost that would have to be passed to the consumer.

On 5<sup>th</sup> July 2016, a draft German Printing Ink Ordinance<sup>2</sup> was published to the TRIS database.

The draft ordinance has in scope all printed food contact materials, irrespective of whether the materials are printed on the non-food contact surface or the food contact surface of the material. Also in scope are materials which are not intended to come into contact with food, but which may come into contact with food for a short period of time, such as napkins. The ordinance aims to prevent unacceptable transfers of chemical substances from the print of a printed food contact material to the food. For this purpose, a list of substances is established which only may be used in the manufacture of printing inks for food contact materials, along with maximum tolerable amounts of these substances transferred to the food. Certain exemptions from the listing requirement are foreseen for substances used in printing inks applied on materials, where the print is not in direct contact with the food. The positive list is designed to be conclusive, which means it is applicable as such after a transitional period. The draft ordinance does not foresee provisional lists of substances which may also be used until the substances are finally evaluated and authorized for use (with the exception of a list of colourants used in printing inks for materials which may come into contact with food for a short period of time). Neither does the ordinance itself provide any rules for the future inclusion of substances on the list. Printed materials where the material constitutes an absolute barrier for substance transfer, such as glass or metal, are not in scope of the ordinance.

Different from previous drafts, the current draft does not stipulate obligatory Declarations of Compliance to be issued from one actor in the supply chain to the next. Nonetheless, relevant information must be exchanged along the chain to enable each actor in the chain to demonstrate compliance of the products within his area of responsibility with the relevant provisions of the ordinance.

Resulting from the very broad scope, the flow of goods at all stages of the food contact material supply and value chains is severely affected: from the manufacture of printing ink raw materials, printing inks, printed materials such as food packaging and items for short-term food contact (e.g. napkins, disposable tableware and retail packaging) through to food packed in printed packaging. The exchange of information in a complex supply chain, such as this one, is already very complicated. Adding new rules for the industry with ambiguous exchange of information requirement would demean the purpose and would not guarantee consumers' safety or boost consumers' confidence

The German Federal Government explicitly emphasizes two circumstances which are relevant for the assessment of the impact of a German regulation with regard to the marketability of non-

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<sup>2</sup> status: 24 June 2016; 21st ordinance amending the existing Consumer Goods Ordinance

compliant products from other countries, and therefore of highest importance for the impact on the internal market:

- *“For the sake of completeness, reference is moreover made to the fact that the draft Regulation itself does not contain any mutual recognition clause. This is already established in the comprehensive German Food and Feed Code in the version published on 3 June 2013 (see § 54 of the German Food and Feed Code; (...)) and also applies in this instance provided the corresponding prerequisites are in place, i.e. are not barred by compelling health protection reasons”*
- *The positive list is being continually extended provided the prerequisites in question are satisfied (other substances are also included during the notification procedure if the assessments in question can be completed)”*

### **Affected Products and Economic Power of the affected Industry Sectors**

Printed food contact materials are an indispensable medium for the entire added value chain in Europe and beyond. They are the material basis for the safe movement of foodstuffs; in particular, printed packaging serves the purposes of transport, storage, product protection, consumer information as well as the various product presentations.

The European Printing Ink Industry employs about 12,000 people. The turnover with printing inks for food contact materials amounts to 1700 million Euros in Europe. However, the impact will be much bigger when considering the entire supply chain of packaging producers, food companies, packfillers, wholesalers, retailers, etc.

### **The principle of Mutual Recognition in the European Union**

In the absence of harmonized Community rules, the principle of mutual recognition obliges the Member States to accept products on their domestic markets which have been lawfully manufactured and placed on the market in other Member States, even if for domestic products other technical rules apply, unless Member States suspend the principle for reasons of health and consumer protection. The application of the principle is governed by the procedures laid down in Regulation (EU) 764/2008, which however - according to studies conducted by the European Commission - are insufficiently observed by Member States, particularly with regard to foodstuffs.

As pointed out by the German Federal Government (see above), the principle of mutual recognition is laid down in § 54 of the Food and Feed Code. The German Federal Government informed that the notified Ordinance is based on Article 6 of the Framework Regulation (EC) No 1935/2004. It consequently holds the view that the general safety provisions set forth in Article 3 of the Framework Regulation are not generally sufficient to appropriately regulate printing inks for food contact materials.

This in turn means that for products in scope of the ordinance which are imported into Germany, the general freedom of the movement of goods does not apply even if they meet the general health requirements of Article 3 (1)(a) of the European Framework Regulation.

