LIFE / FIT FOR REACH

Substitution of bisphenol A in epoxy resins for lining food containers

This case study aims to illustrate a chemical substitution process. It is based on publicly available information on company's experience as well as on substance hazards, alternatives to the hazardous substance and regulatory information. The case study is neither complete nor comprehensive in illustrating all substitution options of a substance but rather exemplary.

1. Case description

Bisphenol A (BPA) is hazardous for human health. It is contained in epoxy resins used for lining food containers. Due to the pressure from the general public and supply chain requests, the producer of food cans using BPA based epoxy resins identifies possible alternatives (in cooperation with a supplier) and initiates testing of those products evaluated as potentially feasible. The process is not yet concluded as testing is ongoing and sufficient hazard data for full product evaluation is lacking.

BPA-based can linings are used, among other reasons, because they:

- Extend the shelf-life of canned goods,
- Prevent bacterial contamination of canned foods as they present another layer of protection
- Prevent leaching of heavy metals from metal food cans into acidic foods
- Are tasteless, odourless and colourless
- Are inexpensive to produce and use.

1.1 Hazards of Bisphenol A (BPA)

Other names: 4,4'-isopropylidenediphenol – BPA; 4,4'-(propane-2,2-diyl)diphenol, p,p'-isopropylidenebisphenol, 2,2-bis(4-hydroxyphenyl)propane)

Bisphenol A (CAS-number 80-05-7; EC-number 201-245-8) is classified for human health (harmonised):

Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Repr. 1B, H360f

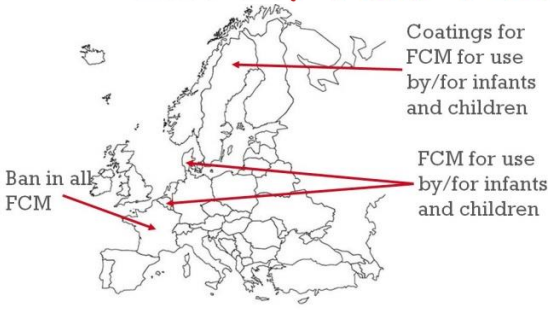
Signal word: Danger

Pictograms: 

In addition, some notifiers reports that BPA is toxic to aquatic life with long lasting effects (Aquatic Chronic 2, H411).

1.2 Regulatory status

BPA, from 12/01/2017 is a substance of very high concern (SVHC) and included in the candidate list for authorisation. Reason for inclusion in this list – toxicity for reproduction.



BPA is restricted in some Member States of the EU. BPA has been banned from infant feeding bottles across the EU since 1 June 2011. In Belgium, Sweden and Denmark, BPA is banned in other materials that come into contact with food intended for infants and children under three years. France has banned BPA in all food packaging, containers and utensils.

In the EU, there is a limit on the amount of BPA that is allowed to leach out of toys for children up to the age of three and in any toys, that are intended to be placed in a child's mouths. Currently, that migration is 0,1 mg/l of BPA. In July 2016, the European Commission published a proposal to lower that limit to 0.04 mg/l. This new limit should come into force in 2018.

In December 2016, the European Commission decided to restrict BPA in thermal paper in the EU. This ban will take effect in 2020, giving manufacturers, importers and users of thermal paper the time to phase it out and find an alternative.

EU legislation on food contact materials (FCM) requires that substances in FCM should not pose risks to the consumers. It defines a specific migration limit (SML) for BPA of 0.6 mg/kg.

