Food
Agroscope Fact Sheet | No. 115 / 2020

Phthalates in the Dairy Industry

Avoiding problematic plasticisers in milk and dairy products

Authors: Jan-Erik Ingenhoff, Thomas Berger, Marc Mühlemann

Background

Phthalates are chemicals commonly used as plasticisers for plastics. These substances have become ubiquitous in the environment due to their industrial use in a wide range of consumer products such as carpets, cables, hoses and packaging. Some phthalates are classed as endocrine disruptors; in other words, these substances can cause health problems by interfering with the hormone system and are known to have a critical effect on the development of reproductive organs in rodents. Many phthalates used as plasticisers are now regarded as environmental and food contaminants and have been heavily regulated by authorities in recent years and banned in some cases. This advisory leaflet deals with phthalates in relation to the dairy industry and proposes preventive measures specific to this sector.

Chemistry

Phthalates, or phthalate acid esters, are esters of ortho-phthalic acid (1,2-benzenedicarboxylic acid). Phthalic acid salts are also classed as phthalates, although these substances play a secondary role in industrial applications.
Different phthalic acid esters can be derived from the same basic molecular structure through the reaction of ortho-phthalic acid or phthalic acid anhydride with different alcohols. The alcohol forms the side chains R_1 and R_2 (Figure 1) of the phthalate and largely determines its physical characteristics. Phthalates with different side chains are used, depending on the purpose.

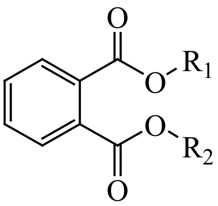

Figure 1: Basic structural formula of a phthalate.

Use

Most industrially manufactured phthalates are used as plasticisers for plastics such as polyvinyl chloride (PVC), nitrocellulose and synthetic rubber. The addition of phthalates increases the flexibility, elasticity and durability of the plastic material. Tubes and hoses, foils, floor coverings, cables, paints and varnishes, grease-free lubricants and anti-foaming agents are among the product groups commonly containing phthalates uses as plastic additives. They are also used as excipients in medicinal products, for example enteric coatings for tablets to prevent the active ingredients dissolving in the stomach (BAG 2019 – Phthalate Factsheet published by the Swiss Confederation's Federal Office of Public Health). The proportion of plasticisers in the end-product ranges from 10 to 60%.
Phthalates containing R_1 and R_2 chains with low molecular weights are used as solvents and carrier fluids for pesticides, cosmetics and perfumes. DBP (dibutyl phthalate) and BBP (benzyl butyl phthalate) are relevant due to the volumes produced and consumed. DIBP (di-isobutyl phthalate) is an important alternative to DBP because it has very similar properties.

DEHP (di-(2-ethylhexyl) phthalate) was long the most widely used universal plasticiser in the world. Now recognised as an endocrine disruptor on account of its reprotoxic properties, DEHP has since been partially replaced by DINP (di-isonnonyl phthalate) and DIDP (di-isodecyl phthalate) (Figure 2), both of which have a higher molecular weight (Figure 2).

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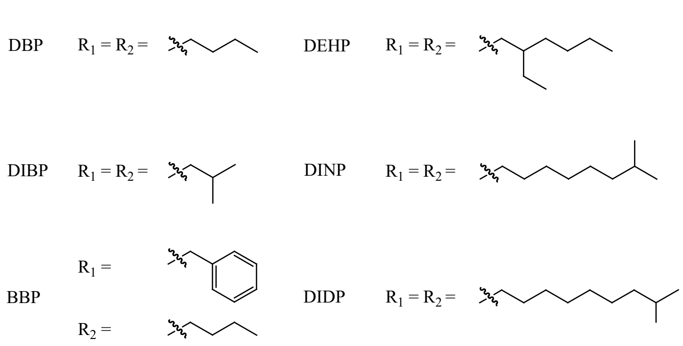

Figure 2: The structural formulae of the R1, R2 groups of some phthalates.

Around 8.4 million tonnes of plasticisers are produced annually worldwide. Roughly 1.5 million tonnes are produced annually in Europe, 70% of which are phthalates (IHS Markit 2018).

Toxicology

Various expert committees in Europe and the US have conducted risk assessments to evaluate the toxicity of phthalates. Phthalates have low acute toxicity, with LD_{50} values (lethal dose: the dose that kills 50% of a group of test animals) of 1-30 g/kg body weight or in some cases higher (Heudorf et al. 2007). However, some phthalates are classed as endocrine disruptors and have the potential to cause harm by interfering with the organism's hormone system. In laboratory animals, repeated or prolonged exposure to phthalates has been found to cause various adverse effects, especially with regard to the development of the male reproductive system. The observed effects include infertility, reduced sperm count, undescended testes, reproductive tract defects and malformation of the reproductive organs (National Research Council (US) 2008). The term 'phthalate syndrome' is often used in the context of animal experiments with mammals. The risk assessments were based on the results of studies involving laboratory animals in view of the lack of comparable data for humans. The resulting toxicological parameters (NOAEL [no observed adverse effect level] and LOAEL [lowest observed adverse effect levels]) were correlated with the available human exposure data and estimates. On the basis of these data, it was recognised that phthalates could also cause reduced sperm counts, changes to testicular histology and reduced fertility in humans (Figure 3).

