



Printed paper and board food contact materials as a potential source of food contamination



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ABSTRACT

Food contact materials (FCM) are estimated to be the largest source of food contamination. Apart from plastics, the most commonly used FCM are made of printed paper and board. Unlike their plastic counterparts, these are not covered by a specific European regulation. Several contamination issues have raised concerns towards potential adverse health effects caused by exposure to substances migrating from printed paper and board FCM. In the current study, an inventory combining the substances which may be used in printed paper and board FCM, was created. More than 6000 unique compounds were identified, the majority (77%) considered non-evaluated in terms of potential toxicity. Based on a preliminary study of their physicochemical properties, it is estimated that most of the non-evaluated single substances have the potential to migrate into the food and become bioavailable after oral intake. Almost all are included in the FACET tool, indicating that their use in primary food packaging has been confirmed by industry. Importantly, 19 substances are also present in one of the lists with substances of concern compiled by the European Chemicals Agency (ECHA). To ensure consumer safety, the actual use of these substances in printed paper and board FCM should be investigated urgently.

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1. Introduction

Food contact materials (FCM) are defined by the European Food Safety Authority (EFSA) as “all materials and articles intended to come into contact with food”. FCM are thus routinely involved

Abbreviations: 4MBP, 4-methylbenzophenone; CEPI, Confederation of European Paper Industries; CLP, Classification, Labelling and Packaging; CMR, Carcinogenic, Mutagenic or Reprotoxic substances; COC, chemicals of concern; CoE, Council of Europe; CoRAP, Community Rolling Action Plan; EC, European Commission; ECHA, European Chemicals Agency; EFSA, European Food Safety Authority; EFTA, European Free Trade Association; ESCO WG, EFSA Scientific Cooperation Working Group; EuPIA, European Printing Inks Association; FACET, Flavours, Additives, and food Contact materials Exposure Tool; FCM, food contact materials; FDA, Food and Drug Administration; IITX, 2-isopropylthioxanthone; NIAS, non-intentionally added substances; OML, overall migration limit; PBT, Persistent, Bioaccumulative and Toxic substances; RASFF, Rapid Alert System for Food and Feed; RCR, Risk Characterisation Ratio; REACH, Registration, Evaluation, Authorisation and restriction of Chemicals; SML, specific migration limit; SVHC, Substances of Very High Concern; vPvB, very Persistent and very Bioaccumulative substances.

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throughout the production, processing, packaging, transport, storage, preparation and serving of food and beverages (EFSA, 2015; European Union, 2015a). Regulation (EC) No 1935/2004 depicts 17 FCM groups including plastics, paper and board, glass, but also printing inks, coatings and adhesives used in product finishing. They should all be sufficiently inert, so that constituents cannot exert any negative effect neither on consumer health nor food quality (European Union, 2004). Migration of FCM substances into food and subsequent consumer exposure has been a concern since several decades and is estimated to be the largest source of food contamination, up to 100–1000 times higher than contamination originating from pesticide residues or environmental pollution (Grob et al., 2006).

In the European Union, general requirements for FCM are described in Reg. (EC) No 1935/2004, but few harmonised legislations exist for the individual FCM types. Targeted regulations or directives have so far only been established for plastic materials [Reg. (EU) No 10/2011] (European Union, 2011), recycled plastic materials (European Union, 2008), ceramics (European Communities, 1984), active and intelligent materials (European Union, 2009) and regenerated cellulose film (European Union,

2007). This implies that the vast majority of FCM is not subject to a specific EU legislation. Moreover, only Reg. (EU) No 10/2011 on plastic FCM comprises a Union List of authorised substances. FCM legislation across the European Member States is divergent regarding both scope and limit settings. National legislation is in place in 19 Member States, but none of these cover all materials and detailed requirements are rarely set (European Union, 2012; 2015b).

Whereas migration issues in the past were predominantly related to plastics (e.g. bisphenol A), an increasing number of food crises nowadays originate from non-plastic compounds (EFSA, 2011a). In 2005, the Italian authorities notified through the Rapid Alert System for Food and Feed (RASFF) the occurrence of 2-isopropylthioxanthone (ITX) in liquid milk for babies, packaged in printed cardboard, at a concentration of 250 µg/L. ITX is a photoinitiator frequently used as a catalyst in the manufacturing of UV-cured inks. Given the very limited toxicological data on this substance, establishing the level of safety concern and the subsequent development of risk management options was a challenging task (EFSA, 2005). A second example is the RASFF notification of 4-methylbenzophenone (4MBP) by multiple Member State authorities in 2009. 4MBP, another photoinitiator, was found in breakfast cereals in concentrations up to 3728 µg/kg. Since insufficient toxicological information was available for 4MBP itself, the preliminary safety evaluation was based on a read-across approach with benzophenone and hydroxybenzophenone, two structurally related substances for which more experimental results could be consulted (EFSA, 2009). In the case of both ITX and 4MBP, EFSA concluded that short term exposure to these substances does not pose a risk to the majority of the population. However, if their use was intended to be continued, more data should be provided to allow a full risk assessment. These examples clearly illustrate that more information regarding non-plastic FCM is urgently needed in order to guarantee the safety of packed food products and prevent food crises in the future.