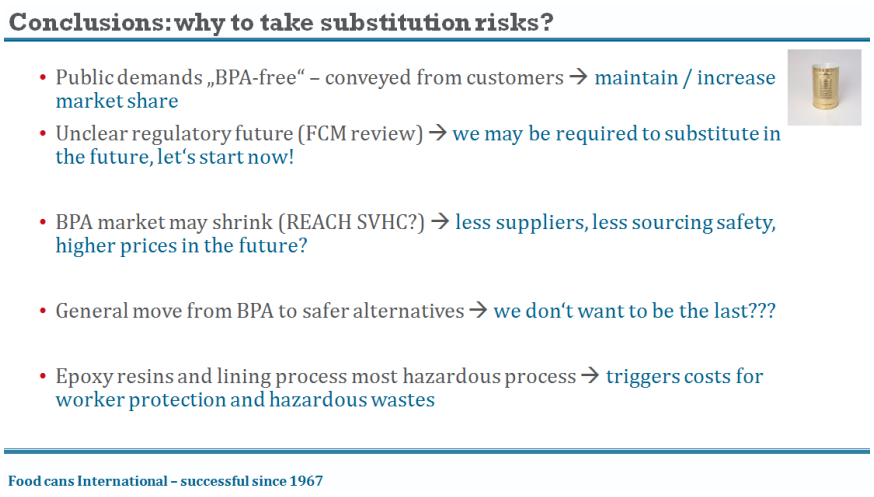
The EU Food Safety Agency (EFSA) is currently reviewing options to improve EU legislation on BPA: it is discussed, among other options, to ban BPA in FCM or restrict its content in FCM based on SMLs. Currently the new limit value of 0.05 mg/kg is under consideration.

The use of BPA in FCM is also restricted in other regions of the world, such as the United States, where several Federal States banned the use of BPA in FCM (for children's use) or Canada, which banned BPA in polycarbonate baby bottles.

2 Substitution process

2.1 Substitution incentives

The product manager of the company started the substitution process in the company. He convinced the company management of the need to look for alternatives with the following summary slide of his presentation.

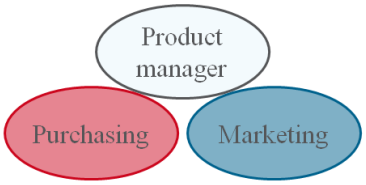


The management decided on a step-wise company internal project.

2.2 The substitution project

2.2.1 Identification of alternatives

Literature research:
- Which alternatives are described?
- How are the alternatives evaluated?
- Which technical performance is achieved?



Supplier communication:
- Types of alternatives?
- Experience, costs, support?
- Properties & technical performance?

Market analysis:
- What are others doing?
- What do consumers request?
- Which solutions appear promising?

Experience

The product manager identified several information sources on potential substitutes; however, they are comparatively general - related to components of resins and alternative materials but the information on hazards and uses are missing for many alternatives. The purchasing department did not receive any replies from the suppliers. The marketing department confirmed that consumers are aware of BPA and want to avoid it but identified no clear trends in consumer demands for particular substitutes nor in activities of competitors.

Results – initial list

Possible alternatives identified
Alternative substances in epoxy resins
Aromatic epoxy resins based on flavonoid extracts, tannins or phenolic acids
Epoxy resins produced from tetramethyl cyclobutane diol (CBDO)
Epoxy resin based on alkylated BPA
Alternative resins
Composite polymer based on polypropylene carbonate polyol (PPC) combined to modified amidon
Copolyester (PTA+CHDM+ethylene glycol + isosorbide)
Copolymer based on styrene and butadiene monomer
Formulations based on derivates of époxyresins and polyols vegetals
Hydroxylated polyester
Isosorbide-based epoxy resin
Oleo-resins
Polyester (based) resins
Polymers based on Tetradécahydroanthracène (TDHA)
Resins produced from natural oils, fatty acids and gelatin

According to the reviewed literature, **diphenolic acid and lauryl gallate** could be suitable alternatives for BPA in epoxy resins. However, research in ECHA's database shows that the substances were pre-registered for registration in 2010 but no registration dossier is included in ECHA's database.

With regard to the alternative resins, **isosorbide-based resins, polyacrylates or oleoresins** were identified as possible alternatives. However, little or no information was identified on their potentially associated hazards, their performance and applicability.

How to move on

The substitution team agreed that close cooperation with a formulator of epoxy resins would be necessary to proceed. As a next step, they decided to make specific requests to their suppliers in writing and with a follow-up call to enquire if they provide the selected alternatives they offer and their willingness to cooperate.

