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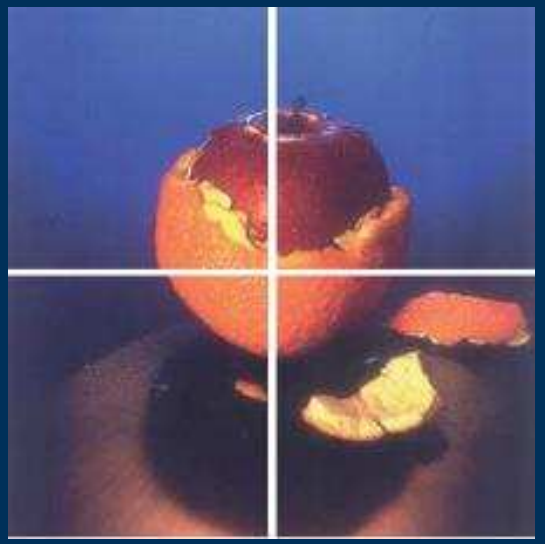

Legislation and guidelines for migration and safety evaluation

Mª do Céu Selbourne, Srishti Singh, Fátima Poças

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FROM
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TO
FOREST

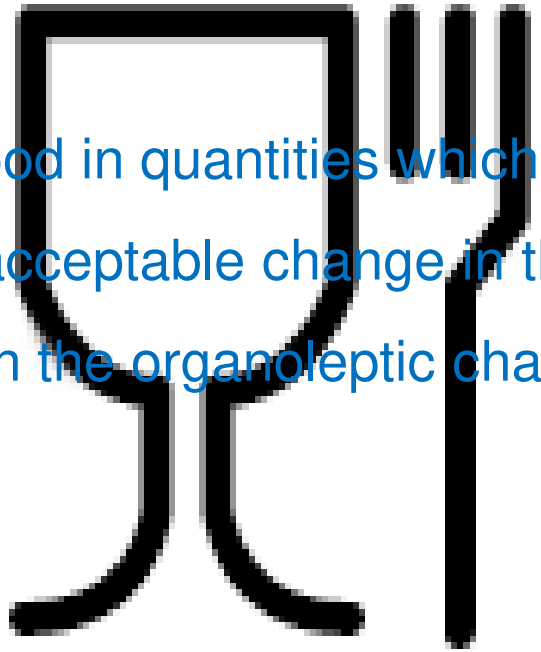
Topics

- Compliance with requirements of Reg. 1935/2004 and Reg. 2023/2006
- Paper and board for food contact – general requirements
- Guidelines and Non-harmonised legislation
- Safety validation of substances: assessment tools
  - Example: Octadecenyl succinic anhydride (18-ASA)

Compliance with Reg. 1935/2004

Reg. 1935/2004 - Article 3 - safety

No transfer their constituents into food in quantities which could endanger human health or bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof.



Compliance with Reg. 1935/2004

Reg. 1935/2004 - Article 15 - Labelling

Food contact materials and articles not yet in contact with food when placed on the market shall be labelled in accordance with Article 15 or relevant national legislation to ensure safe and appropriate use. The label shall be sufficiently clear to avoid any misuse or misinterpretation. It shall not mislead consumers and not rule out reasonably foreseeable uses of repeated use articles.

Compliance with Reg. 1935/2004

Reg. 1935/2004 - Article 17 - Traceability

The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

Compliance with Reg. 1935/2004

Reg. 1935/2004 - Article 16 - Declaration of Compliance

The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them. In the absence of specific measures, this Regulation shall not prevent Member States from retaining or adopting national provisions for declarations of compliance for materials and articles.

Compliance with Reg. 1935/2004

Reg. 1935/2004 - Article 5 - Specific measures for groups of materials and articles

…specific measures may be adopted or amended by the Commission:

List of substances authorized, purity standards, special conditions of use, overall and specific limits on the migration, rules to ensure compliance…

NO SPECIFIC MEASURE FOR PAPER AND BOARD!!!

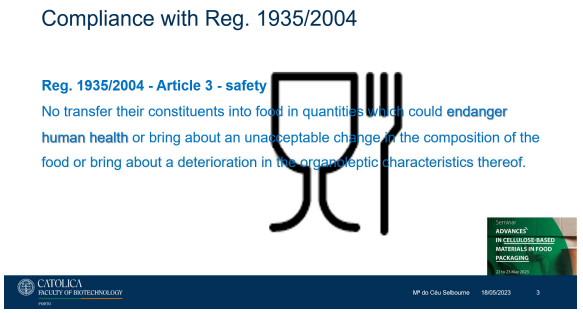
Compliance with Reg. 2023/2006

Reg. 2023/2006 - on good manufacturing practice

If appropriate, guidelines on good manufacturing practice developed by trade and producer associations can also be taken into account without prejudice to any applicable member State legislation.

P&B for food contact – general requirements

- Comply with Regulation (EC) No. 1935/2004 and Regulation (EC) No. 2023/2006, or with relevant national legislation.



- Food business operators shall ensure that they use FCM materials and articles during food production or preparation, storage and distribution in a way that does not compromise compliance with applicable EU and member States' legislation or recommendations for food contact materials and articles.

P&B for food contact – general requirements

1. Substances **may only be used after risk assessment** has been performed; assessment includes consideration of impurities, reaction and/or degradation products.
2. Substances **can be used in compliance with any restrictions applicable to them, if they meet any of the following criteria**:

    2.a) They are **approved by competent authorities** of member States concerned, in accordance with the procedures for the elaboration of **lists of officially evaluated substances**; or

    2.b) They are use **in compliance with material-specific provisions in EU or national legislation or official recommendations**; or

    2.c) **Absence of their release into food**

In CoE/EDQM from 2021 Resolution ResAP (2020) 9

P&B for food contact – general requirements

Substances, their impurities and known or foreseeable reaction or degradation products that meet criterion 2.c) "**Absence of their release into food**" and belong to any of the following categories,

- Substances in nano-form
- Substances CMR
- Substances genotoxic or predicted to be genotoxic using (Q)SAR models; no data is available confirming absence of genotoxicity,

demonstrating absence of release is not sufficient

risk assessment must be performed!

