



Cyclo-di-BADGE (CdB)

Migration from the inner coating of metal cans containing cold beverages

- Belgium -

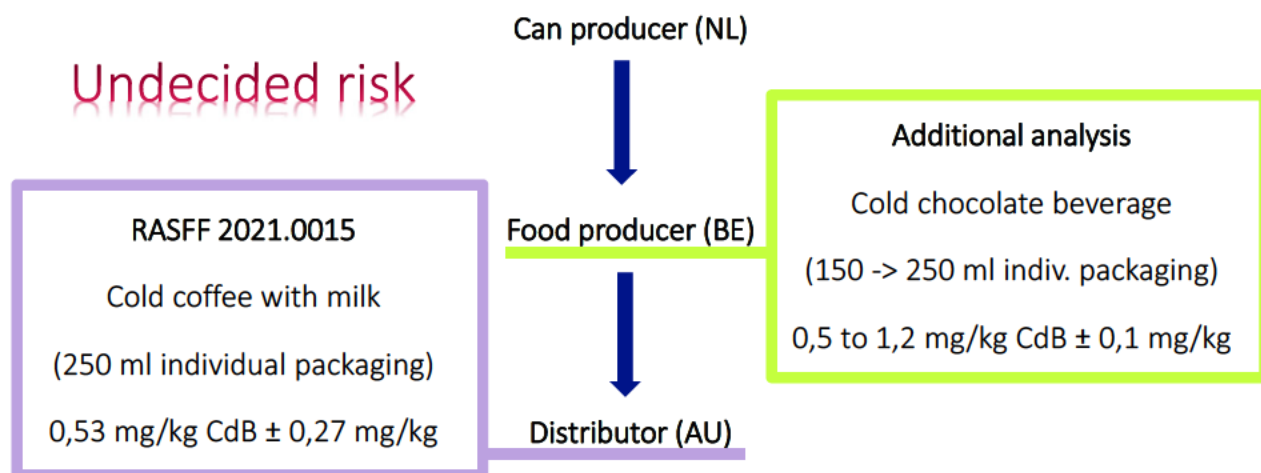
European expert WG on Food Contact Materials

26-27.04.2021



Products & amounts of CdB

Undecided risk



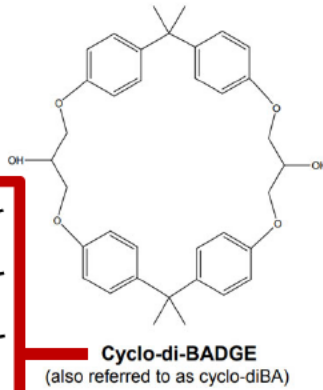
Chemical background & Legislation

Reg 1935/2004
Article 3

~~Reg 1895/2005~~

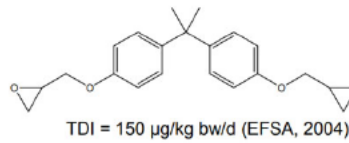
~~Reg 2018/2013~~

~~RD 25 Sept. 2016~~

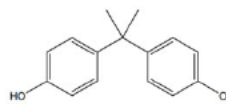


NIAS

Bisphenol-A-diglycidyl ether (BADGE)



Reg 1895/2005



t-TDI = 4 µg/kg bw/d (EFSA, 2015)
Previous TDI = 50 µg/kg bw/d (EFSA, 2006)

Reg 2018/2013



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Hazard assessment

Genotoxicity and carcinogenicity

Because the CdB metabolites exhibit structural similarities with metabolites of BADGE derivatives, **BADGE itself is not genotoxic *in vivo* and no carcinogenic potential could be determined in the gastrointestinal tract or in other tissues in a chronic toxicity/carcinogenicity study with rats after oral administration (EFSA 2004), it can be assumed that these CdB metabolites are likewise not genotoxic and not carcinogenic *in vivo*.**
(Biedermann et al., 2013)

(potentially) Endocrine disruptors

Due to the specific binding of CdB to nuclear receptors, an effect on the endocrine system cannot be excluded.
(BfR, 2016; Biederman et al., 2013)

