

5. FCCG

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Review article

Overview of intentionally used food contact chemicals and their hazards

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Paragraph 2.2 contains links to lists used.

(1) Authoritative sources.

Hazards to HH & ENV based on classifications aligned with GHS from 2 sources :

ECHA-C&L <https://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>

Japanese Government J-GHS https://www.nite.go.jp/chem/english/ghs/ghs_index.html

EDC

ECHA list <http://echa.europa.eu/ed-assessment>

SVHCs due to ED <http://echa.europa.eu/candidate-list-table>

Danish EDC list <https://edlists.org>

United Nations Environmental Programme's report on EDC

https://wedocs.unep.org/bitstream/handle/20.500.11822/25633/EDC_report1.pdf?sequence=1&isAllowed=y

PBT

ECHA list <http://echa.europa.eu/pbt>

SVHC due to PBT/vPvB

US Environmental Protection Agency (EPA) PBT substances

Stockholm Convention on Persistent Organic Pollutants (POPs) <http://www.pops.int>



Consulted Regulatory lists of hazardous substances (Authoritative)

SVHC <http://echa.europa.eu/candidate-list-table>

REACH authorisation list <http://echa.europa.eu/authorisation-list>

REACH restriction list <http://echa.europa.eu/substances-restricted-under-reach>

California's Proposition 65 list <http://oehha.ca.gov/proposition-65-list>

(2) Other hazard information sources

Authoritative (Used to obtain reliable hazard information not for prioritisation)

EU Community Rolling Action Plan (CoRAP) list

<http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>

OpenFoodTox database (EFSA) <https://zenodo.org/record/3693783#.Xq1dY2gzZaQ>

US EPA's Safer Chemical Ingredients List evaluated under Safer Choice Program

<https://www.epa.gov/saferchoice/safer-ingredients#searchList>

Sources providing predicted hazard classifications.

Danish Environmental Protection Agency based on in silico

<https://clp-vejlliste.mst.dk/default.aspx>

Chemsec SIN list <http://chemsec.org/business-tool/sin-list/>

The Endocrine Disruption Exchange (TEDX) list

<https://endocrinedisruption.org/interactive-tools/tedx-list-of-potential-endocrine-disruptors/>

Analysis by German Environment Ministry on PMT and vPvM (Arp and Hale 2019)

Toxicity Values (ToxVal) database by USEPA

http://comptox.epa.gov/dashboard/chemical_lists/TOXVAL_V5

(3) Use related data

Substance registration status in REACH

<https://echa.europa.eu/information-on-chemicals/registered-substances/>

Regulatory status in EU in Chemical universe mapping study ECHA

<https://echa.europa.eu/how-does-the-chemical-universe-mapping-work>

ECHA's database of plastics additives

<https://echa.europa.eu/de/mapping-exercise-plastic-additives-initiative>

Substances associated with plastic packaging (Groh et Al 2019)

US Toxic Substances Control Act (TSCA) <https://www.epa.gov/tsca-inventory/>

New Zealand

http://www.cirs-reach.com/Inventory/New_Zealand_Inventory_of_Chemicals-NZIoC.html

- 67 FCC lists used
- 12285 substances possibly used to make FCM
- 608 FCCs prioritized for further assessment and substitution in FCMs/FCAs

Outcome

Table 2

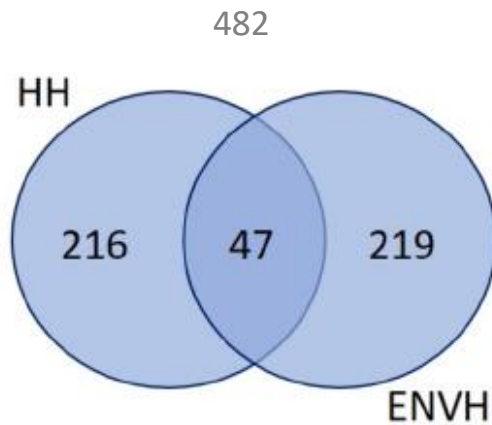
Availability of hazard information for CAS-identified FCCdb chemicals in the sources consulted.