P&B for food contact – general requirements

When none of the criteria 2.a), 2.b) and 2.c) is met and without prejudice to applicable European and **national provisions**, substances may be used in the manufacture of food contact materials and articles, if they are **risk-assessed** by or on behalf of the responsible business operator and in compliance with Article 3 of Regulation (EC) No. 1935/2004 or relevant national legislation.

In CoE/EDQM from 2021 Resolution ResAP (2020) 9

Guidelines and Non-harmonised legislation

There are in total 10 member states with national legislation or instructions on P&B FCM.

- BFR Rec. XXXVI. Paper and board for food contact
- The Netherlands: Warenwet Hoofstuk
- Italy: Decreto Ministeriale
- Belgium: Decree Arrête Royal
- France: DGCCRF Regulation

BfR Recommendation https://www.bfr.bund.de/cm/349/XXXVI-Paper-and-Board-for-Food-Contact.pdf
Warenwet Hoofstuk II- Papier en Karton
Decreto ministeriale 21.03.1973 e relativi aggiornamenti e modifiche
Decree Arrete Royal du 11 MAI 1992 concernant les matériaux et objets destinés à entrer en contact avec les denrées alimentaires
DGCCRF "Aptitude au contact alimentaire des matériaux organiques à base de fibres végétales destinés à entrer en contact avec des denrées alimentaires Fiche MCDA n°4 (V02 – 01/01/2019)

Guidelines and Non-harmonised legislation

- FDA (USA regulations title 21CFR)
  - 176:170: P&B in contact with aqueous and fatty foods
  - 176.180: P&B in contact with dry food
  - 176.260: Pulp from reclaimed fibre

USA Food & Drug Administration CFR Title 21, Subpart B “Substances for Use Only as Components of Paper and Paperboard”

- Guidelines CEPI (Confederation of European Paper Industries)
- CoE/EDQM (European Directorate for the Quality of Medicines & HealthCare) from 2021 Resolution ResAP (2020) 9 Part II. Technical guide

https://www.cepi.org/wp-content/uploads/2020/09/Food-Contact-Guidelines_2019.pdf
https://www.edqm.eu/en/paper-and-board-used-in-food-contact-materials-and-articles

BfR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Germany BFR – general considerations

- No preservative effect on the foodstuff (EN 1104 Transfer of antimicrobial constituents)
- Cd, Pb and Al restrictions (EN 12497 and 12498 Determination of mercury, cadmium, chromium and lead in an aqueous extract)
- Azo dyes must not be used
- Optical brighteners must not migrate (EN 648 Fastness of fluorescent whitened paper and board)
- Colour must not migrate (EN 646 Colour fastness of dyed paper and board)
- Primary aromatic amines my not be release in a detectable amount
- Establishes migration limits for contaminants from recycled fibres

Germany BFR – list of substances

BFR Rec. XXXVI. Establishes lists of substances for raw materials (fibrous materials, filers), for the production aids and for paper refining agents for P&B intended for use at temperatures up to 90 ºC.

A. Raw materials
- I. Fibrous materials
- II. Fillers

B. Production aids
- I. Sizing agents
- II. Precipitating, fixing and parchmentisation agents
- III. Retention agents
- IV. Dewatering accelerators
- V. Dispersion and flotation agents
- VI. Defoamers
- VII. Slimicides
- VIII. Preservatives

C. Special Paper refining agents
- I. Wet-strength agents
- II. Humectants
- III. Colorants and optical brighteners
- IV. Surface refining and coating agents

Germany BFR – list of substances and restrictions

Example: B. Production aids

I. Sizing agents:

1. Colophony, addition products of maleic and fumaric acid and/or of formaldehyde with colophony. No more than 1.0 mg formaldehyde/ dm^2 must be detectable in the extract of the finished product.
2. Casein and animal glue
3. Starch[12]

   3.1 Native[13] starch, physically modified starch, enzymatically modified starch and acid-treated starch, as well as the chemically modified starches listed in Regulation (EU) No. 1333/2008, Annex II, Part B

FDA


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USA: FDA Regulation – list of substances

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

Substances identified in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods, subject to the provisions of this section. Components of paper and paperboard in contact with dry food of the type identified under Type VIII of table

(2) Substances generally recognized as safe for their intended use in paper and paperboard products used in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances that by regulation in parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.

(5) Substances identified in this paragraph, as follows:

List of Substances	Limitations
Acetyl peroxide	For use only as polymerization catalyst.
Acrylamide-methacrylic acid-maleic anhydride copolymers containing not more than 0.2 percent of residual acrylamide monomer and having an average nitrogen content of 14.9 percent such that a 1 percent by weight aqueous solution has a minimum viscosity of 600 centipoises at 75 °F, as determined by LVG-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 30 r.p.m.	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such an amount that the finished paper and paperboard will contain [illegible] not in excess of [illegible] percent by weight of dry fibers in the finished paper and paperboard.
Acrylamide-β-methacrylyloxyethyltrimethylammonium methyl sulfate copolymer resins containing not more than 1[illegible] molar percent of β-methacrylyloxyethyltrimethylammonium methyl sulfate and containing less than 0.2% of residual acrylamide monomer.	For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
Acrylic acid, sodium salt copolymer with polyethyleneglycol allyl ether (CAS Reg. No. 86830–15–1).	For use only in paper mill boilers.

