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

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion and understanding of existing and potential new legislation, but should not in any way be seen as giving a final interpretation of existing legislation or a proposal of new legislation.

DG SANTE, Unit E2
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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Type of respondent

- Business Operator: 26
- An EU professional association: 5
- A national professional association: 2
- Manufacturer of intermediate materials and articles: 2
- Converter or manufacturer of final materials and articles: 2
- Filling or packaging business using FCMs containing phthalates: 2
- Manufacturer of phthalates: 7
- Retailer of FCMs containing phthalates: 1
- Not using phthalates: 6
- Other: 2

Breakdown of BO

- Business Operator: 26
DBP, BBP and DEHP in plastic FCM

According to some business operators

- DBP and DEHP most commonly used, often together, as a 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

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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

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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
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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