Description of grouping or prioritization criteria	Included substances		Consulted information sources (for more details see Section 2.2)
	N	% of total	
All CAS-identified substances included in the FCCdb	11'609	100	FCCdb; only chemicals with CAS identifier
Having at least one classification for HH and/or ENVH	1466	12.6	ECHA-C&L and J-GHS inventories of substance classifications for health hazards (HH) and/or environmental hazards (ENVH) aligned with Globally Harmonized System (GHS) for chemical classification and labeling
Prioritized for HH (i.e., sum hazard score $\geq 10'000$)	263	2.3	
Prioritized for ENVH (i.e., sum hazard score ≥ 1000)	266	2.3	
Criterion 1: Prioritized as above for HH and/or ENVH*	482	4.2	
On the ECHA's Endocrine disruptor assessment list	61	0.5	
On the EDC Lists by the Danish Environmental Protection Agency	67	0.6	Selected authoritative sources on assessment and identification of endocrine disrupting chemicals (EDCs), persistent, bioaccumulative, toxic (PBT) and very persistent, very bioaccumulative (vPvB) chemicals, and persistent organic pollutants (POP), e.g., by European Union (EU), European Chemicals Agency (ECHA), US Environmental Protection Agency (US EPA), United Nations Environment Programme (UNEP), national authorities
EDC or potential EDC listed in the UNEP report (UNEP, 2018)	47	0.4	
On the ECHA's PBT assessment list	83	0.7	
Recognized as EDC in the EU under REACH or Biocides regulations	22	0.2	
Recognized as PBT and/or vPvB in the EU and/or US, or as POP	32	0.3	
Criterion 2: Prioritized as recognized EDC, PBT and/or vPvB, or POP	54	0.5	
Included on REACH Candidate List of SVHCs for Authorization	123	1.1	
Included on REACH Authorization List**	36	0.3	
Included on REACH Restriction List	255	2.2	
Included on US California Proposition 65 List (Prop65)	175	1.5	
Criterion 3: Prioritized as substance on REACH list(s) or Prop65 list	378	3.3	
Prioritized based on any of the three criteria highlighted in bold above	608	5.2	All authoritative sources listed above

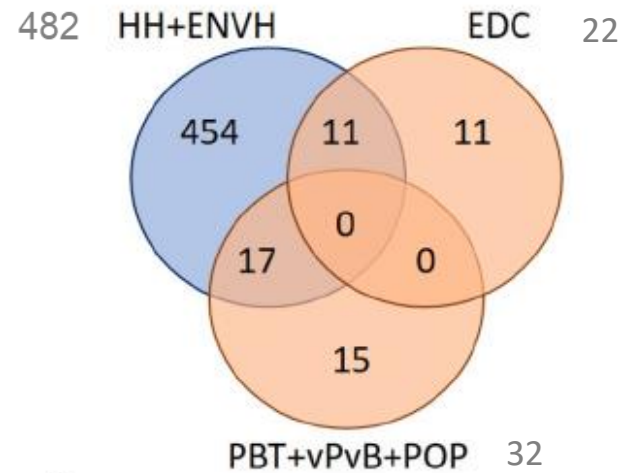
Included on the EU Community Rolling Action Plan (CoRAP)	248	2.1	Additional authoritative sources not used for prioritization described above but to further explore the availability of reliable hazard data for FCCdb substances
Included in the EFSA's OpenFoodTox database (Ceriani et al., 2018)	1424	12.3	
Included on the US EPA's Safer Chemical Ingredients List	655	5.6	
Covered by at least one of the sources above	3001	25.9	All authoritative sources listed above
Having no information in any of the sources above	8608	74.1	
Having at least one predicted classification for HH and/or ENVH	2889	24.9	Advisory GHS-aligned classifications for HH and/or ENVH predicted by the Danish EPA through <i>in silico</i> modeling; CMR, carcinogenic, mutagenic, or toxic to reproduction properties
Predicted HH of concern (i.e., predicted CMR properties)	864	7.4	
Predicted ENVH of concern (i.e., highest category of aquatic toxicity)	436	3.8	
Prioritized due to concern about potential genotoxicity	106	0.9	(Van Bossuyt et al., 2017)
Included on the TEDX list of potential EDCs	367	3.2	TEDX list of potential EDCs
Assessed for PMT/vPvM properties	198	1.7	Report on persistent, mobile, toxic (PMT) and very persistent, very mobile (vPvM) substances (Arp and Hale, 2019)
Identified as PMT/vPvM based on self-defined "high quality" assessment	45	0.4	
Included on the SIN List	308	2.7	Substitute It Now! (SIN) list
Identified as chemical of potential concern based on predictive sources	1798	15.5	Predictive (non-authoritative) sources above
Covered by at least one of the sources above	4986	42.9	All sources listed above, authoritative and non-authoritative (predictive)
Having no information in any of the sources above	6623	57.1	
Found in the ToxVal database (Williams et al., 2017)	8328	71.7	Toxicity Values (ToxVal) database by US EPA
Covered by at least one of the sources above	8711	75.0	All sources listed above, authoritative and non-authoritative (predictive)
Having no information in any of the sources above	2898	25.0	