No acute reference value

Chronic risk



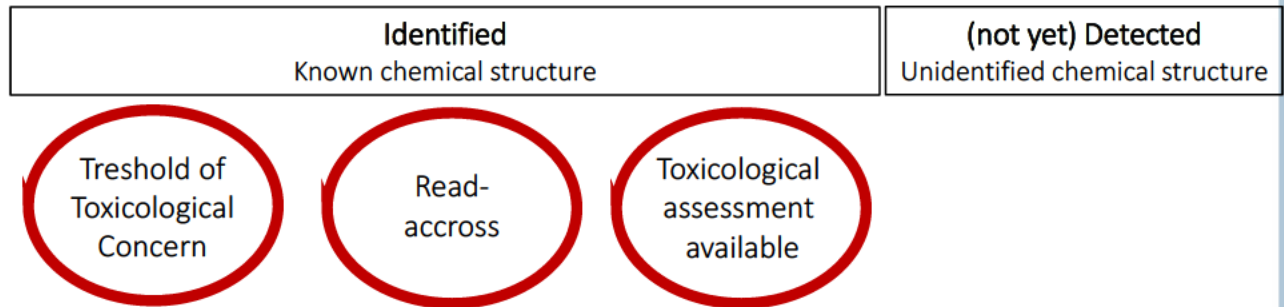
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Toxicological assessment

Starting substances ——— IAS
NIAS



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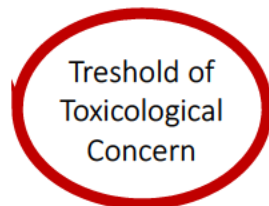
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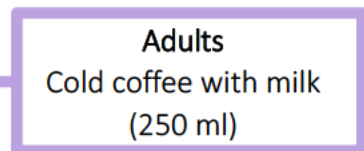
Risk assessment

BfR opinion O22/2016 of 15 April 2016

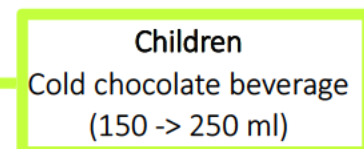
<https://www.bfr.bund.de/cm/343/epoxidharz-beschichtungen-von-konservendosen-stoffuebergaenge-in-oelhaltige-lebensmittel-sind-moeglich.pdf>



Possible chronic risk from 1,5 µg/kg bw
(Cramer class III)



Higher possible chronic risk



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Food categories	Population driving the consumption (a)	Food consumption to be considered for the estimation of exposure (g/kg bw per day)
Water and baby bottle contents such as reconstituted milk formula	Infants (b)	150
Milk, milk products and other non-alcoholic drinks (e.g. fruit and vegetable juices)	Toddlers (c)	80
Solid foods specially intended for infant and toddlers	Toddlers	50
Foodstuffs not covered by the 3 other food categories	Toddlers	20

Food consumption figures based on the categorisation of application(s) of the FCMs
EFSA, 2016



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Counter risk assessment



No serious risk
but
remaining uncertainties

Adults
Cold coffee with milk
(250 ml)

No serious risk
but
unsuitable exposure
estimation

Adults
Cold chocolate beverage
(150 -> 250 ml)

children were not taken into account



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Overview in other MS

RASFF history

- 7 notifications
- Serious (3) or undecided risk (4)
- Aubergines, mussels, fish...
- Withdrawal from the market : if results $\geq 800 \mu\text{g}/\text{kg}$ CdB

RASFF 2018.0140 notified by Germany

product category	date	reference	product type	notification type	notification basis	notified by	countries concerned	subject	operators	action taken	distribution status	fo low-up	importance	risk decision
fish and fish products	18-01-18	2018.0140	food	alert	official control on the market	Germany	Czech Republic (D) Germany (D) Latvia (D) Poland (D)	migration of cyclo-di-BADGE (2003 $\mu\text{g}/\text{kg}$ - ppb) in canned sprats in rapeseed oil from Latvia	e-platform: Amazon Logistic Pragues.r.o. exporter: Unda Ltd. importer: Dovgan GmbH	informing recipient(s)	distribution to other member countries		4	serious



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Discussion EU Commission

- Several discussions in our WG in the past
- Last discussion in 2018:
 - Put on the agenda by Germany (see RASFF)
 - Tox data was asked by Germany
 - No data was submitted by industry



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Undertaken measures and actions

Food producer (BE)

- Blocking of the cans at the premises
- The manufacturer is currently adapting the can production process
- No market withdrawal or recall

Authorities (BE)

- Discussions between Belgian authorities (FASFC - FPS Public Health)
- Consultation of the other European countries
- Request to the Commission



Request to the Commission

- Harmonized approach between member states
 - Mandate EFSA for an opinion (+ children)
 - Harmonised legislation via BADGE, BPA or new legislation



Thank you for your attention

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