Developmental studies have also examined the possible correlation between increased exposure to phthalates and increased prenatal mortality, reduced growth and birth weight, and skeletal, visceral and external malformations (Heudorf et al. 2007).

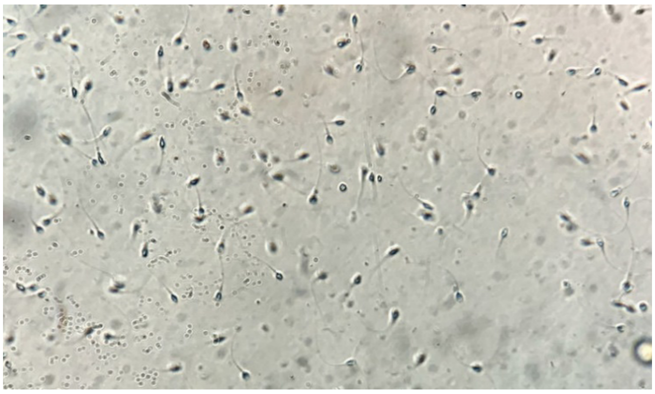

Figure 3: Animal studies have shown that phthalates disrupt the hormonal balance and can adversely affect male fertility.

Entry into the dairy industry process chain

Official exposure studies at European level have shown that DEHP residues in food are the primary source of phthalate exposure. A Belgian study conducted by Fierens et al. (2013) examined the process chain for milk producers and processors. It showed that phthalates could be detected in the raw milk of dairy cows and that DEHP and DIBP could be absorbed though feed (silage and in the case of DEHP, pasture as well). Furthermore, both DEHP and BBP can enter the milk via teat cup liners on milking machine clusters, flexible hoses on the milking machine, and plastic pipes (Figure 4).

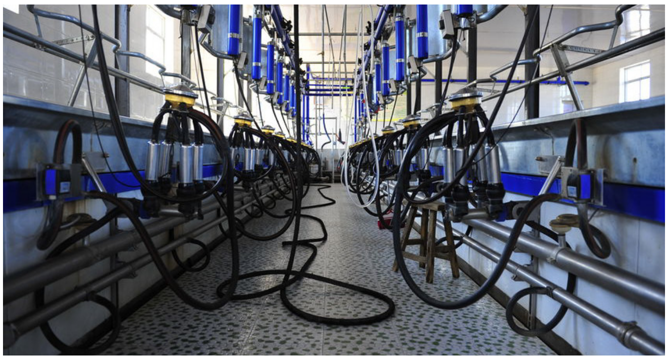

Figure 4: Phthalates are mainly used as plasticisers for plastics. The addition of phthalates increases the flexibility, elasticity and durability of hoses, seals and synthetic rubber parts.

A further rise in DEHP levels was observed after centrifugation, pasteurisation, standardisation and cooling of the milk in the dairy. Possible sources of contamination in this case are materials containing DEHP which come into direct contact with food, for example hoses and seals. DEHP is also known to have a higher diffusion coefficient at high temperatures than at lower temperatures (Kim et al. 2003).

Thus it can be assumed that the heating of milk during pasteurisation could considerably accelerate DEHP migration (Figure 5).

Figure 5: Plasticisers can enter the milk production and processing chain through direct contact between the milk and plastic materials containing phthalates.

Preventive measures in the dairy industry and alternative materials

To minimise phthalate contamination, it is important to ensure that materials that come into contact with milk and dairy products are certified phthalate-free by the manufacturer or supplier (Figure 6). Non-certified products should be tested by an accredited laboratory before use. Phthalate analysis typically involves the use of gas or liquid chromatography coupled with mass spectrometry.

Figure 6: It is important to ensure that materials that come into contact with milk and dairy products are certified phthalate-free by the manufacturer or supplier.

There is a wide range of alternative phthalate-free materials available for flexible items of plastic equipment: high-density polyethylene (HDPE), polypropylene (PP), polystyrene (PS), acrylonitrile-butadiene-styrene copolymer (ABS), styrene-butadiene-styrene copolymer (SBS), polylactic acid (PLA), starch, polyhydroxyalkanoate (PHA), cellulose, natural rubber, and silicones.
The following alternative plasticisers can be added to these PVC-free carrier materials to increase flexibility and elasticity: 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). These are listed in EU Regulation 10/2011 as approved plasticisers for use in materials intended to come into contact with food (EU 2011 and IDF 2017).

