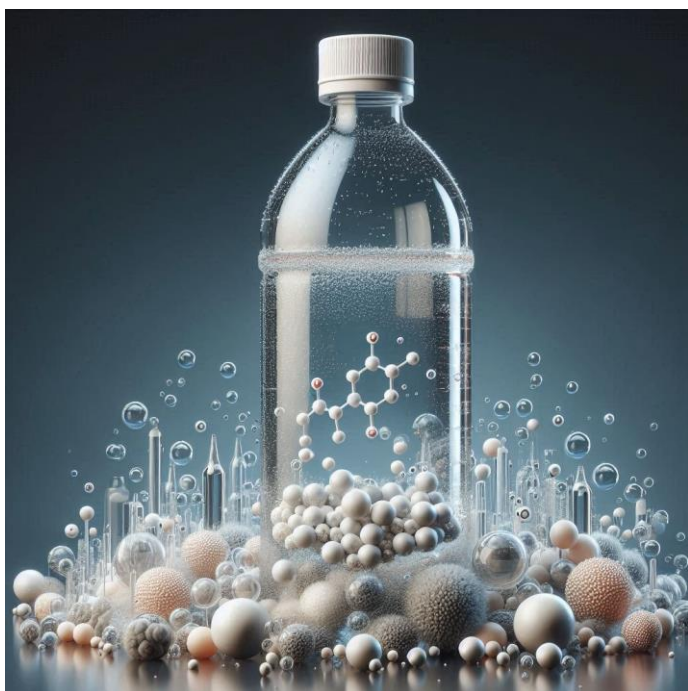


Phthalates in Food Contact Materials: Problem, Compliance, and Analytical Services

I. Problem Statement: Phthalates in Food Contact Materials



Phthalates such as diisobutyl phthalate (DIBP), di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), butyl benzyl phthalate (BBP), and diisononyl phthalate (DINP) are plasticizers commonly used to enhance the flexibility of plastics in food contact materials (FCMs). These substances are found in packaging, containers, and other materials that come into contact with food. However, they can migrate into food, especially under conditions of heat or acidity, posing risks such as endocrine disruption and reproductive toxicity.

Health Concerns:

- **Endocrine Disruption and Reproductive Toxicity:** Classified as endocrine disruptors and reproductive toxins, phthalates have been shown to interfere with hormonal systems, particularly in children. Studies have demonstrated the migration of DIBP from reusable plastic bottles, especially after multiple dishwashing cycles, highlighting the dangers of repeated use[1].
- **EFSA and ECHA Findings:** The European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) emphasize the risks associated with phthalates in FCMs. EFSA highlights the need for tighter regulations and continuous monitoring of dietary exposure to phthalates, particularly for vulnerable groups[2;4]. ECHA has classified several phthalates, including DEHP, DBP, BBP, and DIBP, as substances of very high concern (SVHCs) due to their reproductive toxicity[3].

II. Compliance Requirements for Phthalates in Food Contact Materials

To mitigate the health risks associated with phthalates, manufacturers must comply with a range of stringent regulations governing the use of phthalates in FCMs. These regulations ensure that phthalate migration into food remains within safe limits.

1. Regulation (EC) No 1935/2004:

- This overarching regulation lays down the general principles for all materials and articles intended to come into contact with food, ensuring they do not release substances that pose a risk to human health, alter the composition of the food, or adversely affect its taste or smell. Article 3 of this regulation mandates that food contact materials must be manufactured in compliance with good manufacturing practices (GMP)[3].

2. REACH Regulation (EC) No 1907/2006:

- Phthalates such as DEHP, DBP, BBP, and DIBP are classified as SVHCs under REACH. Their use in FCMs is tightly controlled, and businesses must comply with strict authorization procedures or face significant restrictions (Annex XIV and XVII).

3. Food Contact Materials Regulation (EC) No 10/2011:

- This regulation sets specific migration limits (SMLs) for phthalates in food contact plastics, with DEHP's limit at 1.5 mg/kg and DINP and DIDP combined limited to 9 mg/kg. Compliance with these limits ensures minimal migration of harmful substances into food[3].

4. Testing Standards for Compliance:

- **NEN 1186-2, 1186-3, 1186-4:** These standards provide detailed methods for determining the overall migration of substances from plastics into food simulants[3].
- **NEN-EN 14372:2004:** This standard outlines the procedures for testing phthalates in childcare articles and FCMs.
- **NEN 13130-1:** Specifies analytical methods for determining the migration of plasticizers from food contact materials into food[3].
- **JRC EUR 23814 EN 2009:** This report provides comprehensive guidance on migration testing under Regulation (EU) No 10/2011, with particular emphasis on phthalates[2;4].

III. Analytical Services to Ensure Compliance

Our laboratory offers a range of expert services designed to help manufacturers meet regulatory requirements for phthalates in food contact materials, using the latest international testing standards, including **NEN** and **JRC** guidelines for food contact materials.

1. Advanced Phthalate Detection:

- We employ advanced techniques such as **gas chromatography (GC)** and **liquid chromatography-mass spectrometry (LC-MS)** to detect trace levels of phthalates, including DIBP, DEHP, DBP, BBP, and DINP. These methods ensure that even the smallest quantities of these substances are identified and quantified, guaranteeing compliance with regulatory requirements[1].

2. Migration Testing:

- We conduct migration testing in accordance with **NEN 1186-2/3/4** and **JRC EUR 23814 EN 2009**, simulating real-world conditions by using food simulants and subjecting materials to varying temperatures and exposure times[2;4][3]. This ensures that any migration of phthalates from FCMs into food remains within legal limits.
- Our services also include testing under **NEN-EN 14372:2004**, which is especially important for products intended for children.

3. Regulatory Compliance Documentation:

- We provide detailed documentation of testing results, demonstrating full compliance with the relevant EU regulations, including **EC No 1935/2004**, **EC No 10/2011**, and **REACH**. We also adhere to **NEN 13130-1** to provide data on plasticizer migration, ensuring manufacturers can prove regulatory compliance [3].

4. Consulting Services:

- In addition to testing, we offer consultation services to help manufacturers transition to phthalate-free alternatives. Our experts assist in selecting safer materials that maintain product performance while ensuring compliance with EU regulations.

IV. Conclusion: Partnering with Experts to Ensure Phthalate Compliance

Complying with regulations such as **Regulation (EC) No 1935/2004**, **EC No 10/2011**, and **REACH** requires precise testing and a thorough understanding of the latest regulatory standards. Our laboratory provides comprehensive testing and consulting services, ensuring that your products meet these regulations and protect consumer health. By

partnering with us, manufacturers can ensure compliance, reduce the risk of harmful phthalate migration, and safeguard their reputation.

Contact us today to learn more about how our phthalate testing and compliance services can support your business.

References:

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