WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Database of substances known by members states of Council of Europe and used in FCM

Toxicology-Consumer Safety
Department Food, Medicines and Consumer Safety

EFSA
25-05-2016

.be

isp WIV

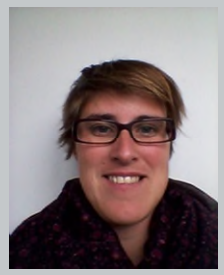
COMMUNICABLE AND INFECTIOUS DISEASES

FOOD, MEDICINES AND CONSUMER SAFETY

PUBLIC HEALTH AND SURVEILLANCE

EXPERTISE, SERVICE PROVISION AND CUSTOMER RELATIONS

UNIT OF CONSUMER SAFETY



Els Van Hoeck

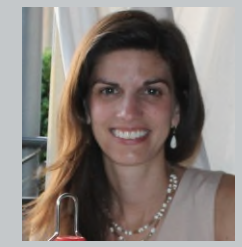
Fabien Bolle

NRL for FCM
Expertise in legislation & Research on FCM

Research related to FCM

UNIT OF TOXICOLOGY

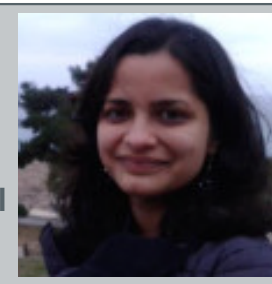
Melissa Van Bossuyt



Birgit Mertens

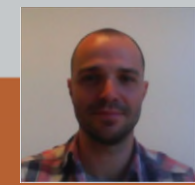
JOINT PROJECT

Database of substances known by member states of the Council of Europe and used in FCM

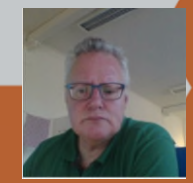


Padmaja Kamath

With support from ICT



Cédric Malache



Erwin Bautens

.be

WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

Database of substances known by member states of the Council of Europe and used in FCM: Practical applications

Overview

- **Introduction**
- Database CoE-MS-FCM
- Practical applications of the database
  - TTC
  - Safety color schemes
  - Research project on Printed Paper and Board
- Conclusion

Problem of non-evaluated substances

European Regulation exists only for plastic materials and articles intended to come into contact with food

EU Commission Regulation 10/2011

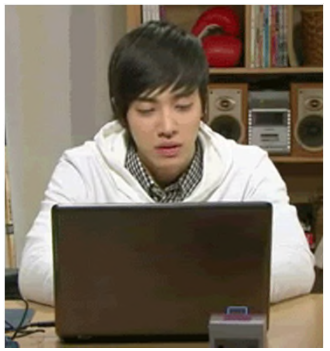

REGULATIONS

COMMISSION REGULATION (EU) No 10/2011
of 14 January 2011
on plastic materials and articles intended to come into contact with food

Union list: authorized substances

But colorants, solvents, polymer production aids are *STILL* subject to national laws

…..continued



No harmonized European regulation for non-plastic FCM,

but

1. **Resolutions** of the Council of Europe: Evaluated and non-evaluated lists

Coatings	**Paper&Board**	**Rubber**
Printing Inks	**Resins**	**Silicones**

2. **ESCO WG** on non-plastic FCM (2011): An overview of the evaluations available in Member States

List A (10%): ***Substances evaluated by Member States after 1991***
List B (90%): ***Substances evaluated by Member States before 1991***

3. **Swiss Ordinance** on materials and articles

Packaging inks may only be manufactured from the substances in Annex 6:

binders, colorants and pigments, solvents, additives, photo-initiators

Thousands of substances are being used while they were not evaluated by the Member States!

WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

Database of substances known by member states of the Council of Europe and used in FCM: Practical applications

Overview

- Introduction
- **Database CoE-FCM**
- Practical applications of the database
  - TTC
  - Safety color schemes
  - Research project on Printed Paper and Board
- Conclusion

Database CoE-FCM

Belgium has developed an exhaustive database containing all substances known and used by Member States of the Council of Europe

….continued

Following lists are included in the database:

Plastic
- 72/2002/EC
- 2011/10/EC

Printing ink
- Swiss ordinance on food contact materials 817.023.21
- EFSA 2012:EN-139 (ESCO WG)

Paper & Board
- ResAP(2002)1, v4. (2009)
- EFSA 2012:EN-139 (ESCO WG)

Colorants
- EFSA 2012:EN-139 (ESCO WG)

Coating
- ResAP (2004)1, v3. (2009)
- EFSA 2012:EN-139 (ESCO WG)

Cork
- ResAP (2004)2, v2. (2007)
- EFSA 2012:EN-139 (ESCO WG)

Rubber
- ResAP (2004)4, v1. (2004)
- EFSA 2012:EN-139 (ESCO WG)

Silicone
- ResAP (2004)5, v1. (2004)
- EFSA 2012:EN-139 (ESCO WG)

Resins
- ResAP (2004)3, v3. (2009)

…..continued

Plastic

- 72/2002/EC
- 2011/10/EC

Printing ink

- Swiss ordinance on food contact materials 817.023.21
- EFSA 2012:EN-139 (ESCO WG)

Paper & board

- ResAP(2002)1, v4. (2009)
- EFSA 2012:EN-139 (ESCO WG)

Colorants

- EFSA 2012:EN-139 (ESCO WG)

v3. (2009)
39 (ESCO WG)

Cork

- ResAP (2004)2, v2. (2007)
- EFSA 2012:EN-139 (ESCO WG)

Rubber

- ResAP (2004)4, v1. (2004)
- EFSA 2012:EN-139 (ESCO WG)

Silicone

- ResAP (2004)5, v1. (2004)
- EFSA 2012:EN-139 (ESCO WG)

Resins

- ResAP (2004)3, v3. (2009)

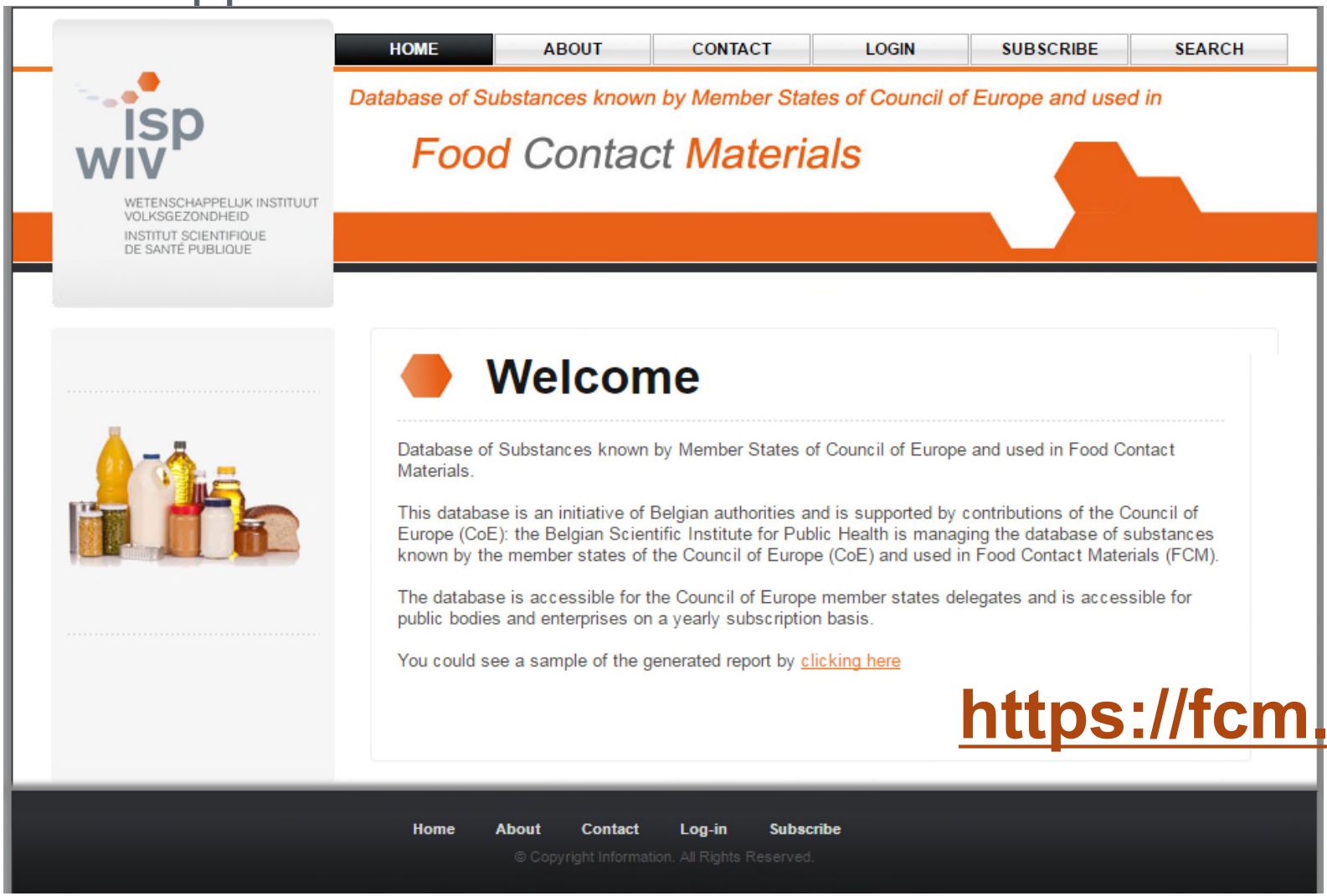
Finally!