Products which do not comply with the national health protection requirements as stipulated by the draft German Printing Ink Ordinance are marketable only if a product-related assessment was applied for at and performed by the Federal Office of Consumer Protection and Food Safety (BVL) and if a general permission was granted provided that there are "no compelling health protection reasons" (procedures according to Section 54 subsection 2 LFGB).

The European food packaging supply chain holds the firm view that national legislation is detrimental to European businesses.

In a single market, there must be one harmonized legislation. Any national measure works against simplicity, coherence and enforceability.

Most of the companies of the food packaging supply chain operate on a pan-European or even global basis. The companies representing the different members of the supply chain operate across national boundaries and are characterized by a truly European identity and method of operation.

This implies that the flow of goods is extremely complex: It is common practice that a food contact material ink is manufactured in one Member State, sold to a converter in another Member State, who prints and sells the printed food contact material to a food packer in yet another Member State. The packed food is then sold across Europe, and enforcement authorities in the various Member States undertake controls. How should a manufacturer further up the chain know that his product finally ends up on the German market, and would have to comply with the Printing Ink Ordinance or would have to be granted a general permission according to §54 LFGB.) It is foreseeable that this does not work in practice.

It can be anticipated that other Member States would follow suit, and issue their own set of provisions for printing inks for food contact materials. Various national legal systems with different provisions for printings inks would cause severe problems.

The best example to illustrate the patch work is the comparison between the existing Swiss Ordinance on food packaging inks and the draft German ordinance which Germany initially stated they would copy. The Swiss Ordinance has in scope (and is restricted to) printing inks and varnishes applied to the non-food contact surface of food packaging. The draft German ordinance includes in scope also printing inks intended to come into direct contact with food (printing on the food contact surface) and expands the scope to food contact materials other than food packaging. Substances that migrate below 10 ppb and are not classified as CMRs may only be used for products marketed in Switzerland if they are listed in a special part of the Swiss positive list. The draft German Ordinance does not stipulate that these substances to be listed, which provides more freedom to formulate inks compliant with the requirements of the draft German Ordinance, but non-compliant with the Swiss provisions.

Heat seal coatings, cold seal coatings or coatings that fulfil purely protective functions (e.g. food contact can coatings) are out of the scope of the German ordinance. However, within the scope of the German ordinance are print lacquers which are applied in a printing or lacquering process on the food contact material and which are used to obtain the effect of marking, colouring, imaging or gloss or which are used to obtain adhesion or protection of the printing ink. If

lacquers with those properties are applied on the food contact side, these coatings are also covered by other national regulations, e.g. the Dutch Warenwet and the Belgian Coatings Regulation which do not distinguish between the purposes of an applied coating. As such, if Germany did not recognize the legislation of other Member States as valid for relevant materials within its own borders, then the provisions for this type of material would constitute an additional barrier to trade.

Another complication with legislation based on positive lists (such as the draft German ordinance), is the likelihood that key substances used in these inks are allowed in some countries and not in others. Equally so, national authorities may conclude on different acceptable amounts of a given substance transferred to the food, and fix these in their relevant positive lists. The question arises to which standards a printing ink manufacturer would have to formulate an ink, and to which standards a converter should produce a printed food contact material, if he wanted to trade in a single European Market.

Positive listing of substances requires prior petitioning for their authorization. If authorizations had only to be petitioned for the use of a substance in a printing ink in Germany, then this could lead to a situation where a substance manufacturer may refrain from applying for authorization merely because the future sales in Germany do not cover the costs. Likewise, if a substance would have to be authorized in several Member States under different national rules, then this would result in a multiplication of costs. In either case, the result is a loss of opportunities for food safety improvement through innovation.

In addition to the problems that industry would have to face, consumer trust in the safety of food contact materials would be at stake if different legislation were in place and applicable across Europe arousing the impression that different levels of safety would prevail.

For products from other Member States which do not comply with the German Ordinance on printing inks but which comply with the EU Regulation (Article 3 of the Framework Regulation) the German Food and Feed Code offers the option that the marketer can apply for a general permission by administrative measures.

In this case it does not really matter whether companies producing in or importing into Germany would opt to comply with the requirements of the Ink Ordinance or to apply for a general permission. In either case, they would have to comply with standards different from the rest of Europe leading to a disruption of the free movement of goods: Products marketed elsewhere in Europe have to comply with the general requirements of the Framework Regulation (EU) No 1935/2004 and the GMP Regulation (EU) No 2023/2006 only. As the German Ordinance sets additional specific requirements it results that products which can lawfully be marketed elsewhere in Europe, cannot be marketed as such in Germany.