USA: FDA Regulation – list of substances

Styrene-isobutylene copolymers (weight average molecular weight not less than 6,300).	For use only in coatings for paper and paperboard intended for use in contact under conditions of use D G described in table 2 of paragraph (c) of this section, with food of Types I, II, IV-B, VI-B, VII-B, and VIII described in table 1 of paragraph (c) of this section; and limited to use at a level not to exceed 40 percent by weight of the coating solids.
Styrene-maleic anhydride copolymers	For use only as a coating or component of coatings and limited for use at a level not to exceed 2 percent by weight of paper or paperboard substrate.
Styrene-methacrylic acid copolymers containing no more than 5 weight percent of polymer units derived from methacrylic acid.	
Styrene-vinylidene chloride copolymers containing not more than 40 weight percent of vinylidene chloride in the finished copolymers. The finished copolymers may contain not more than 5 weight percent of total polymer units derived from acrylic acid, fumaric acid, itaconic acid, and/or methacrylic acid.	For use only as coatings or components of coatings.
2-Sulfoethyl methacrylate, sodium salt [Chemical Abstracts Service No. 1804–87–1].	For use only in copolymer coatings under conditions of use E, F, and G described in paragraph (c) of this section, table 2, and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.

USA: FDA Regulation – testing conditions

(c) The food-contact surface of the paper and paperboard in the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of this paragraph, shall yield net chloroform-soluble extractives (corrected for wax, petrolatum, mineral oil and zinc extractives as zinc oleate) not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in paragraph (d) of this section.

TABLE 1—TYPES OF RAW AND PROCESSED FOODS

I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
IV. Dairy products and modifications:
A. Water-in-oil emulsions, high- or low-fat.
B. Oil-in-water emulsions, high- or low-fat.
V. Low-moisture fats and oil.
VI. Beverages:
A. Containing up to 8 percent of alcohol.
B. Nonalcoholic.
C. Containing more than 8 percent alcohol.
VII. Bakery products other than those included under Types VIII or IX of this table:
A. Moist bakery products with surface containing free fat or oil.
B. Moist bakery products with surface containing no free fat or oil.
VIII. Dry solids with the surface containing no free fat or oil (no end test required).
IX. Dry solids with the surface containing free fat or oil.

TABLE 2—TEST PROCEDURES WITH TIME TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM THE FOOD-CONTACT SURFACE OF UNCOATED OR COATED PAPER AND PAPERBOARD, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Condition of use	Types of food (see table 1)	Food-simulating solvents			
		Water	Heptane[1]	8 percent alcohol	50 percent alcohol
		Time and temperature	Time and temperature	Time and temperature	Time and temperature
A. High temperature heat-sterilized (e.g., over 212 °F).	I, IV-B, VII-B	250 °F, 2 hr			
	III, IV-A, VII-A	do	150 °F, 2 hr		
B. Boiling water sterilized	II, VII-B	212 °F, 30 min.			
	III, VII-A	do	120 °F, 30 min.		

Guidelines


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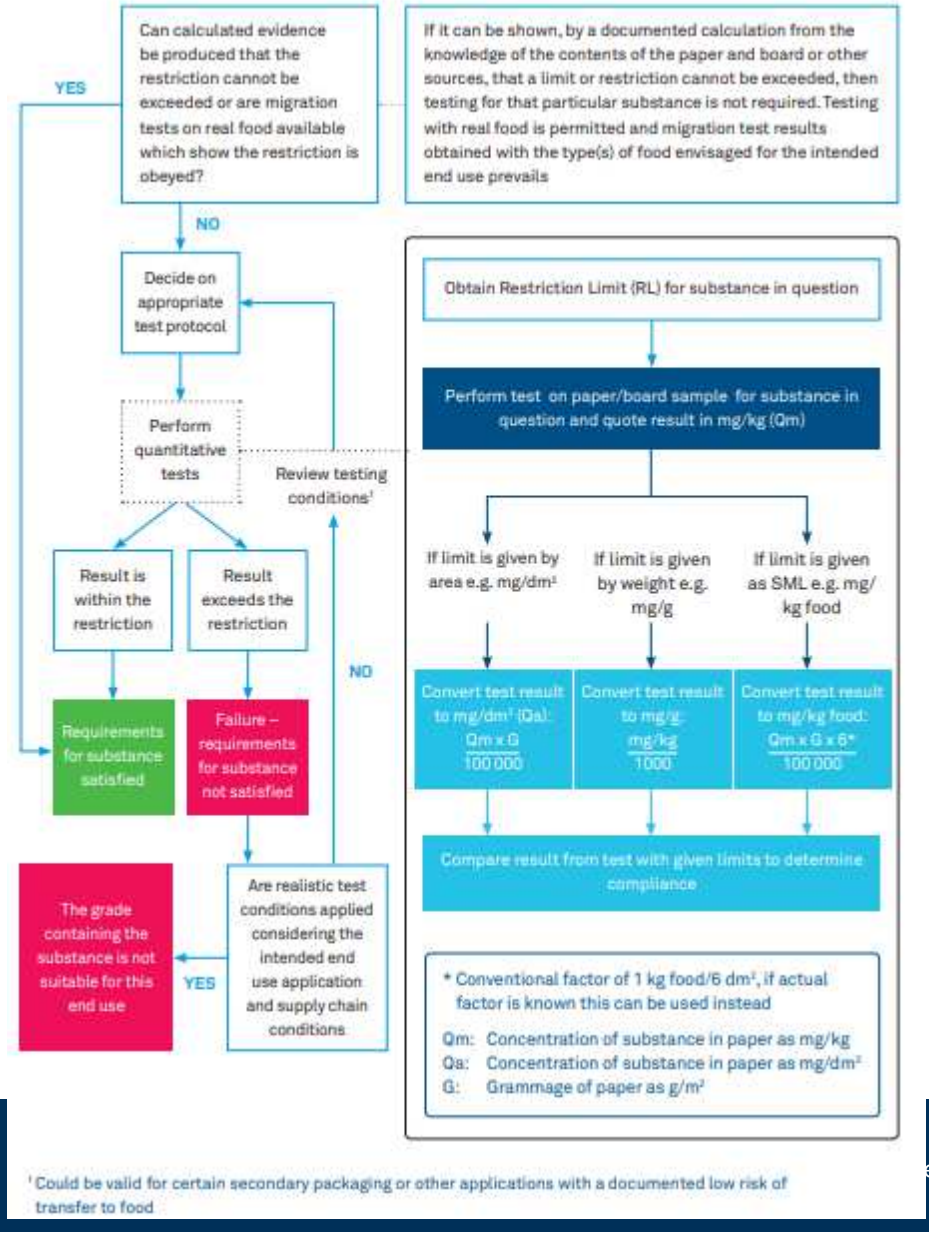
Guidelines