9566 substances are used in FCM applications with five identifiers:

CASRN, Name, EC number, EEC packaging reference number and FCM number

.....continued

Web application



https://fcm.wiv-isp.be

WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

Database of Substances known by Member States of Council of Europe and used in

Food Contact Materials

Find substances

Search the database by selected criteria. If the criteria is inaccurately introduced, the search will return several results and you will be able to choose for the searched substance.
The information available in the database is printed in a PDF file.

Select criteria...

- Select criteria...
- SUBSTANCE
- CASNo
- EEC packaging material reference number
- FCM number, EC10/2011

Coming soon:
SMILES, PubchemID,
ChemspiderID

The WIV-ISP ensures accurate introduction of the information provided by the Advisory Group and the Member Countries of the Council of Europe delegates into the database, but cannot be held responsible for the scientific accuracy of this information.

In addition, the toxicological data of the substances contained in the database are largely based on a in silico analysis using different toxicological software, and not on experimental data. The WIV-ISP allows the access to the database and its contents for the Subscriber for informational purposes only and does not guarantee the accuracy of scientific data that is not generated at WIV-ISP.

The presence of a substance in the database is not an agreement for its use in materials and articles intended to come into contact with foodstuffs.

isp wiv

WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID

INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

Database of Substances known by Member States of Council of Europe and used in

Food Contact Materials

Welcome

Search tab and sample report available before subscription

Database of Substances known by Member States of Council of Europe and used in Food Contact Materials.

This database is an initiative of Belgian authorities and is supported by contributions of the Council of Europe (CoE): the Belgian Scientific Institute for Public Health is managing the database of substances known by the member states of the Council of Europe (CoE) and used in Food Contact Materials (FCM).

The database is accessible for the Council of Europe member states delegates and is accessible for public bodies and enterprises on a yearly subscription basis.

You could see a sample of the generated report by clicking here

isp wiv

WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

Database of Substances known by Member States of Council of Europe and used in

Food Contact Materials

Find substances

Search the database by selected criteria. If the criteria is inaccurately introduced, the search will return several results and you will be able to choose for the searched substance.
The information available in the database is printed in a PDF file.

CASNo ▾ 50-00-0

Search

SUBSTANCE	CASNo	EEC	FCM number
Formaldehyde	0000050-00-0	17260 54880	98
Ethanol, 2-[2-[2-(dodecyloxy)ethoxy]ethoxy]-, hydrogen sulfate, sodium salt	0013150-00-0	No data available	

DISCLAIMER:
The WIV-ISP ensures accurate introduction of the information provided by the Advisory Group and the Member Countries of the Council of Europe delegates into the database, but cannot be held responsible for the scientific accuracy of this information.

In addition, the toxicological data of the substances contained in the database are largely based on a in silico analysis using different toxicological software, and not on experimental data. The WIV-ISP allows the access to the database and its contents for the Subscriber for informational purposes only and does not guarantee the accuracy of scientific data that is not generated at WIV-ISP.