Printed paper and board cover a large part of the non-plastic FCM. Specifically for food packaging, these materials are used very frequently. Indeed, 90% of all manufactured foodstuffs are sold in printed package (Lago et al., 2015), whereas paper and board have been the most important packaging materials since years (Leks-Stepien, 2011). For obvious reasons, industry does not communicate detailed information on substance usage. Through the EU-funded Flavourings, Additives, and food Contact materials Exposure Tool (FACET) project, however, information on relative substance use was provided by 13 European FCM trade associations. The resulting information was collected in a freely available software tool that contains the substances confirmed to be used in the manufacturing of primary packaging FCM (Hearty et al., 2011).

In the present study, both printing inks and paper(board) used in FCM applications were investigated as a potential source of food contamination. To this extent, an inventory was created combining all substances which may be used in printed paper and board. Next, the evaluation status of these substances was examined as this has an important impact on their safety assessment. Substances for which a toxicological evaluation has been performed are considered to be safe in case their migration does not exceed the established migration limit (European Union, 2011). In contrast, non-evaluated substances that are able to migrate into the food and that are bioavailable, are assumed to be of potential concern for human health. Physicochemical data linked to migration and bioavailability potential were collected for the non-evaluated single substances. To obtain an indication of their actual use, the FACET tool was consulted for the compounds with the potential to migrate into food and become bioavailable after oral intake. For those compounds that were present in the FACET tool, inclusion in

different lists with substances of (potential) concern compiled by the European Chemicals Agency (ECHA) was verified. Based on this information, a high priority list was obtained containing non-evaluated substances for which the actual use in printed paper and board FCM should be urgently investigated.

2. Materials and methods

2.1. Compilation of the combined inventory

A combined inventory of substances known and used in printed paper and board FCM was compiled based on a variety of freely available documents listing substances that can be used in printing inks or paper(board) for FCM applications. They are described in detail below.

■ Swiss Ordinance on Materials and Articles in Contact with Food: Annex 6 (Swiss list)

Switzerland, as member of the European Free Trade Association (EFTA), has adopted a specific legislation on printing inks used in FCM. The Swiss Ordinance on materials and articles in contact with food [RS 817.023.21] (Swiss Confederation, 2005) stipulates that packaging inks may only be manufactured from the substances set out in annexes 1 and 6 of the Ordinance. Annex 1 recites substances that can be used as monomers or other starting products (list I), additives (list II) and particular requirements (list III) for the fabrication of plastic materials and articles. Annex 6 sums up the permitted substances for the manufacture of packaging inks, categorised by their function, i.e. binders (list I), dyes and pigments (list II), solvents (list III), additives (list IV) and photoinitiators (list V).

Each list in annex 6 is further subdivided into parts A and B, with part A containing the evaluated substances that have been subjected to officially recognised scientific testing (e.g. by EFSA) and part B containing the substances for which this is not the case. The global migration limit of the substances in part A is set at 10 mg/dm² or 60 mg/kg, unless a specific migration limit (SML) is mentioned. The SML indicates the maximum amount of a substance allowed to migrate into food, whereas the global migration limit is the default value assigned to the FCM as a whole. The use of substances in part B is permitted if no transfer to food or food simulants can be detected in a migration test in the lowest possible concentration at which it may be detected applying a valid method of analysis. In no case, the detection and migration level of 0.01 mg/kg food or food simulant may be exceeded. Both the results of practical experiments and “worst case” calculations are accepted to estimate migration. The use of unlisted packaging ink substances must be reported to the Swiss authorities prior to marketing.

■ Resolution of the Council of Europe on paper and board materials and articles intended to come into contact with foodstuffs (CoE list)

The Council of Europe (CoE) has compiled resolutions for several non-plastic FCM including paper and board. These policy statements are meant to serve as a guidance in case no specific regulation is adopted for a particular FCM group. Resolution ResAp (2002)1 (Council of Europe, 2009) is completed by five Technical Documents, of which the first contains a list of additives that may be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs. The list is further divided in sublists 1 and 2.

Substances in list 1 of Technical Document 1 are approved (assessed), while substances in list 2 are not approved (not yet

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