- Substances intended used
  - Lists from other referential documents
- Substances not intentionally used (NIAS)
  - Criteria for virgin fibre
  - Criteria for recycled fibre

CEPI Guidelines

Testing framework



CEPI Guidelines

TABLE 1: TESTING RECOMMENDATIONS FOR KNOWN NIAS

NIAS REQUIREMENTS FOR ALL PAPER/BOARD GRADES IRRESPECTIVE OF FIBRE SOURCE					
Substance	Requirement		Source	Method	Food type
	QMA[a]	SML[b]			
NIAS in intentionally added chemicals according to information from suppliers	According to communication from suppliers	According to communication from suppliers	According to communication from suppliers		According to communication from suppliers
Cadmium (Cd)	5 ug/l cold water extract 0.5 mg/kg paper or board	–	DE:BfR XXXVI[7] FR: DGCCRF[30]	EN 12498[30] EN 12498	Moist and/or Fatty Moist and Fatty
Lead (Pb)	10 ug/l cold water extract 3 ug/dm2 paper or board 3 mg/kg paper or board	–	DE:BfR XXXVI IT: DM 21.03.73[32] FR: DGCCRF	EN 12498 Allegato IV Sez VI.5.2 EN 12498	Moist and/or Fatty All Moist and/or Fatty
Mercury (Hg)	0.3 mg/kg paper or board	–	FR: DGCCRF	EN 12497[33]	Moist and/or Fatty
Chromium (CrVI)	0.25 mg/kg paper or board	–	FR: DGCCRF	EN 12498	Moist and/or Fatty
Pentachlorophenol (PCP)	0.1 mg/kg paper or board	–	FR: DGCCRF	EN-ISO 15320[34]	All
Antimicrobial substances	The finished paper or paperboard must have no preserving effect on the foodstuffs with which they come into contact.	–	DE:BfR XXXVI FR: DGCCRF	EN 1104[35] EN 1104	All All

[a] Maximum permitted content in paper or board expressed as mg/kg paper or board or as mg/dm^2 paper or board

[b] Maximum permitted transfer to food expressed as mg/kg food

CEPI Guidelines

NIAS REQUIREMENTS ONLY RELEVANT FOR PAPER/BOARD GRADES USING RECYCLED FIBRE PULP					
Substance	Requirement		Source	Method	Food type
	QMA	SML			
Polychlorinated Biphenyls (PCBs)	2 mg/kg paper or board 2 mg/kg paper or board	–	IT: DM 21.03.73 FR: DGCCRF	EN-ISO 15318[36] EN-ISO 15318	All All
4,4,-bis(dimethylamino)-benzophenone (Michlers ketone)	–	0.01 mg/kg food	DE:BfR XXXVI	Castle et al[37]	Moist and/or Fatty
Azo colourants/Primary Aromatic Amines (PAAs)	–	0.01 mg/kg food (sum of PAAs)[a] 0.002 mg/kg food (Individual PAAs)	DE:BfR XXXVI	prEN 17163[38]	All
Colour fastness[b c] (Dyes and Colourants)	No migration of colourants to the foodstuff (Value 5 acc. to EN 646)		DE:BfR XXXVI IT: DM 21.03.73 FR: DGCCRF	EN 646[39] EN 646 EN 646	Moist and/or Fatty
Fastness of fluorescent whitening agents (FWAs, OBAs)[b c]	No migration of OBAs/ FWAs to the foodstuff (Value of 5 acc. to EN 648)		DE:BFR XXXVI IT: DM 21.03.73 FR: DGCRF	EN 648[40] EN 648 EN 648	Moist and/or Fatty
Dibutylphthalate (DBP)		0.3 mg/kg food	DE:BFR XXXVI	EN 16453[41]	All
Diisobutyl phthalate (DIBP)		0.3 mg/kg food	DE:BFR XXXVI	EN 16453	All
Di(2-ethylhexyl)phthalate (DEHP)		1.5 mg/kg food	DE:BFR XXXVI	EN 16453	All
Sum DBP-DiBP		0.3 mg/kg food	DE:BFR XXXVI	EN 16453	All
Benzophenone		0.6 mg/kg food	DE:BFR XXXVI	Castle et.al[42]	All

[a] Sum of listed amines acc. to Regulation (EC) No 1907/2006 Annex XVII Appendix 9

[b] If colourants /Dyes or FWAs are intentionally added to paper and board this testing is mandatory also for paper and board solely made from fresh fibres.See 3.2.2 above

[c] For tissue materials and articles a value of 4 is acceptable

CEPI Guidelines

Sum: Benzophenone + 4-methybenzophenone		0.6 mg/kg food	DE:BFR XXXVI	Castle et al	All
Diisopropylnaphthalenes (DIPN)	As low as technically achievable		DE:BFR XXXVI	EN 14719[43]	All
Bisphenol A (BPA)	n.d. /2 mg/kg paper or board[d]	0.24 mg/kg food	DE:BFR XXXVI FR: DGCCRF	prEN[e] FR: Acetonitrile extraction 23°C, 24 h[44]	Moist and/or Fatty FR: All food types
Polyaromatic Hydrocarbons (PAHs)		0,01 mg/kg food[f]	EFSA, BFR	prEN	All

[d] Requirement : Shall not be present. 2 mg / kg is an indicative threshold for recycled materials which if exceeded will not result in non-compliance

[e] Work in progress, EN standards under preparation by CEN TC 172, WG3.