The presence of a substance in the database is not an agreement for its use in materials and articles intended to come into contact with foodstuffs.

No pdfs available

isp wiv

WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

Database of Substances known by Member States of Council of Europe and used in

Food Contact Materials

Welcome
Kamath Padmaja

Find substances

Search the database by selected criteria. If the criteria is inaccurately intro
results and you will be able to choose for the searched substance.
The information available in the database is printed in a PDF file.

Pdf reports generated with available information

CASNo ▾ 50-00-0

Search

SUBSTANCE	CASNo	EEC	FCM number	
Formaldehyde	0000050-00-0	17260 54880		PDF
Ethanol, 2-[2-[2-(dodecyloxy)ethoxy]eth… sulfate,sodium salt				PDF

Coming soon: Structure visualization
Reports in other formats
Information from select tools

DISCLAIMER:
The WIV-ISP ensures accurate introduc… the Member Countries of the Council of Europe delegates into the database, but cannot be held respons… for the scientific accuracy of this information.

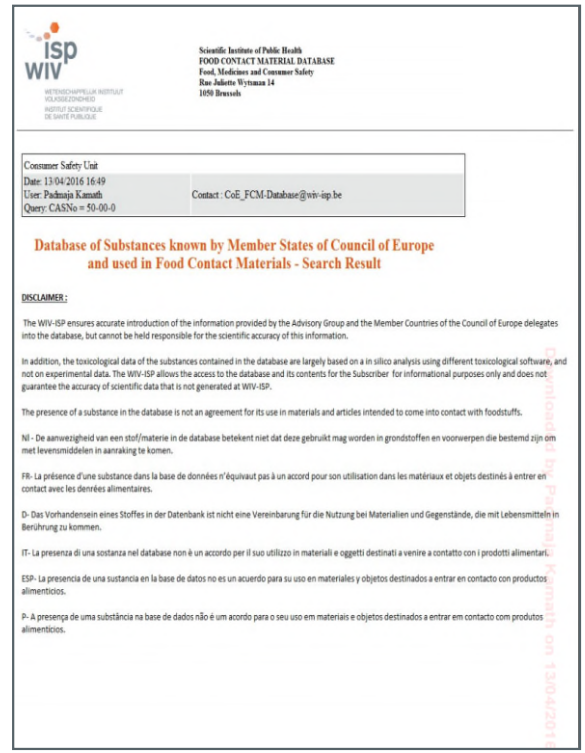
In addition, the toxicological data of the substances contained in the database are largely based on a in silico analysis using different toxicological software, and not on experimental data. The WIV-ISP allows the access to the database and its contents for the Subscriber for informational purposes only and does not guarantee the accuracy of scientific data that is not generated at WIV-ISP.

The presence of a substance in the database is not an agreement for its use in materials and articles intended to

….continued

Report

- Generic information
- Reference in lists from ECHA and NGOs
- Reference to legislations
- Toxicological information



Scientific Institute of Public Health
FOOD CONTACT MATERIAL DATABASE
Food, Medicines and Consumer Safety
Rue Juliette Wytsman 14
1050 Brussels

Consumer Safety Unit
Date: 13/04/2016 16:49
User: Padmaja Kamath
Query: CASNo = 50-00-0
Contact : CoE_FCM-Database@wiv-isp.be

Database of Substances known by Member States of Council of Europe and used in Food Contact Materials - Search Result

DISCLAIMER :

The WIV-ISP ensures accurate introduction of the information provided by the Advisory Group and the Member Countries of the Council of Europe delegates into the database, but cannot be held responsible for the scientific accuracy of this information.

In addition, the toxicological data of the substances contained in the database are largely based on a in silico analysis using different toxicological software, and not on experimental data. The WIV-ISP allows the access to the database and its contents for the Subscriber for informational purposes only and does not guarantee the accuracy of scientific data that is not generated at WIV-ISP.

The presence of a substance in the database is not an agreement for its use in materials and articles intended to come into contact with foodstuffs.