*Rows in bold show prioritization criteria and numbers of substances prioritized according to these criteria based on selected authoritative sources (see sections 3.3.1–3.3.4). Blue, orange and green backgrounds correspond to Venn diagram colors used in Fig. 2.

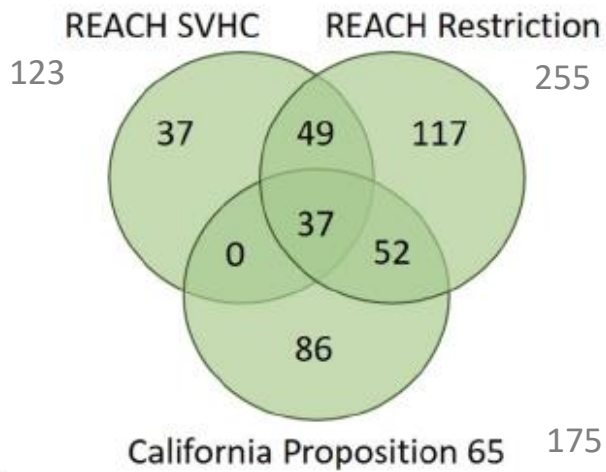
**All substances on this list are also included in the REACH SVHC List.



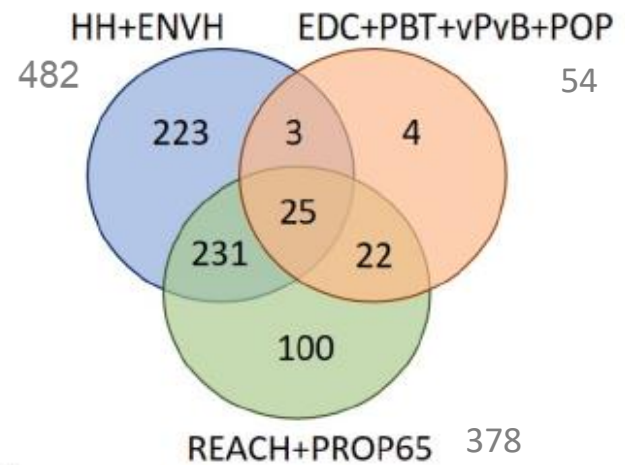
A



B



C



D

Table 1

Total numbers and overlaps between substances assigned to 16 global inventories for different food contact materials and other food contact applications.

		global inventory, FCM type: plastics																																
overlap with global inventories for other FCM types	plastics	4742	coatings		rubber			silicones			IERs		P & B		cellophane		textiles		cork/wood		adhesives		colorants		inks		wax		inorganics*		A & I		other**	
	coatings	2008	2886																															
	rubber	726	582	1043																														
	silicones	507	471	254	784																													
	IERs	415	378	203	298	555																												
	paper/board	1334	1270	488	350	281	2950																											
	cellophane	301	262	156	111	79	257	365																										
	textiles	77	77	37	14	16	169	25	207																									
	cork/wood	124	168	79	53	43	184	32	12	219																								
	adhesives	1275	981	461	254	205	1032	216	51	163	1788																							
	colorants	224	129	44	31	14	88	15	4	8	40	316																						
	printing inks	1955	1590	549	555	392	1309	17	72	109	744	183	5625																					
	wax	57	114	28	10	9	123	10	4	98	118	2	38	142																				
	inorganics	57	36	28	17	4	38	11	5	4	15	12	38	0	101																			
	A & I	75	70	51	37	41	83	26	7	16	49	8	74	4	6	100																		
	other	130	75	39	25	42	84	27	7	10	52	10	101	4	1	9	208																	
unique substances	1437	331	172	144	84	745	17	20	6	154	38	2926	3	26	8	42																		
prioritized hazardous substances	total	325	219	175	75	76	256	22	19	33	147	10	377	8	28	18	19																	
	unique	36	6	12	2	5	39	0	0	2	1	0	83	0	5	0	0																	