[f] Sum of listed PAHs according to EN standard under preparation.

Notes for Table 1

1	The reason for some limits being quoted in units of weight/weight, weight/volume of extract and some in weight/kg food is the different sources for the limits. In practice, an analytical measurement will give a weight/weight result. A conversion to weight/surface area using the actual grammage of the paper and board will be required for comparison with limits expressed as weight/food. (See note in Figure 1 in Chapter 5.3.1 of this Section.)
2	If it is assumed that complete migration of a substance occurs from the paper and board to the food (worst case scenario) it is possible to convert limits in food (SMLs) to a total quantity of the substance in paper and board. The standard packaging/food ratio in EU risk assessment of migration is 6 dm2 packaging material in contact with 1 kg food. Using this "standard" ratio, the SML should be multiplied by 0.167 (or divided by 6) to obtain a maximum permitted content in 1 dm2 of paper and board (QMA). The actual packaging to food ratio should be used instead of the standard ratio, if available. There is a wide range of end use applications for paper and board food packaging which vary greatly in their potential for substances to migrate to food.
3	Studies on mineral oil hydrocarbons found in foodstuffs have raised questions about consumer safety. According to these studies, one possible source (but not the only one) of traces of mineral oils which migrate to food is mineral oil based cold offset printing ink (commonly used in newspapers). It is present both on the printed surface of packaging and in paper for recycling used in the production of packaging papers. CEPI and CITPA made a commitment in 2011 to use mineral oil free inks for printing of packaging and this commitment is widely followed by the producers of food packaging in Europe. The European Food Safety Authority (EFSA) published a scientific opinion on the topic in June 2012 (amended and updated in August 2013)[45]. In the absence of a nationally or internationally accepted test method and with the uncertainty continuing to surround the hazard posed by mineral oil hydrocarbons, it is not currently possible to include limits values in Table 1. The paper and board sector has, however, taken a number of measures to limit the presence of mineral oil hydrocarbons in the paper-based food contact materials and articles by making commitments to use only mineral oil-free inks for printing this packaging and using a careful selection of grades of paper for recycling.

MOSH/ MOAH

CEPI Guidelines

Declaration of Compliance

Table 3. Declaration of Compliance – List of Contents

MAIN ELEMENT	DETAILS	COMMENTS
Date	1. Date of Declaration of Compliance (DoC)	
Business operator issuing the DoC	2. Identity and address of the organisation which manufactures the materials or articles	
	3. The address of the manufacturing site. The address of the manufacturer.	Only if different from the first address
Identity of the materials and articles	4. Generic product description	
	5. Trade name or grade description, including other relevant identifying information. Description of the product.	
Confirmation of compliance with legislation and Food Contact Guidelines	6. Statement that the product complies with the relevant requirements of the Framework Regulation and relevant Food Contact Guidelines	
	7. Statement that the different non-harmonised materials (paper and board, inks, adhesives, coatings) as well as polymer layers in MMMLs comply with existing reference legislation and food contact guidelines, when these exist	
	8. Known migrants with SML restrictions for paper and board in BfR XXXVI or other relevant lists of authorised substances, and intentionally added substances that, based on risk assessment can potentially migrate to food, should be communicated to downstream operators	Compulsory
	9. Dual use substances (deliberately added only) with quantitative restrictions in food legislation	When risk assessment indicates that there is a risk of transfer to food
	10. Statement on end uses or the restrictions of use, if any (e.g. food type, temperature)	

CEPI Guidelines

Declaration of Compliance

Table 4. Declaration of Compliance – List of Supporting Documentation

COMPLIANCE ELEMENT	DETAILS	COMMENT
Labelling	General details of the system used to label materials and articles which are not yet in contact with food when placed on the market.	Compulsory. Illustrates how the labelling requirement is being complied with.
Traceability	Documented routine for recall of products including the appropriate information needed for traceability as described in Section 5.	Compulsory. Illustrates how the traceability requirement is being complied with.
Documented risk assessment and/or evaluation of the product for which the DoC is issued based on Section 3 of this Guideline	Adequate information on potential migrants in the intended end use as defined in upstream DoCs or similar documents. May include concentration and/or migration testing, sensory testing, and/or worst case calculations based on risk assessment of intentionally added substances and NIAS. The risk assessment also covers the overall compliance of the material/article taking into account the multiple sources of substances. The same substance may originate from different materials used.	Compulsory. Illustrates how Article 3 of the Framework Regulation is complied with. See Section 3 for possible testing methods.
Identification and verification of the authorisation status of intentionally added substances and raw materials used in the formulation of the material/article	• Composition of the material/article. • DoC from upstream suppliers of chemicals authorised for use. • DoC from upstream suppliers of polymers if MMMLs are produced. • DoC or similar document with adequate information from upstream suppliers of materials which are not covered by a specific measure such as paper and board, inks, adhesives, varnishes, etc.	Compulsory
Identification and verification of quality and purity criteria for authorised substances	• DoC from upstream suppliers of chemicals.	Compulsory for business operators adding chemicals to their product. Otherwise not needed. Upstream DoC should provide the necessary information.
Dual use substances[a]	• DoC from upstream suppliers of chemicals and polymers used in MMMLs. • DoC or similar document with adequate information from upstream suppliers of materials which are not covered by a specific measure such as paper and board, inks, adhesives, varnishes, etc. • Risk assessment to see if there is a risk of transfer to food	Compulsory.
Identification and risk assessment of NIAS	• Scientific literature. • Results from testing of known NIAS. • Migration modeling. • Toxicological information of a substance.	Probably not possible at the current time until a realistic method is available.