Nl - De aanwezigheid van een stof/materie in de database betekent niet dat deze gebruikt mag worden in grondstoffen en voorwerpen die bestemd zijn om met levensmiddelen in aanraking te komen.

FR- La présence d'une substance dans la base de données n'équivaut pas à un accord pour son utilisation dans les matériaux et objets destinés à entrer en contact avec les denrées alimentaires.

D- Das Vorhandensein eines Stoffes in der Datenbank ist nicht eine Vereinbarung für die Nutzung bei Materialien und Gegenstände, die mit Lebensmitteln in Berührung zu kommen.

IT- La presenza di una sostanza nel database non è un accordo per il suo utilizzo in materiali e oggetti destinati a venire a contatto con i prodotti alimentari.

ESP- La presencia de una sustancia en la base de datos no es un acuerdo para su uso en materiales y objetos destinados a entrar en contacto con productos alimenticios.

P- A presença de uma substância na base de dados não é um acordo para o seu uso em materiais e objetos destinados a entrar em contacto com produtos alimentícios.

Generic information

Substance identification	
Compound	Phthalic acid, bis(2-ethylhexyl) ester
CAS number	0000117-81-7
EC number (EINECS	To be completed
EEC packaging material reference number	74640
FCM number (EC 10/2011)	283
Elemental composition	C24H38O4
Exact mass	390.27701
Facet Id	1619
Pubchem Hit	8343
InChIKey(retrieved from PubChem	BJQHLKABXJIVAM-UHFFFAOYSA-N
InChI(retrieved from PubChem)	InChI=1S/C24H38O4/c1-5-9-13-19(7-3)17-27-23(25)21-15-11-12-16-22(21)24(26)28-18-20(8-4)14-10-6-2/h11-12,15-16,19-20H,5-10,13-14,17-18H2,1-4H3
IUPAC name(retrieved from PubChem)	not available
Canonical Smiles(retrieved from PubChem)	CCCCC(CC)COC(=O)C1=CC=CC=C1C(=O)OCC(CC)CCCC
Isomeric Smiles(retrieved from PubChem)	CCCCC(CC)COC(=O)C1=CC=CC=C1C(=O)OCC(CC)CCCC
Rotatable Bond Count (retrieved from PubChem)	16
Molecular Formula (retrieved from PubChem)	C24H38O4
Molecular Weight (retrieved from PubChem)	390.55612
Total Formal Charge (retrieved from PubChem)	0
XLogP (retrieved from PubChem)	7.4
Hydrogen Bond Donor Count (retrieved from PubChem)	0
Hydrogen Bond Acceptor Count (retrieved from PubChem)	4
Complexity (retrieved from PubChem)	394
Heavy Atom Count (retrieved from PubChem)	28
Atom Chiral Count (retrieved from PubChem)	2
Atom Chiral Def Count (retrieved from PubChem)	0
Atom Chiral Undef Count (retrieved from PubChem)	2
Bond Chiral Count (retrieved from PubChem)	0
Bond Chiral Undef Count (retrieved from PubChem)	0
Isotope Atom Count (retrieved from PubChem)	0
Covalent Unit Count (retrieved from PubChem)	0
Tautomer Count (retrieved from PubChem)	1

Coming soon: Chemspider

Reference to lists

SIN List reasons for inclusion	Classified CMR (Class I & II) according to Annex 1 of Directive 67/548/EEC ,Record: EC Number: 204-211-0 CAS Number: 117-81-7
Sin list (Bio)monitoring data	No data available
Annex XIV of REACH ("Authorisation List")	Toxic for reproduction (category 1B), record: EC Number: 204-211-0 CAS Number: 117-81-7
Candidate List of substances of very high concern (SVHC)	Equivalent level of concern having probable serious effects to the environment (Article 57 f); Toxic for reproduction (article 57c), record: EC Number: 204-211-0 CAS Number: 117-81-7
Endocrine disruption	TEDX List of Potential Endocrine Disruptors

Substances intended to be discontinued (phase-out)

non-profit organisation, identifying chemicals using criteria established by the EU chemicals regulation REACH.

