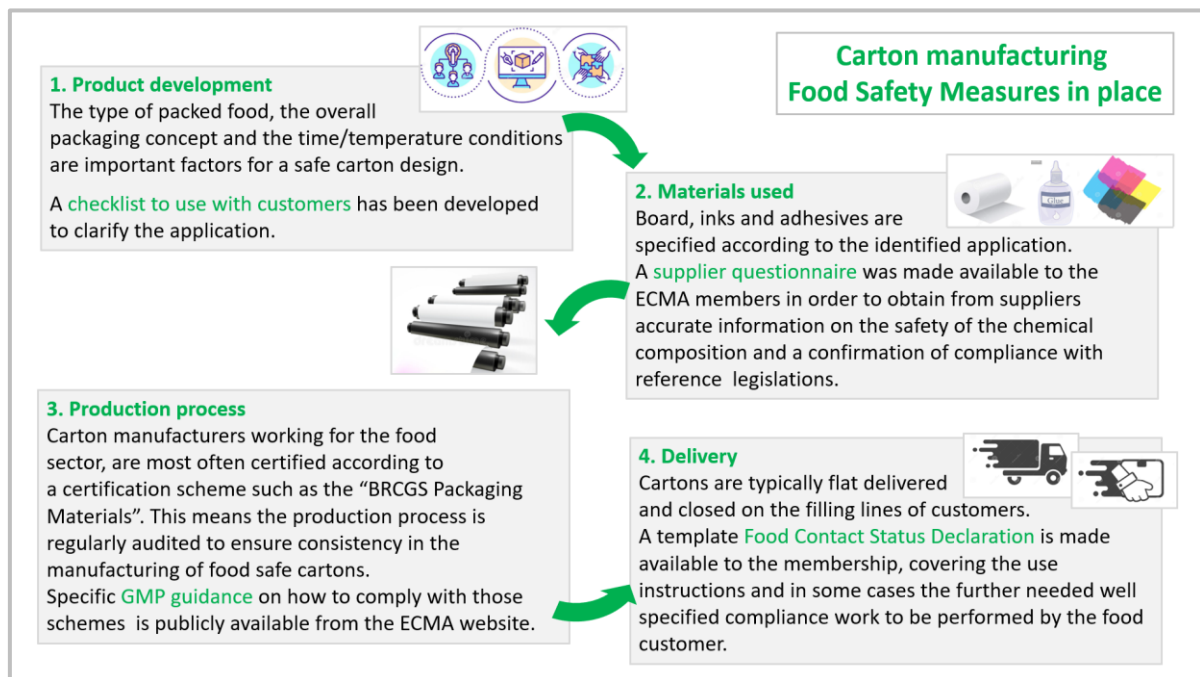


## Food Safety Infographic

Over the years, many guidance documents have been developed regarding the food safety of cartons. When explaining this guidance and the implemented measures to non-experts it is often not easy to provide a short, simplified overview.

In recent meetings, the ECMA Food Safety Committee made an attempt to develop such an overview in 4 steps, the product development, the materials used, the production process and the delivery to customers, with for these different steps - also highlighted in green - the available guidance documents. The slide below - which may be further adapted - will be made available in PowerPoint on the "Members Only" section of the ECMA website.



## German Printing Ink Ordinance (GIO)

As mentioned in the [FC update 02/09](#) and the Quarterly Update 2021 Q3 (8/11), the German Printing Ink Ordinance has been submitted to the Bundesrat.

The text (dated 18/08) was approved on 26/11 and the Federal Government will now publish the Ordinance soon. <https://dserver.bundestag.de/brd/2021/0655-21.pdf>

The **essence** of the Ordinance is a positive list of substances that may be used to manufacture printing inks that come into contact with food. Other substances may also be used if certain criteria are met and migration remains below 10 ppb.

The Ordinance provides for a transition period of 4 years and for some pigments of 5 years.

At meetings of the German Supply Chain and the Packaging Ink Joint Industry Task Force (PIJITF), the ink industry has urged that compliance with the Ordinance should not yet be required.

The ink manufacturers supply food safe FCM inks, but need the transition period to have the dossiers for a number of missing substances approved by the BfR. As stated in the FFI Circular Letter (30/11) inks and varnishes may also be reformulated in view of the GIO.

The German Food Industry Federation has pointed out the need for harmonised measures at European level in a position paper (29/11) and the PIJITF will similarly write once more to the Commission.

More background information from FFI is available on request.



## Food Contact Chemicals Database (FCCdb) - Prioritised substances

As indicated in the FC update 29/09, ECMA has submitted questions to CEPI, EuPIA and FEICA, the European associations representing the paper & board, the ink and the adhesive industries, regarding the 608 prioritised substances in a study by the Food Packaging Forum.

This prioritisation is based on authoritative sources (ECHA, Japan, Denmark, United Nations, US Environmental Protection Agency, Stockholm Convention, Californian Proposition 65) and takes into account both the health and environmental hazard, with the aim of further assessment and (if necessary) substitution in FCMs/FCAs.

As reported, the database indicates that of the prioritised substances, respectively 256, 377 and 147 are present in the inventories of substances for manufacturing paper and board, inks and adhesives.

ECMA asked about the actual use of the substances and how they are risk assessed by the suppliers, especially those not included in reference legislation.

Hereafter the first obtained reactions.