COMPLIANCE ELEMENT	DETAILS	COMMENT
Substances intended to be used behind a functional barrier which are not authorised for use in paper and board materials and articles	• Adequate written information confirming that the substance does not meet the criteria for classification as mutagenic, carcinogenic or toxic to reproduction according to Reference 15. • Confirmation that the substance is not intentionally manufactured to be in nanoform.	Compulsory but there are unlikely to be many affected materials or articles.
Good Manufacturing Practice	Business operators must keep documentation on the application of the quality assurance and quality control systems which they use, as set out in Reference 3.	Compulsory.

Guideline CoE/EDQM from 2021

- Guidance on the list of supporting documents on compliance and safety (supporting documentation)
- Declaration of Compliance
- Compliance testing
  - Reference to the guidelines of the Join Research Centre (JRC)
- Part II. Technical guide on paper and board used in food contact materials and articles

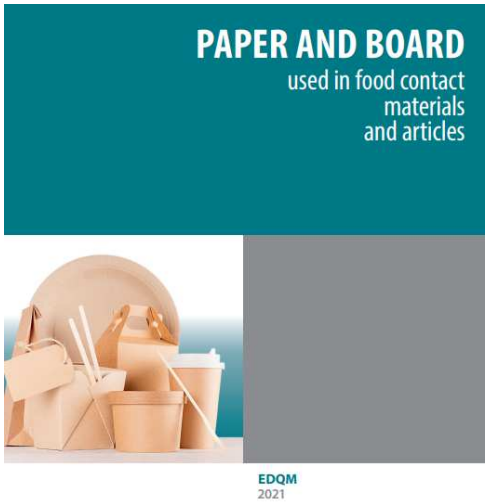
CoE/EDQM from 2021

- Relevant national regulations and official recommendations apply
- Specific migration limits listed in Table 1 apply
- Inertness – overall migration into MPPO (EN 14338)
- No migration Optical brighteners (EN 648)
- Sensorial evaluation (transfer of odour/flavour)
- Suitable microbiological purity
- No preservative effect on the foodstuff

Table 1

Substance	CAS No.	SML (mg/kg in food/ food simulant)	Notes	Reference and explanations
4,4'-Bis(dimethylamino) Benzophenone (Michler's ketone)	90-94-8	ND	1	Carcinogen class 1B according to Table 3.1 of Annex VI of Regulation (EC) No. 1272/2008
Bisphenol A	80-05-7	0.05	1	EFSA Journal (2015;13(1):3978): t-TDI 4 µg/kg bw per day, average bw 60 kg, allocation factor 20 %. Regulation (EU) No. 2018/213
		ND	1	Regulation (EU) No. 2018/213: applications for infants and young children as referred to in Regulation (EU) No. 609/2013
Sum of benzo(a) pyrene, benzo(a) anthracene, benzo(b)fluoranthene and chrysene	50-32-8 56-55-3 205-99-2 218-01-9	ND	1	The method of analysis should have a limit of detection: a) not higher than 0.001 mg/kg for migration in food simulant from paper and board not yet in contact with food; b) appropriate to ensure that compliance of the final food with Regulation (EC) No. 1881/2006 will not be compromised. Standard methods for analysis are listed in Annex III
Mineral oil hydrocarbons (MOH)	—	under discussion	1, 2	
Sum of benzophenone, 2-methyl benzophenone, 3-methyl benzophenone and 4-methyl benzophenone	119-61-9 131-58-8 643-65-2 134-84-9	0.6	1	Regulation (EU) 10/2011, EFSA Journal (2009; 1104: 1-30): TDI 0.01 mg/kg bw per day, average body weight 60 kg, no allocation factor. Swiss Ordinance (SR 817.023.21) Annex 10

CoE/EDQM from 2021



Substance	CAS No.	SML (mg/kg in food/ food simulant)	Notes	Reference and explanations
Sum of 2-methyl benzophenone, 3-methyl benzo-phenone, 4-methyl benzophenone	131-58-8 643-65-2 134-84-9	0.05	1	Swiss Ordinance (SR 817.023.21) Annex 10
Sum of dibutyl-phthalate (DBP) and diisobutyl-phthalate (DiBP)	84-74-2 84-69-5	0.3	1, 3	Regulation (EU) No. 10/2011 EFSA Journal (2005; 242: 1-17): TDI for DBP: 0.01 mg/kg bw per day. DiBP: comparable structure
Di(2-ethylhexyl) phthalate (DEHP)	117-81-7	1.5	1, 3	Regulation (EU) No. 10/2011, EFSA Journal (2005; 243: 1-20): TDI 0.05 mg/kg bw per day
1A/1B Classified PAAs		ND (0.002)	1, 4	Hazard class Carc./ Muta./Repr. 1A or 1B according to Table 3 of Annex VI of Regulation (EC) No. 1272/2008, especially those listed in Appendix 8 Entry 43 of Regulation (EC) No. 1907/2006
Sum of all primary aromatic amines (PAAs)		ND	1, 4	Table 3 of Annex VI of Regulation (EC) No. 1272/2008
Lead (Pb)	7439-92-1	ND	5	Regulation (EU) No. 10/2011
PFAS (per- and polyfluoroalkyl substances)		under discussion	6	The Opinion was adopted at the CONTAM Plenary meeting on 9 July 2020 and published in the EFSA Journal [26]

Safety validation of substances: assessment tools

Example:

- Wet-end non-PFAS sizing agents: Alkenylsuccinic anhydride (ASA)

Octadecenyl succinic anhydride (18-ASA) is the main component of the commercial samples of ASA

Validation *status* as an FCM??