Multinational operating manufacturers and trading firms specify food and its packaging for the entire EU according to EU law, irrespective of the member state in which the goods are actually sold. Separate German provisions regarding printing inks result in goods for Germany having to be packed separately. As a consequence, certain goods may no longer come to Germany or may be significantly more expensive in Germany.

Language barriers: Especially for SME companies the language barrier is an additional hurdle. The text of the relevant ordinance is only available in German. Germany notified and provided a translation into English of the Printing Ink Ordinance which however is not a stand-alone regulation, but an amending ordinance which cannot be understood without the knowledge of the context of the entire Consumer Goods Ordinance. Especially SME companies are likely not to have staff for assessing such a complex piece of legislation in a foreign language. How would they be able to comply? They would have to employ or commission experienced translators, or they are out of business. This constitutes a barrier to trade especially for small and medium sized companies.

The process of applying and obtaining a general permission is time consuming both for industry and authorities. Because of the broad range of products concerned (printing inks and printing ink raw materials, printed materials including packaging and issues such as napkins and disposable tableware as well as packaged food), the high number of marketers as well as the complexity and volume of the existing flow of goods, a high number of applications can be expected. How should the two relevant authorities handle and manage these applications legally and according to the requirements? What supporting arguments would be accepted by them for proof of safety of the imported printed material other than the provisions of the Printing Ink Ordinance?

### **Completion of the positive list**

The German Federal Government acknowledges that the positive list as annexed to the notified draft is still incomplete and concedes that more substances may be included during the notification process provided the relevant requirements are met. The positive list is the key element of the draft ordinance, as it determines the future composition of the printing inks, as well as the future printing conditions. It may even follow that costly changes of packaging designs must be performed if key printing ink raw materials were not available. The question arises how the European Commission and the Member States will ever be able to assess the extent of the impact of the ordinance if the positive list is not final? The European Printing Ink Industry Association EuPIA analyzed the positive list as annexed to the notified draft, and discovered that 138 priority substances which are currently used in the manufacture of printing inks, are missing from the positive list. Among these are 55 critical substances, which are widely used by the ink industry for various types of printing inks, and which all fulfill a specific function in the printing ink or the printing process such that they cannot be easily substituted, if they were not included in the positive list.

If these substances are not included on the positive list until the ordinance enters into force or becomes applicable, then this would have severe consequences for the printing of food contact materials.

For the printing of packaging mainly the following printing processes are used: flexography, rotogravure and sheetfed offset printing. For sheetfed offset printing, two types of printing inks are used: conventional printing inks (oxidatively drying or setting) or UV inks (Printing inks which are cured through UV radiation).

About 50% of all printed packaging is made using the flexographic printing technique. The vast majority of packaging printing companies are flexo printing companies.

In flexographic printing of food packaging, mostly solvent-based flexographic inks as well as UV inks are used. Currently 18 important solvents are missing from being positively listed. One of these solvents is, for example, iso propyl acetate; printing inks based on this solvent account for an added value of €50 Million only for the printing ink sector; the added value achieved with printed packaging based on this solvent is many times higher.

Also critical is the fact that among those solvents that have already been evaluated, the so-called “extreme retarders” are missing. In recent years these retarders have considerably gained importance for the flexo printing, as they support the technical progress of improving and refining the print image along with the optimization of the screen rollers and press technology. Retarders have the technical function of retarding the drying of the ink layer transferred in the printing press, which is extremely important in view of the ever thinner ink layers and corresponding reduced ink consumption. Therefore, these substances are indispensable for flexo printing.

Future non-availability of these retarders would cause serious injury to flexo printing as being such an important technique for the printing of food packaging, and would impede technical progress also in view of sustainability. As 50% of all food packaging is printed using this technology, a market volume amounting to billions is at stake.

A similar threat will be experienced by the UV technology. 15 photoinitiators that are currently in use are missing from the list. These photoinitiators are predominantly used in so-called “low migration” systems which have been specially developed to meet the high standards for food contact materials. They have all been risk assessed to be compliant with the framework regulation. If not listed, 50% of the current “UV low migration” market would be at stake.

The draft German Ink Ordinance includes in scope also articles which may come into contact with food for a very short time only, such as napkins. The ordinance stipulates that all substances used in inks to be printed on these articles have to be fully evaluated and subsequently positively listed. This is seen by industry as a disproportionate requirement: firstly, there is no unanimous view in Europe that these articles must be regarded as food contact materials (see Council of Europe Policy Statement concerning tissue paper, kitchen towels, and napkins), and secondly, given the short-term contact, if any, full evaluation of the substances used so as if they were intended to be in contact with food for a long or permanent period of time, is not proportionate. Except for a very few, the majority of substances used in these applications is missing from the positive list, and although a longer transitional period is foreseen, it is doubtful whether these substances will be able to be evaluated in time.