*Covers metals, glass, ceramics

**Covers other food contact uses, e.g., during food processing or preparation.

Abbreviations: FCM, food contact material; IERs, ion-exchange resins; P & B, paper and board; A & I, active and intelligent materials.

Mail to CEPI 26/08

- FCCdb 256 prioritized substances may be present in P&B substrates used for FCMs. Which substances are really used and how are those substances risk assessed ?
- Titanium dioxide classified as a suspected carcinogen when inhaled and new EFSA assessment on use as food additive.

Data available on migration behaviour of TiO₂ present in paper and board coatings ?

- Natural materials.

Fresenius conference 24-25 June : *“When processing wood into useful fibres, the degradation of lignin and hemicellulose is leading to lots of uncontrolled chemicals”*.

Studies available ?

Obtained reply

- Food Packaging Forum and Fresenius NGO like. Not credible.
- TiO₂ Concern inhalation related. Usually well embedded and does not tend to migrate. Very low levels may occur only in case of moist and fatty foods.

- Natural questioned. Sector dealt with this and the results are that all is under control, environment and safety.
- FCCdd is hazard based. Risk assessment is correct approach.

RA is what ECMA is asking for !

- IAS are covered by positive lists. In case not covered company responsible. RA included in DoC's.
- Objective of FCCdb to convey an NGO message on the large number of chemicals ... Caffeine 295, Ethanol 296 ...
- **Proposal to treat in Food Contact Coordination Group. (FCCG)**

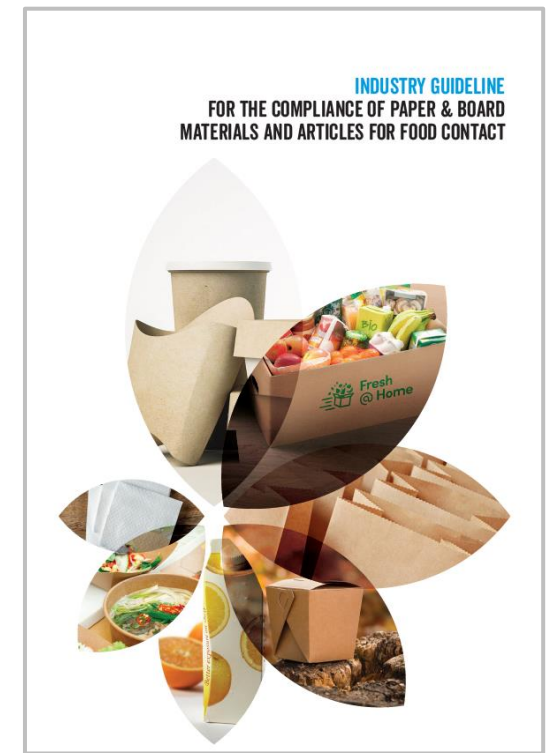
+ NIAS in recycled P&B

1.4.4 Compositional Requirements - Non intentionally added substances (NIAS)

General

The paper and board industry continuously evaluates and engages in relevant research projects aimed at examining NIAS in food contact paper and board materials and articles. The objective is to assess and control any relevant risks related to NIAS. Until that work is complete, the following two sub-sections covering GMP and Supply Chain Communications should be used to ensure non-authorized substances, whilst not being fully eliminated, will not present a significant safety risk.

It is known that the use of paper for recycling may cause the occurrence of NIAS in the finished paper and board materials and articles. As an interim measure, before the aforementioned work on NIAS results in a control framework, a set of testing rules using a list of known impurities is described in Section 3 of this Guideline. Section 3 also contains more details on purity requirements and NIAS.



Outcome study with FERA ?