Safety validation of substances: assessment tools

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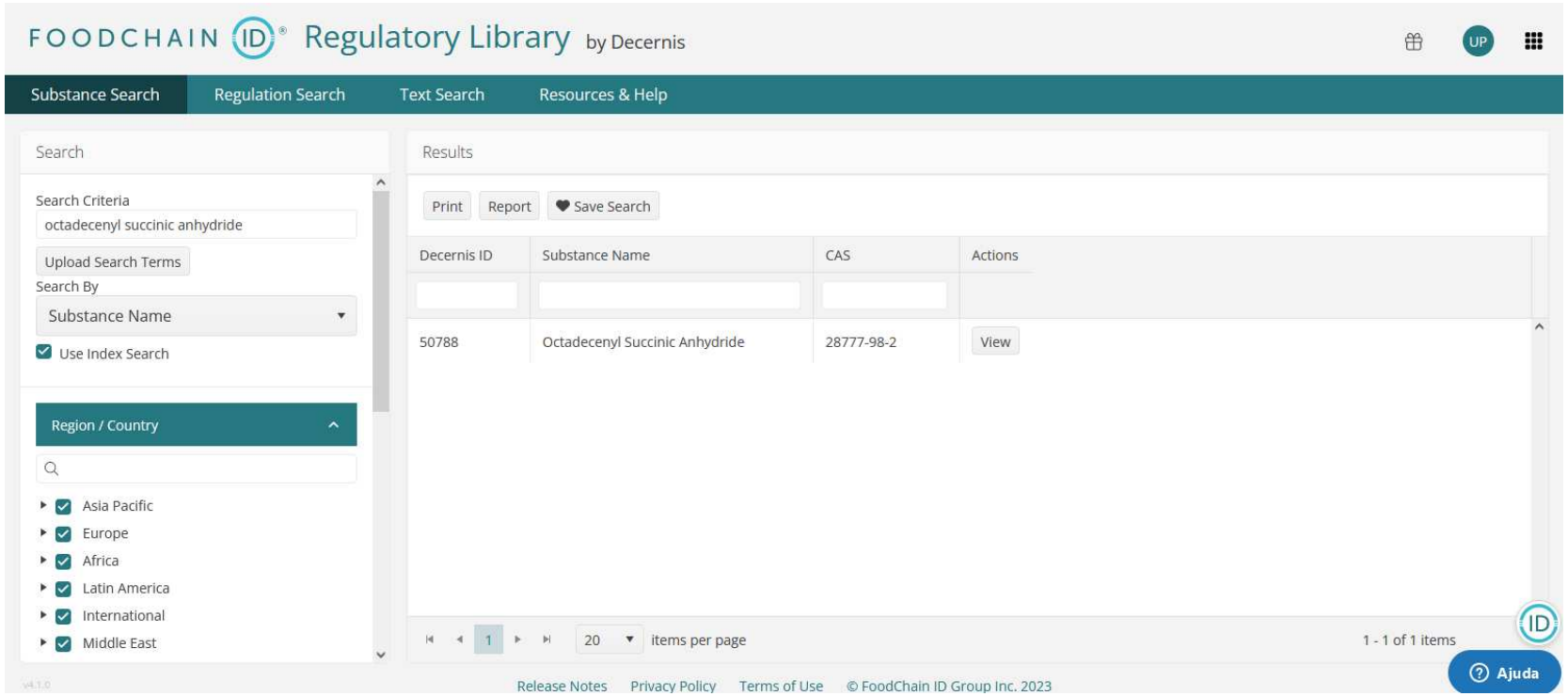

Safety validation of substances: assessment tools

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DECERNIS

Substance Search Results

Page 1 of 1

	Published	CAS	Substance	Country	Topic	Subtopic	Citation
+	2010-02-09	28777-98-2	Octadecenylsuccinic anhydride	Council of Europe	Food Contact Substrate	Paper and Paperboard	Technical document No 1 - List of substances to be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs (Version 3) (Part 1) (2010-02-09)(English)
+	2009-01-12	28777-98-2	Octadecenylsuccinic anhydride	Council of Europe	Food Contact Substrate	Paper and Paperboard	CoE Resolution AP (2002)1 on Paper and Board (Version 3) (2009-01-12)(English)
+	2020-12-01	28777-98-2	Succinic anhydride, octadecenyl-	Israel	Food Contact General	Printing Inks	Israeli Standard SI 136 Part 2/2020: Hermetically sealed and rigid metal packaging for food products: Coatings and varnishes (Hebrew)(Copyright)
+	2012-06-01	28777-98-2	Succinic anhydride, octadecenyl-	Associations	Food Contact General	Printing Inks	Guidance EuPIA: Inventory List Comprising Packaging Ink Raw Materials Applied to the Non-Food Contact Surface (2012-06-01)(English)
+	2020-12-01	28777-98-2	Succinic anhydride, octadecenyl-	Switzerland	Food Contact General	Printing Inks	817.023.21 Ordinance Of The FDHA On Materials And Articles Intended To Come Into Contact With Food - Annex 10: List Of Permitted Substances For The Production Of Packaging Inks, And Related Requirements (Consolidated 2020-12-01)(English)

Safety validation of substances: assessment tools

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- Listed in CoE “B. TEMPORARY APPENDIX TO LIST 1 OF ADDITIVE” Version 3 and 4 (2009 - 2010)

Restriction – “TO BE FIXED”

- Listed 817.023.21 Ordinance Of The FDHA On Materials And Articles Intended To Come Into Contact With Food - Annex 10: List Of Permitted Substances For The Production Of Packaging Inks, And Related Requirements

