

Ortho-Phthalate esters (phthalates) are a group of chemicals that have been extensively used since the 1920s in a wide variety of common household products such as carpets, wall covering, cables, tubes, packaging materials and paint. They have become ubiquitous environmental contaminants. There is some consumer concern about their effects on infants specifically with regards to reproductive system development particularly from phthalates' historical use in children's flexible plastic toys. About 30 different phthalates are used as plasticisers and which are now regarded as environmental and food-contaminants. The most widely used phthalate has historically been diethylhexyl phthalate¹, more usually known by the abbreviation, DEHP. However, due to increasing evidence for the adverse effects of this substance on male reproductive development, DEHP has often been replaced in recent years with non-phthalate alternatives. This is particularly the case for sensitive applications (e.g. food contact materials FCMs), medical tubing and infant toys. Though newer and not as well characterised as DEHP, these novel alternatives generally have more promising safety profiles.

What are the health effects from phthalates in foods?

The risk to humans from dietary exposure to phthalates is not always clear and varies depending on the individual ortho-phtalate additive used. Acute toxicity is very low, but animal studies have shown that phthalates cause reproductive and developmental effects, particularly for males. Phthalates are regarded as endocrine disruptors i.e. chemicals that can interfere with hormone systems at certain doses. They show anti-androgenic properties i.e. inhibit the action of male sex hormones.

What are the regulatory and consumer responses to phthalates in foods?

Some regulatory bodies have set limits for migration of phthalates from FCMs (e.g. Europe), while others have set limits for phthalates in foods (e.g. China). In some cases, phthalates are regulated by permitted levels for FCM and/or food by specific migration limit (SML) or maximum permitted quantity of additives (QM). For example, EU and Chinese regulations include DEHP at 1.5 mg/kg (SML). Apart from Regulations, there are also voluntary measures in place. The general public has an awareness of, and concern about, the potential presence of phthalates in foods from media accounts during the last two decades.

What is the concern for milk & dairy products?

In flexible plastics, phthalates are not chemically bonded and so can potentially leach out. Being soluble in fat, phthalates readily dissolve into the fat portion of foods including milk, which has a typical fat content of about 4%. Therefore there is a risk of food contamination if phthalates are used in FCMs such as flexible teat cup liners on milking machines, flexible hosing at the dairy farm/ factory, or dairy product packaging materials.

Laboratory testing for phthalates in food

Because of the widespread historic use of phthalates, they are ubiquitous in the environment. Hence, special care must be taken during analysis to ensure that the laboratory itself does not contaminate the samples being analysed. This needs to be regularly checked by including appropriate quality control samples/blanks. Phthalates are most commonly analysed by either gas- or liquid-chromatography, coupled with mass spectrometry detection. A globally harmonised testing method does not exist, i.e. different laboratories may use different methods with different limits of detection.

How can the dairy industry minimize phthalate contamination of products?

Milking equipment on the farm, as well as processing equipment at milk collection centres and dairy factories, can be sources of phthalates residues. To minimize phthalate contamination, it is important that all materials that come in contact with milk and milk products are certified by their suppliers as being free from ortho-phthalates. If such certification is not provided, then the equipment should be regarded as suspect, and will require testing at an accredited laboratory. The following

¹The chemical name of DEHP is Bis(2-ethylhexyl) phthalate (CAS 117-81-7). Also known as Dioctyl phthalate (DOP)

(non-exhaustive) list contains items known to be risk factors for phthalate contamination of milk and milk products:

- teat cup liners on milking machine clusters;
- connection hoses;
- flexible gaskets and washers;
- silicon-based hoses (e.g. in peristaltic pumps);
- PVC (polyvinyl chloride) hoses and tubing (PVC materials are a particular risk).
- ingredients and processing aids;
- packaging materials;
- equipment used to transport the milk from farm to the manufacturing plant and between manufacturing plants.

There is a wide range of alternative phthalates-free materials available for flexible items of equipment that may have contact with milk or milk products.

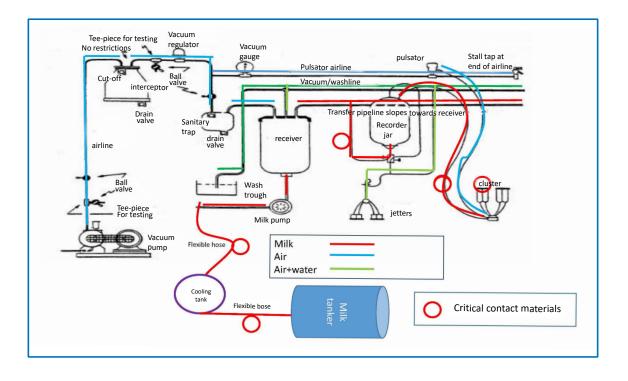
For FCMs, non-PVC materials include: polyurethane (PU); polyethylene terephthalate (PET); high density polyethylene (HDPE); polypropylene (PP); polystyrene (PS); poly(acrylonitrile butadiene styrene) (ABS); poly(styrene butadiene styrene) (SBS); polylactic acid (PLA); starch; polyhydroxyalkanoate (PHA); cellulose; natural rubber; and silicones.

Alternative plasticisers to use with these alternative FCMs include: trimellitate esters; (CAS 3319-31-1); citrate esters (CAS 77-90-7); terephthalate esters (CAS 6422-86-2); epoxidised soybean oil (CAS 8013-07-8); adipate esters (CAS 103-23-1); sebacate esters (CAS 109-43-3) and cyclohexane dicarboxylate esters (CAS 166412-78-8).

Those alternative plasticizers are allowed and listed in EU No 10/2011 on plastic materials and articles intended to come into contact with food and have SMLs in acceptable range from 18 to 60 mg/kg.

Summary

Residues of phthalates in milk and dairy products are of concern to regulatory bodies and consumers. Although these compounds are ubiquitous as environmental contaminants, milk and milk product contamination can be avoided to a large extend by substituting known high-risk flexible FCMs with alternative materials that are certified by their suppliers as being phthalate-free.





References

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International Dairy Federation www.fil-idf.org