2.3 Selected alternative and justification

Only one of the company's suppliers answered to the specific request for information on the alternatives identified as feasible by "Food cans international". Together with the supplier they discussed the alternatives and made a preliminary assessment. The results of their screening assessment are shown in the following table.

	Offered	Data source	Acute toxicity	STOT	CMR	Sensi-tisation	Env hazards	Lack of data	Comment on hazard data	Known limitations
Acrylic resins										
Coating based on methacrylic acid (MMA) - monomer data	Yes	ECHA	Cat 3/4 all routes	SE3	not classi-fied	Resp	No	No	In use for long	
Acrylic	No	Lit			C	Resp		?	Compound from literature unclear	No use for fatty foods
Mixture of acrylic acids & styrene	No	Lit			EDC, C	Resp		?		No use for infant formula
Ethylene-acrylic acid copolymer (monomer data)	Yes	SDS	Irrit. (all routes)				Acute 1	Yes	SDS incomplete, no data for input materials	
Co-polymers of acrylates & styrene	No	Lit			EDC, C	Resp		Yes		No use for infant formula
Acrylic resins from acrylates, including phenolic resins	No	Lit			EDC					No use for infant formula
Plant based compounds										
Isosorbide based resins	No	Lit						Yes		
Oleoresins	Yes	Lit						Yes	No data, literature suggests low hazardousness	No acidic food, high price; poor adherence, long drying time, imparts

	Offered	Data source	Acute toxicity	STOT	CMR	Sensi-tisation	Env hazards	Lack of data	Comment on hazard data	Known limitations
										taste corrosion?
Epoxy resins without BPA										
Diphenolic acid	No	CLI	Irrit (eye, skin)			Resp	No	?	not registered although pre-registration date passed	
Lauryl gallate	No	CLI				Skin	No	?		

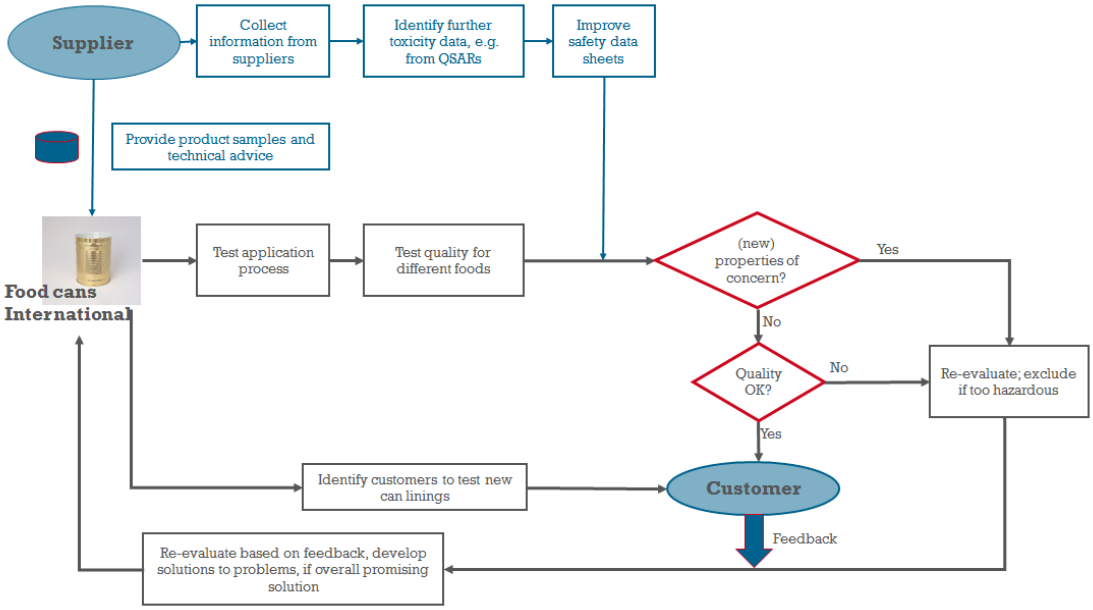
The outcome and evaluation of the alternatives by the project team in cooperation with the supplier are documented in the following table.