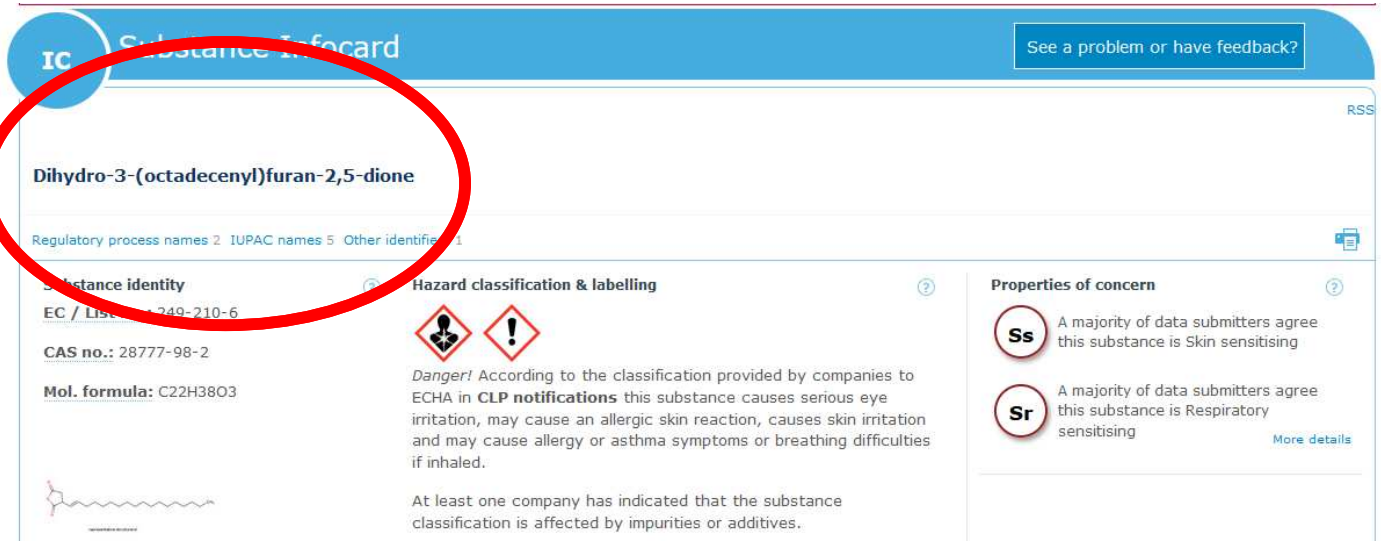
Restriction – used as an additive; List B (not evaluated), SML < 10 ppb

Safety validation of substances: assessment tools

https://www.echa.europa.eu/

UPAC name Octadecenylsuccinic Anhydride (mixture of isomers)

Suspected hazardous to the aquatic environment#Suspected persistent in the environment#Suspected respiratory sensitiser#Suspected skin irritant#Suspected skin sensitiser



NO CMR
Carcinogenic
Mutagenic
Toxic to reprodution

Safety validation of substances: assessment tools

Approach TTC/QSAR - Software available to assist on classify substances into Cramer classes

Refers to the establishment of a generic exposure level for all chemicals below which there would be no appreciable risk to human health

The Cramer classification scheme (decision tree) attributes a class to the substance based on its chemical structure. ***https://doi.org/10.2903/j.efsa.2019.5708***

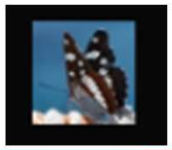
Table 1: Structural classes for chemicals proposed in the Cramer scheme (Cramer et al., 1978)

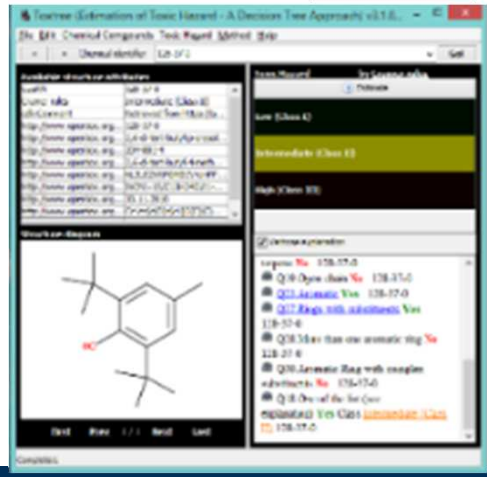
Class I	Substances with simple chemical structures and for which efficient modes of metabolism exist, suggesting a low order of oral toxicity. This class would include normal constituents of the body (excluding hormones); simply-branched, acyclic aliphatic hydrocarbons; common carbohydrates; common terpenes; substances that are sulfonate or sulfamate salts, without any free primary amines
Class II	Substances which possess structures that are less innocuous than Class I substances, but do not contain structural features suggestive of toxicity like those substances in Class III. This class would include common components of food; substances containing no functional groups other than alcohol, aldehyde, side-chain ketone, acid, ester, or sodium, potassium or calcium sulfonate or sulfamate, or acyclic acetal or ketal and are either or without a ring ketone
Class III	Substances with chemical structures that permit suggest significant toxicity or have reactive functi that contain elements other than carbon, hydrog benzene derivatives; certain heterocyclic substan three types of functional groups

Table 2: TTC values – classification of substances

Classification	TTC value in µg/person per day	TTC value in µg/kg bw per day[a]
Potential DNA-reactive mutagens and/or carcinogens	0.15	0.0025
Organophosphates and carbamates	18	0.3
Cramer Class III	90	1.5
Cramer Class II	540	9.0
Cramer Class I	1,800	30

Toxtree





Example: 18-ASA

- It is not listed in positive lists for FCM P&B;
- Restriction from printing inks (used as an additive; List B (not evaluated), SML < 10 ppb)
- It is not CMR
- No valid data confirming absence of genotoxicity is available.
- Substance is Cramer Class III:
  - Scenario (1) - estimated exposure **below the TTC** value of 90 µg/person per day **low probability of adverse health effects**.
  - Scenario (2) - estimated exposure **higher than the TTC** value of 90 µg/person per day a non-TTC approach (e.g. **substance-specific risk assessment**) is required in order to reach a conclusion on potential adverse health effects.

Not allowed to migrate

Conclusions

- Regulations for P&B harmonised do not exist
- General safety principles and criteria for FCM do apply
- May need to use a combination of different documents
- Work under development
- Lack of relevant toxicity data
- Need of risk assessment
- Potential for combining different strategies for safety assessment

Thank you for your attention

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