Regulations

Data from human biomonitoring studies (determination of chemical levels in blood, urine or hair) and exposure estimates are used to evaluate the degree of plasticiser exposure. Authorities introduce measures to reduce phthalate exposure on the basis of these data.
In Switzerland, the Chemical Risk Reduction Ordinance (ChemRRV, SR 814.81) prohibits the supplying of reprotoxic substances and preparations to consumers for private use. This ban does not apply to the following product groups: pharmaceuticals, artists' pigments and engine fuels. Suppliers and producers who supply articles containing more than 0.1 per cent by weight of reprotoxic phthalates (e.g. DEHP, BBP, DBP, DIBP) are legally bound to inform consumers of the presence in the article of 'substances of very high concern' in accordance with Annex 3 of the Chemicals Ordinance (ChemO). They must also indicate the measures required to ensure safe use of the article. This information must be provided to professional and commercial users without being requested.
Annex 1.18 of the ChemRRV governs the levels of these plasticisers in imported products. In Switzerland it is prohibited to place on the market an article containing more than 0.1% by weight of the four phthalates listed in the annex (DEHP, BBP, DBP and DIBP). This ban also applies if only part of the article comprises plasticiser materials.
The use of phthalates of very high concern in packaging film that comes into contact with food is universally prohibited.

Exposure via milk and dairy products

The German Federal Institute for Risk Assessment (BfR) investigated dietary exposure to DEHP for certain product groups in Germany and calculated the exposure risk on the basis of experimentally proven phthalate levels (BfR 2012). In the deterministic estimation of daily DEHP intake by the population aged 14–80, the milk and dairy products group accounted for a significant proportion of exposure (16%), although not as high as the fruit and vegetables group (21%). While the quantity consumed seems to be the determining factor for fruit and vegetables, in the case of milk and dairy products, the comparatively high level of DEHP contamination also plays a role in addition to the amount consumed. Across all food products, foods with a higher fat content tend to have higher DEHP levels. This can be attributed to the high fat solubility of phthalates.
Within the dairy products group, the percentage DEHP exposure was highest for butter and cheese. Phthalate exposure via relatively low-fat foods such as milk and fermented dairy products (yoghurt and other sour milk products like kefir, butter milk, etc.) is considerably lower. Cream and sour cream products also play a secondary role in this group due to the low estimated consumption levels.

Risk assessment

In the light of new scientific findings, the European Food Safety Authority (EFSA) recently investigated five phthalates used in plastic food-contact materials and assessed the current dietary exposure to these substances in Europe (EFSA 2019). These five phthalates include DBP, BBP and DEHP as well as the DEHP alternatives DINP and DIDP. A new safety limit – expressed as a group tolerable daily intake (TDI) – of 50 microgrammes per kilogramme of body weight (µg/kg bw) per day has been established for four of these five phthalates, namely DBP, BBP, DEHP and DINP. The limit takes into account the effect of the substances on the reproductive system and estimates the amount of a substance that a person can ingest daily throughout their lifetime without an appreciable risk to health. The reduction in foetal testosterone levels was the critical factor in the establishment of TDI values for phthalates. Since DIDP has no measurable effect on testosterone levels in foetuses, the TDI level was set at 150 µg/kg bw per day. The EFSA set this value on the basis of the effect of the plasticiser on the liver.

Unlike previous assessments, this assessment takes into account combined exposure to several phthalates simultaneously and is expressed in the form of the new group-based TDI value.

According to the assessment, current dietary exposure to these five phthalates does not pose a risk to public health. Europe-wide, the aggregated dietary exposure for the four phthalates DBP, BBP, DEHP and DINP is 7 µg/kg bw per day on average, and 12 µg/kg bw per day for high consumers. These values are thus respectively seven and four times lower than the established safety limit. At below 0.1 µg/kg bw, dietary exposure for DIDP was estimated to be as much as 1500 times lower than the specified TDI value.

Summary

Phthalate residues in milk and dairy products should not be underestimated. Although these substances are ubiquitous, food contamination can be largely avoided through targeted measures. For example, critical food-contact materials can be replaced with alternative materials certified phthalate-free by the manufacturer. Some of the known sources of phthalate contamination of milk and dairy products include:

- Teat cup liners on milking machine clusters
- Silicone or PVC hoses
- Flexible seals and washers
- Plastic pipes
- Additives and processing aids

If a device or plastic product is not certified, it should be assumed to be suspect and tested by an accredited laboratory.

Further information

Bundesamt für Gesundheit (BAG), 2019. Factsheet Phthalate

International Dairy Federation (IDF), 2017. Faktencheck 5/2017 «Phthalate in Melktechnik»

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Imprint

Publisher	Agroscope Schwarzenburgstrasse 161 3003 Berne
Information	jan-erik.ingenhoff@agroscope.admin.ch
Edited by	Ariane Sotoudeh, Cécile Stäger
Photos	123 RF
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