Given the above, it is not possible to conclusively assess the impact of the ordinance on grounds of the current positive list. From today’s perspective, well established and technically mature printing technologies would be severely restricted or even lost completely.

## **Verifications of Compliance**

The draft German Ordinance does not provide any specific testing methodology. In the absence of such methodology, it is expected that the conditions outlined in the Plastics Regulation will be used/specified. These conditions have been designed specifically for plastic food contact materials and are not appropriate for testing of migration from prints. For example, some of the liquid food simulants can penetrate the substrate and soften or dissolve the print, resulting in much higher migration than is seen in packed foods. It has also been seen that the higher accelerated testing scenarios using higher temperatures devised for plastics introduced from the beginning of 2016 give unrepresentative migration results, especially for printed food contact materials made from paper and carton board. This means that a migration limit of 10 ppb for substances used in accordance with §8 (7) of the draft ordinance, might only be achievable by limiting the storage time for printed food contact materials to only ten days (hence the packed food would ne to be removed or repacked before its shelf-life had expired).

## **Innovation**

The draft German Ordinance does not stipulate a procedure or mechanism for the inclusion of substances on the positive list. It is merely in the “official justification” which is not part of the legal text that the Federal Government addresses the amendment of the positive list: Petitions for changes or amendments of the positive list can be addressed to the Federal ministry of Nutrition and agriculture, which decides on the inclusion or not on the positive list after taking into consideration a statement by the Federal Institute of Risk Assessment BfR. If a positive decision for the inclusion of a substance on the positive list has been taken, then the actual inclusion of the substance on the positive list occurs through drafting an amending ordinance to the principal legislation, which is an onerous and slow process. In addition, it can be anticipated that a certain number of substances due to be included on the positive list will be collected, before issuing an amending ordinance will be regarded justifying the effort.

This leaves industry with an unacceptable uncertainty, as to whether a given substance for which the relevant dossiers have been prepared, will be accepted at all to be included on the positive list, and if accepted, according to which timelines the inclusion on the positive list takes place in order that the substance can be lawfully used. Neither the draft Ordinance nor the “official justification” gives any indication of such timelines.

The lack of defined procedures leads to severe delays of market access, and has also a negative effect on consumers, because opportunities for improvement of food contact material safety are lost.

## **Massive cost burden**

According to calculations of the food chain, consequential costs in the scale of EUR 660 million are anticipated in Germany alone. These include: the cost of creating the positive list an producing requisite scientific dossiers, adaptations of printing ink recipes and technical conversions, as well as testing and certification costs at all stages of the chain. These costs are

incurred irrespective of the requirement to issue formal Declarations of Compliance or not. Compliance with the requirements of ordinance will have to be demonstrated anyhow, and for this relevant information has to be generated and exchanged along the supply chain.

### **View of the European Food Packaging Supply Chain**

In the recent past, the European Food Packaging Supply Chain, as organized in the Packaging Ink Joint Industry Task Force, has approached the European Commission (letters of 27<sup>th</sup> February 2015 and 17<sup>th</sup> July 2015) highlighting the reasons why the draft German Ink Ordinance constitutes a disruption of the internal market, and had appealed to the Commission to adopt a specific European Regulation for Printing Inks for Food Packaging as a specific measure according to Article 5 of the Framework Regulation (EC) No 1935/2004.

### **Conclusion**

The European Food Packaging Supply Chain organized in the Packaging Ink Joint Industry Task Force (PIJITF) holds the firm view that the draft German Printing Ink Ordinance will lead to a severe disruption of the internal market.

A recent study by the European Parliamentary Research service (“European Implementation Assessment: Food Contact Materials-Regulation (EC) No 1935/2004”), based on a survey conducted among stakeholders including Member States and industry, came to the conclusion that principally food contact materials should follow harmonized rules and that the framework regulation forms the basis of such harmonization; however the current implementation is incomplete, and should be completed by the adoption of specific measures for those materials listed in Annex 1 to the Framework Regulation. In doing so, priority should be given to certain of these materials, and the vast majority of all stakeholders having participated in the survey opted for printing inks to be the No 2 priority. Any national measure such as the draft German Ink Ordinance is assessed to be detrimental to the functioning of the internal market.

The European Food Packaging Supply Chain calls on the European Commission to create and implement a European Regulation of Printing Inks for Food Packaging, within the context of the Framework Regulation (EC) No 1935/2004, which would be proportionate, relevant and practical, whilst ensuring consumer safety.