### CEPI

- The database is hazard-based and further risk assessment is indeed required.
- In paper and board manufacturing for food contact, the intentionally used substances are selected from positive lists contained in reference legislation. If other substances are used, the mill is responsible and information on risk assessment is typically included in the Declaration of Compliance.
- The questions raised need to be discussed in the Food Contact Coordination Group (FCCG), a platform in which paper and board production and converting industries are represented and in which ECMA is involved as a CITPA delegate.

In the same exchanges with CEPI, ECMA asked for background information regarding TiO<sub>2</sub> and the decomposition products of natural materials. (See FC update 29/09)

As in inks and plastics, CEPI confirmed TiO<sub>2</sub> is usually well embedded in the paper and board coating and does not tend to migrate. Very low levels may occur only in case of moist and fatty foods.

How should questions about the safety of lignine and hemicellulose decomposition products be addressed?

CEPI confirmed the sector has addressed this issue and the results show that everything is well under control, both environmentally and in terms of food safety.

### EuPIA

- From the association perspective it is not possible to provide, a status for each and every substance on the list, and information whether the substance is used or not and in which ink technology.
- General principles are helpful when dealing with the list:  
Substances on the Swiss list A have been assessed and are considered acceptable for use.  
The environmental hazardous properties of substances are not relevant for a health assessment. In well-run industrial premises there is no release into the environment.  
Substances present on REACH Annex XVII are used according to the restriction.  
POPs (Persistent Organic Pollutants) are legally prohibited.  
Substances on the REACH Authorisation list may only be legally used according to the authorisation.
- Taking in account the general principles, the number of substances is according to the EuPIA assessment reduced from 377 to 152 and this number can be further reduced based on the hazard classification and the EuPIA exclusion policy  
<https://www.eupia.org/our-commitment/eupia-exclusion-policy-for-printing-inks-and-rel> , as the CMR classification (Category 1A or 1B) is the most likely reason for identification as a SVHC, an Annex XVII restriction or an entry on Proposition 65.
- For the non-listed substances, EuPIA members follow the procedures described in the “EuPIA Guidance for risk assessment of non-intentionally added substances (NIAS) and non-listed substances (NLS) in printing inks for food contact materials.”  
<https://www.eupia.org/key-topics/food-contact-materials/risk-assessment>
- EuPIA members supply a statement of composition, which contains all relevant information on potential migrants (IAS and NIAS) as well as their official or self-derived SMLs.



### FEICA

- The method for putting the list together requires further explanation and especially the sources of information indicating all the listed substances are intended for use in adhesives is questioned. The inventory list seems not appropriate to FEICA.
- The majority of substances used in adhesives intended for food contact materials are either listed in Regulation 10/2011 or in national provisions. Self-assessments for non-listed substances might also be part of the compliance work, in accordance with the principles described in 10/2011.
- To allow downstream users to carry out a further risk assessment, relevant information on certain substances is provided in the food contact documentation.
- Adhesive companies also screen migratable substances with regard to new information on classification and labelling.

Although this database and the assessment made do not originate from public authorities, the information included is from official sources and fits somehow in the Chemicals Strategy for Sustainability. The policy, the Commission has in mind will aim at reducing exposure to the most harmful substances “CMR, EDC, PBT (Persistent, Bio accumulative and Toxic) and vPvB (very Persistent, very Bio accumulative)”. Ignoring the study results in a more vulnerable position, as NGO’s and customers are well aware of this initiative.

### **Bio assay study on paper and board packaging**

At its meetings of 14/07 and 8/10, the ECMA Food Safety Committee discussed the paper “Food contact materials: an effect-based evaluation of the presence of hazardous chemicals in paper and cardboard packaging” by Erica Selin et Al.

<https://www.tandfonline.com/doi/full/10.1080/19440049.2021.1930200>

The article published in June reports on a bioassay study for 67 food packages taken from the Swedish market.

For a number of extracts analysed (cereal boxes, pizza-boxes, cake/pastry, infant formula, porridge and flour mixes), the outcome of the oxidative stress testing was above the safe cut off level, especially for the highest concentrations.

Four extracts were further analysed and the results indicate the presence of genotoxic substances.

Especially for the pizza-box extract, the genotoxicity signal is considered as high, which may be due to the inks, coatings and the use of a standard recycled substrate.

The scientific article on this study also reports on other endpoints, oestrogenic response, androgenic effects and the aryl hydrocarbon receptor activity and refers to certain categories of substances that may be responsible for the bioassay response.

This study brought also a good opportunity to revisit the value of bio assay testing.

Back in 2017 (FC update 21/08 2017), the FS Com had a meeting with Bio Detection Systems in Amsterdam and at that time bioassay testing was presented by BDS as a cost-effective approach e.g., widely used in the pharma sector.

In later FS Com meetings (2019) it was reported how those tests are sensitive enough to certain substances such as EDCs but not to genotoxicity. It would be particularly interesting to be able to demonstrate the absence of genotoxicity, as this would allow the TTC Cramer Class III limit (90 µg/person/day) to be used instead of 10 ppb or below when evaluating gas chromatograms.

In an updated assessment (08/10/2021) of the value of bio assay testing, the ECMA Food Safety Committee recommends to be very careful when using bioassay testing for natural materials.

Trees, in the course of their evolution, have learned to protect themselves against bacteria and fungi, which means toxic compounds may be present in a tree, as for instance in broccoli.

The use of bioassays for complex product constructions also leads to results of which you do not know where the response comes from. Is the result coming from one substance with a high response or from many substances with a low response? Bio assay testing can however be helpful at the substance level or for known mixtures.