Consists of substances which may have serious and often irreversible effects on human health and the environment as per regulation REACH

organization that focuses primarily on the human health and environmental problems caused by exposure to chemicals cause endocrine disruptors

Coming soon: ***Harmonized C&L inventory:*** **when a supplier identifies a substance as "acute toxicity category 1 (oral)", the labeling will include the hazard statement "fatal if swallowed", the word "Danger" and a pictogram**

Reference to legislations

Plastics	
Commission Directive 2002/72/EC, lists (1)	Not listed
EU10/2011 (2), Restricti	= 1,5 mg/kg food simulant. To be used only lasticiser in repeated use materials and contacting non-fatty foods; (b) technical agent in concentrations up to 0,1 % in the oduct. [Listed as plastic additive (add01.) 3.1.13. in the European Pharmacopoeia]
SCF-Lists as in Synoptic do	

Plastics

Resolution ResAP(2004)	
Restrictions / Specifica (2004)1 on coatings (7), a	kg food simulant. To be used only cizer in repeated use materials and ontacting non-fatty foods; (b) technical pport agent in concentrations up to 0,1 % in the final product
ESCO Compilation, Safety evaluation by, (5)	Not listed
SCF List as in ResAP(2004)1 (8)	2

Coatings

Printing Inks	
Swiss Ordinan	
Restrictions / contact mater	nnex 1 list III.27.2

Printing inks

Rubber	
ResAP(2004)4 on Rubber, presence (9)	In
ResAP(2004)4, Index list C (9) national level in	
SCF Status as in ResAP(20	g/kg
Restrictions / Specificatio	mg/kg (FR), maximum use level 5 %, for all phthalates and not for foods for migration test with simulant D is required. (DM 17/12/99) (IT), SML=40 (NL)
ESCO Compilation, Safety evaluation by, (5)	B (FR), B (IT), B (NL)

Rubber

Paper & Board	
ResAP(2002)1 on paper and board, lists and appendices (7)	Not listed
Restrictions / Specifications : ResAP(200 paper and board (6), and ESCO docu	kg but intended to be revised to 15
ESCO Compilation, Safety eval	

Paper and Board

Silicones	
ResAP(2004)5 on silicones (11)	
Restrictions / Specifications : Re silicones (11), and ESCO docume	
ESCO Compilation, Safety evaluatio	

Silicones

Toxicological information

Toxtree

VEGA

Q(SAR) softwares	
Endpoints	
Toxtree: Non-Genotoxic Carcinogenicity	N
Toxtree: Genotoxic Carcinogenicity	N
Toxtree: Cramer Structural class	I
Toxtree : Octanol water partition coefficient (XLogP or Log Kow)	7.65
Vega: Mutagenicity (Ames test) model (CAESAR)	NONMutagenic (EXPERIMENTAL value)ADI:1
Vega: Mutagenicity (Ames test) model (SarPy/IRFMN)	NON-Mutagenic (EXPERIMENTAL value)SM118; SM146; SM163; SM169; SM170; SM182ADI:1
Vega: Mutagenicity (Ames test) model (ISS)	NON-Mutagenic (EXPERIMENTAL value) ADI:1
Vega: Mutagenicity (Ames test) model (KNN/Read-Across)	NON-Mutagen (good reliability) ADI:0.989
Vega: Carcinogenicity model (CAESAR)	Carcinogen (EXPERIMENTAL value) P (Carcinogen):0.592 P(NONCarcinogen):0.408 ADI:1
Vega: Carcinogenicity model (ISS)	Carcinogen (EXPERIMENTAL value)SA41 Substituted nalkylcarboxylic acids; SA42 Phthalate diesters and monoestersADI:1
Vega: Carcinogenicity model (IRFMN/Antares)	Carcinogen (EXPERIMENTAL value)Carcinogenity alert no. 88ADI:1
Vega: Carcinogenicity model (IRFMN/ISSCAN-CGX)	Carcinogen (EXPERIMENTAL value)Carcinogenity alert no. 29ADI:1
Vega: Developmental Toxicity model (CAESAR)	NONToxicant (low reliability) ADI:0
Vega: Developmental/Reproductive Toxicity library (PG)	Toxicant (EXPERIMENTAL value) ADI:1
Vega: Relative Binding Affinity model (IRFMN)	Active (EXPERIMENTAL value) ADI:1
Vega: Skin Sensitization model (CAESAR)	Sensitizer (moderate reliability) O(Active):0.72 O (Inactive):0.28 ADI:0.776

open source application, which is able to estimate toxic hazard by applying a decision tree approach

a platform of different computational models that predicts different toxicological endpoints

a software application to identify and fill (eco)toxicological data gaps for chemicals hazard assessment