	Hazard conclusion	Limitations for application	Workers protection	Pragmatic aspects	Decision
Acrylic resins					
Coating based on methacrylic acid (MMA) - monomer data	Hazards known, only sensitisation of high concern; workers risks remain, low hazards for consumers expected	None known	No improvement to current situation	Product testing directly possible; no technology changes expected, some experience exists (supplier)	Select for testing
Acrylic	High concern due to carcinogenicity and sensitisation → exclude from further work				
Mixture of acrylic acids & styrene	High concern due to carcinogenicity and sensitisation→ exclude from further work				
Ethylene-acrylic acid copolymer (monomer data)	Some hazards known, high degree of uncertainty due to lack of data	Not for use in foods for infants	Improvement (no respiratory protection); if no further hazards are identified	Product testing directly possible; no technology changes expected, some experience exists (supplier)	Select for testing
Co-polymers of acrylates & styrene	High concern due to carcinogenicity and sensitisation→ exclude from further work				
Acrylic resins from acrylates, including phenolic resins	High concern due to carcinogenicity and sensitisation→ exclude from further work				
Plant based compounds					
Isosorbide based resins	Lack of data; risk of hazard identification at a later stage	Not known	Unclear due to lack of data	Supplier to be identified	Select for testing, search supplier
Oleoresins	Lack of data; risk of hazard identification at a later stage	No acidic foods; properties regarding corrosion, adherence, and taste critical (literature); long drying times, higher prices	Unclear due to lack of data	Product testing directly possible; (some) changes in process expected	No testing, as not applicable to all types of foods, too many limitations known
Epoxy resins without BPA					
Diphenolic acid	Lack of information, sensitisation and irritation may be of lower concern in the resin	Not known	No improvement to current situation	Supplier to be found, state of development unclear, necessary changes in processing unclear	Identify supplier, decide based on further information
Lauryl gallate	Lack of information, sensitisation and irritation may be of lower concern in the resin	Not known	Improvement (no respiratory protection); if no further hazards are identified		

2.4 Implementation

Implementation plan

The substitution team developed a substitution plan to test and gather further information on the resins.



State of play

The company started testing the new resins in the coating process. They are still looking for suppliers of the two drop-in solutions to replace BPA and respective resin producers that could provide samples for testing.

There is no clear result from the testing yet. Problems encountered include

- coating machines needed to be adapted to new resins, e.g. different dosing due to different viscosities,
- processing times change due to different curing / drying behaviour
- the lining varies in thickness and the final product testing needs to be performed to identify optimal layer quality
- about 2 years (product shelf life term) is needed for company to test the overall impact of the new lining for their product

Up to now, no further information was obtained on as yet unknown hazards of the product.

2.5 Communication of substitution

As the process is not finalised, no marketing strategy was developed, yet.

Contacts with core customers, who had already communicated their wish to substitute BPA in can linings, were positive. Out of 10 customers, 3 volunteered to test the product assortment with new cans and provide feedback.

2.6 Costs and savings

As the process is not finalised, no cost implications can be identified, yet. The testing process as such does not (yet) influence production as it is carried out with facilities which are not operated at full capacity.

The initial research for alternative products, communication with the supplier and setting up the substitution project cost approximately 10.000 Euro (working time of involved people). The costs for testing cannot be differentiated from the overall production costs. Lab-costs are comparatively low.

Costs for Personal Protection Equipment of workers might slightly decrease due to the lower hazards posed by the alternative products.

2.7 Evaluation

No full-scale evaluation is possible yet but the following is concluded at the current state of play:

- There are alternatives to the use of BPA, which are less hazardous. However, there are uncertainties due to lack of data for many of the alternatives, this includes lack of information on monomers as well as additives used in the resin mixtures
- The alternatives require different processing approaches but are likely to be applicable with the current equipment.
- Testing with epoxy resins using 1:1 substitutes for BPA are still pending due to a lack of suppliers

3 References

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