



Phthalates in food contact materials (FCMs)

Results from a short survey on the use of phthalates (esters of phthalic acid) in FCMs from October 2019

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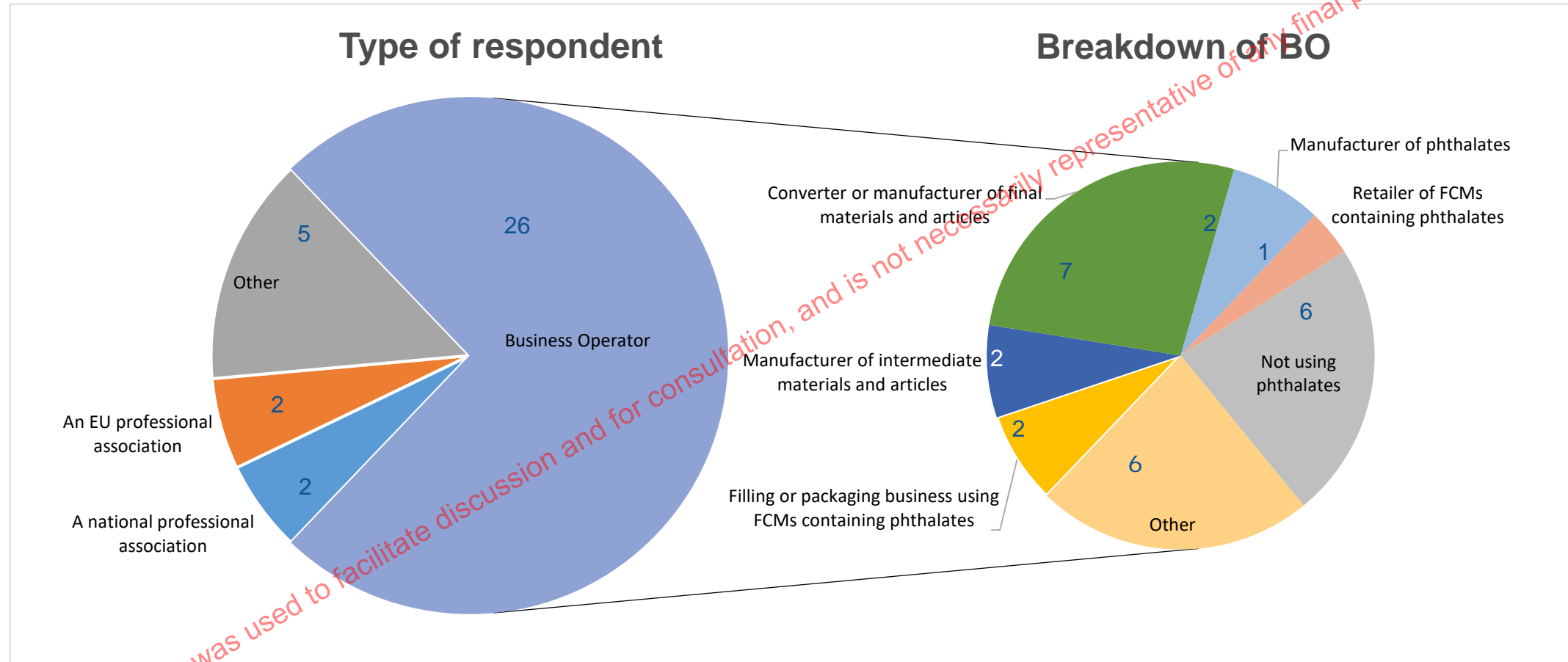
DG SANTE, Unit E2

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Respondents overview

- 35 valid responses, most from business operators (BOs) including manufacturers and users of phthalates (convertors and producers of final articles)
- Very small sample size → Not representative, in particular lack of input from importers of FCMs
- Two EU professional associations took part, representing:
 - EU producers of phthalates
 - EU Rubber industry

Respondents overview



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DBP, BBP and DEHP in plastic FCM

According to some business operators

- DBP and DEHP most commonly used, often together, as technical support agent (aid to polymerisation) in a catalytic system
- Used to make polypropylene flexible packaging, films
- Quantity: < 15 ppm by volume in final material
- Only 1 producer declaring to use BBP combined with DiBP as a technical support agent
- Examples of supply chain information stipulating 'PVC free liner' with phthalates ND

According to a professional association

- Possibly used in flexible vinyl FCM (hoses, gloves, conveyor belts, table cloths) imported into EU (normally up to 30% but can be higher)
- Largely deselected by EU FCM manufacturers

DINP and DIDP in plastic FCM

According to a very limited number of business operators

- DINP used together with DiBP as technical support agent in a catalytic system
- Sometimes used with ESBO or PE plasticisers
- Used to make flat film or as adhesion layer on conveyor belt
- Ranged between 1 – 10 ppm by volume in final material
- DIDP used as technical support agent together with DiBP according to one BO

According to a professional association

- Used in flexible vinyl FCM (gloves, conveyor belts, table cloths) (normally less than 30% but can be higher)
- Use in flexible vinyl closures replaced by ESBO; used in hoses and pipes replaced by DOTP and DINCH

Non-listed phthalates in plastic FCM

According to five business operators

- DiBP most mentioned (4) as a technical support agent (aid to polymerisation) together with DEP
- Isobutyl phthalate and DNOP among the other non-listed phthalates mentioned
- Article 6(4)(b) includes aids to polymerisation as a derogation for substances not included in the Union list

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Replacement substances

- Increased pressured from consumers, change in the supply chain and regulatory issues mentioned as reasons to switch to “replacements”
- Replacements include:
 - Epoxidised Soybean Oil (ESBO)
 - Acetyl Tributyl Citrate (ATBC)
 - 2-Ethylhexyl Diphenyl phosphate (EHDP)
 - 2-Ethylhexyl Diphenyl Hexanedioic acid (DEHA)
 - Triphenyl phosphate (TPhP) “Disflamoll®”
 - Hexanedioic acid
 - Dibutyl sebacate
 - Hydrogentated acetylated castor oil
 - Isosorbide esters
- Opinion for authorisation of Trimellitic acid, tris (2-ethylhexyl) ester (TOTM, TEHTP) recently published by EFSA
- Used mainly as plasticisers

Replacement substances

- ESBO used to replace DINP and DIDP in lid closures (+ sodium bicarbonate as blowing agent to replace azodicarbonamide) in EU (DINP and DIDP still used in lid closure outside EU and therefore possibly in imported products)
- DINP and DIDP in flexible vinyl hoses and tubing replaced to a significant extent by EU manufacturers with DOTP and DINCH
- DOTP and DINCH also being used to replace DINP and DIDP in Europe for other flexible vinyl FCM (gloves, conveyor belts, table cloths)
- Polymeric plasticisers (using hexanedioic acid) also used for low migration properties with fatty foods

Phthalates in non-plastic FCM

According to EU rubber industry

- DBP, BBP, DEHP, DINP, DIDP used as plasticisers but progressively phasing out those that are of a low molecular weight
- Also used as catalyst for polymerization

Cellophane applications

- Possibly some use of DCHP (authorised in Directive 2007/42)

Adhesives and printing inks

- Possibly used in FCM imported from outside EU
- Not used at national level in Germany in adhesives following REACH restrictions

Questions?



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