OECD QSAR ToolBox (14)	
Endpoints	
Estrogen Receptor Binding	Non binder
Carcinogenicity (genotox and nongenotox) alerts by ISS	Yes
DNA alerts for AMES, MN and CA by OASIS v.1.2	No alert found
DNA binding by OASIS v.1.2	No alert found
DNA binding by OECD	No alert found
in vitro mutagenicity ("Ames test") alerts by ISS	No alert found
in vivo mutagenicity (Micronucleus) alert by ISS	Yes
Oncologic Primary Classification	Not classified

Based on the chemical structure do we have evidences for:

Carcinogenicity,
Mutagenicity
Reproductive Toxicity?

WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

Database of substances known by member states of the Council of Europe and used in FCM: Practical applications

Overview

- Introduction
- Database CoE-MS-FCM
- Practical applications of the database
  - TTC
  - Safety color schemes
  - Research project on Printed Paper and Board
- Conclusion

Threshold of Toxicological Concern

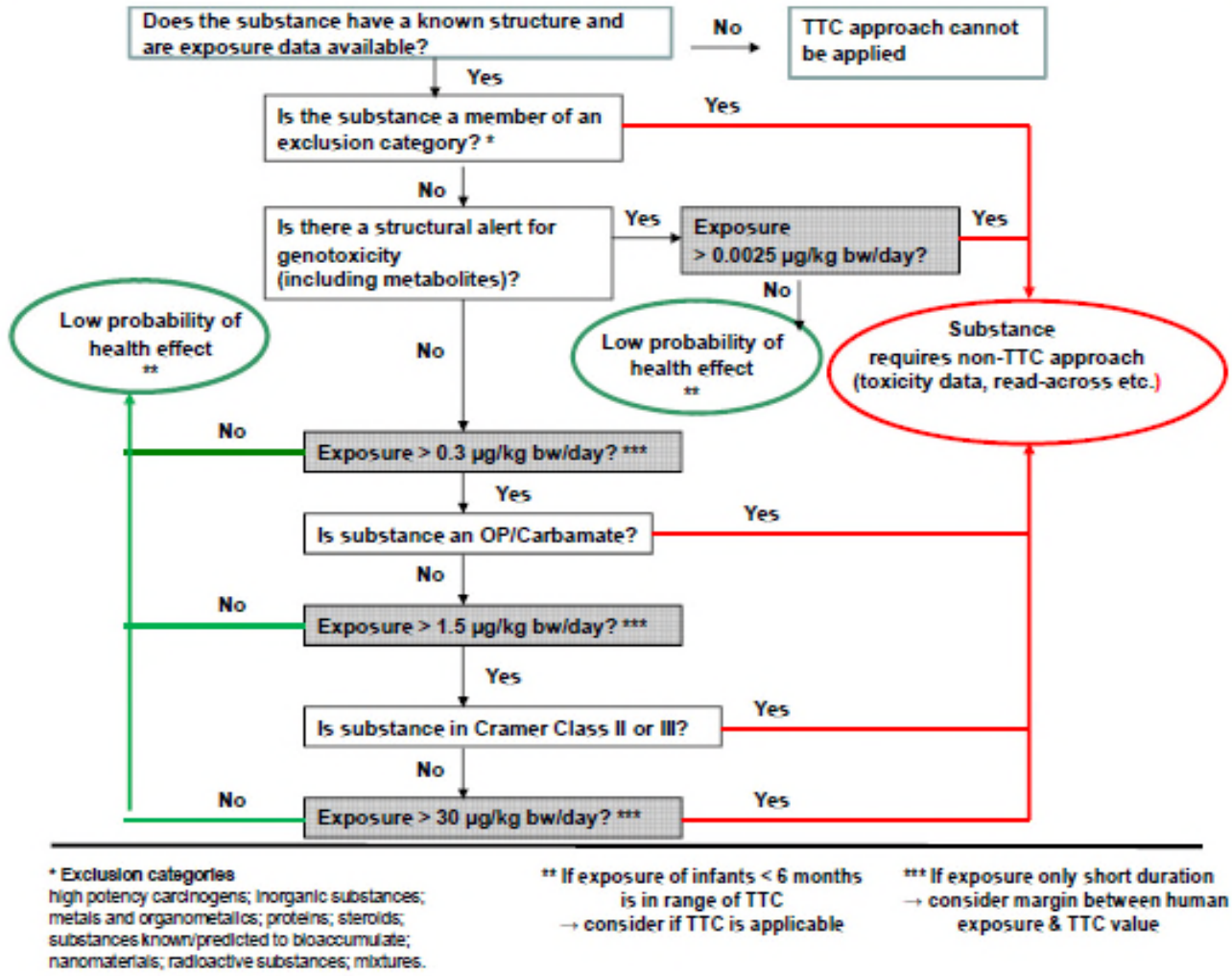
- *Useful screening tool for priority setting OR for deciding whether exposure to a substance is so low that the probability of adverse health effects is low and that no further data are necessary*

- *TTC may not be used when there is a requirement to submit toxicity data: (e.g. Not for technically active substances in pesticides, food additives, nutrient sources, feed additives, etc.)*

…continued

efsa
European Food Safety Authority

Opinion on Threshold of Toxicological Concern



* Exclusion categories
high potency carcinogens; inorganic substances; metals and organometallics; proteins; steroids; substances known/predicted to bioaccumulate; nanomaterials; radioactive substances; mixtures.

** If exposure of infants < 6 months is in range of TTC → consider if TTC is applicable

*** If exposure only short duration → consider margin between human exposure & TTC value

Safety Color Schemes for substances
(illustrative example - remains under discussion…)

DBID	Bioaccumulation	Mutagenicity Software 1	Mutagenicity Software 2	Mutagenicity Software 3	Endocrine disruption	Other genotoxic alerts
ABC	Yes	Yes	Yes	Yes	Yes	Yes
XYZ	Yes	No	No	No	Yes	Yes
DEF	No	No	No	No	No	No

WETENSCHAPPELIJK INSTITUUT
VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE
DE SANTÉ PUBLIQUE

THANK YOU FOR YOUR ATTENTION !

Special thanks to:

Dr. Els Van Hoeck
Dr. Birgit Mertens
Dr. Padmaja Kamath
Melissa Van Bossuyt

WETENSCHAPPELIJK INSTITUUT
VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE
DE SANTÉ PUBLIQUE

Exercices on database

Dr Fabien Bolle
Unit Consumer Safety
Department Food, Medicines and Consumer Safety

EFSA
25/05/2016

Rue Juliette Wytsmanstraat 14 | 1050 Brussels | Belgium
T +32 2 642 51 11 | F +32 2 642 50 01 | email: info@wiv-isp.be | www.wiv-isp.be

Welcome to the FCM Database

Search: FCM database wip

Website link: https://fcm.wiv-isp.be

Login: efsa@mail.com

Password: efsa

Research by CAS n°

CAS n° 75-65-0

Question :

In wich material is listed this substance ?

What means SCF list 3 ?

What about Endocrine Disruption ?

Research by name :

Name : 2-Butenal

Question :

In wich material is listed this substance ?

What about Cancero or mutagenicity?

Results of consultation of DB

Research by CAS n°

CAS n° 75-65-0

Question :

In wich material is listed this substance ? Inks, P&B, Coatings

What means SCF list 3 ? List 3

“Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.
Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material or a specific limit of migration is stated. This is because the available toxicological data would give a TDI which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive”.

What about Endocrine Disruption ? No alerts

Research by name :

Name : 2-Butenal

Question :

In wich material is listed this substance ? Inks

What about Cancero or mutagenicity? Yes, a lot of alerts and presence in lists

WETENSCHAPPELIJK INSTITUUT
VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE
DE SANTÉ PUBLIQUE

THANK YOU FOR YOUR ATTENTION !

Special thanks to:

Dr. Els Van Hoeck
Dr. Birgit Mertens
Dr. Padmaja Kamath
Melissa Van Bossuyt