

Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the presence and safety of plastics as contaminants in food

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Abstract

The use of plastics is widespread in both industry and domestic life as food packaging material and as a material that comes into contact with food. Therefore, plastics and their environmental impact, especially in the marine environment, arouse great interest and concern. Microplastics have been the focus of most of the studies carried out so far due to their growing presence in the natural environment and their potential to be transferred between trophic levels. It is necessary not only to make an exhaustive assessment of the presence of microplastics in the environment and food, but also of their effects on human's health.

This report attempts to review the presence of microplastics in food and address dietary exposure to plastics that access the food chain after contaminating the environment.

The data on levels of microplastics in foods come, mainly, from fish, molluscs and crustaceans. Among the non-seafoods studied, drinking water and salt stand out, among others. However, quality data on the occurrence of microplastics in food remain scarce, especially for non-seafoods. The determination of plastic polymers not only requires the standardisation of methods of analysis that allow for the reproducibility and comparison of the results alongside their monitoring but also a consensus on the definition, description and expression of the results.

Micro- and nanoplastics have the potential to be transferred between trophic levels and, therefore, the risk characterisation and the assessment of dietary exposure to them constitutes a current challenge for food safety alongside the study of the role of plastics as vectors of other contaminants and pathogenic microorganisms.

With the information and data currently available, there is insufficient information to characterise the potential toxicity of microplastics in humans. The potential effects of microplastics on the health of consumers are still unknown and require further research. The lack of extensive knowledge on the toxicokinetics and toxicodynamics of these pollutants and their health effects prevents from making a solid risk characterisation, although many authors expect that the risk derived from dietary exposure to plastics and derivatives is low. Despite this, the publication of experimental and epidemiological studies that associate prolonged exposure to very small doses with adverse effects keeps alive this growing concern of the scientific community regarding dietary exposure to plastics and their additives.

This Committee concludes that the exposure assessment of plastics, microplastics and nanoplastics cannot be assessed yet and the risk assessment cannot be concluded, although it suggests that future research on these food contaminants may provide innovative solutions for the implementation of measures that minimise human dietary exposure, and at the same time, regulate the maximum levels of their main molecules in foods.

The global commitment to reduce, reuse or recycle plastic materials is the best tool to mitigate the environmental and health impact of these pollutants.

Key words

Plastics, microplastics, contaminants.

Acronyms

BBP	Benzyl butyl phthalate
BPA	Bisphenol A
DEHP	Bis(2-ethylhexyl) phthalate
DnBP	Di-n-butyl phthalate
EPS	Expanded polystyrene
PAHs	Polycyclic aromatic hydrocarbons
HDPE	High density polyethylene
LDPE	Low density polyethylene
MP	Microplastics
NOAEL	Non observed effect level
NP	Nanoplastics
PA	Polyamide
PAAM	Polyacrilamide
PC	Polycarbonate
PCBs	Polychlorinated biphenyls
PE	Polyethylene
PET	Polyethylene terephthalate
PLA	Polylactic acid
PMMA	Poly(methyl metacrylate)
POM	Polyoxymethylene
PP	Polypropylene
PS	Polystyrene
PSU	Polysulfone
PVC	Polyvinyl chloride
PUR	Polyurethane

1. Introduction

Plastics are widely used at both industrial and domestic levels. The last decades have witnessed a significant increase in their production and use (Ogunola et al., 2018). According to the European Strategy for Plastics in a Circular Economy, published by the European Commission in 2018, the world production of plastic has multiplied by twenty times since the 1960's, reaching 322 million tonnes in 2015 and it is calculated that it will double again within the next 20 years.

The use of plastics as food packaging material and as a contact material has also increased considerably (Van Eygen et al., 2017) (Smithers Pira, 2018) mainly due to population growth, market expansion and the need to reduce food waste (Andrady and Neal, 2009) (Sohail et al., 2018). There is an increasing presence of plastic packaging or other products for consumption that are discarded after being briefly used. They are rarely recycled and often end up in the trash, for example, small packages, bags, cups, straws and cutlery where plastic is often used due to its lightness, low cost and practical features (EC, 2018a).

The migration of plastic substances from packaging to food is regulated by the Regulation (EC) No. 10/2011 on plastic materials and articles (EU, 2011) and although migration not being the the aim of this report, it has been considered relevant to include a reference to this widely studied phenomenon. It is expected that all plastic materials meant for contact with food products shall be sufficiently inert in order to avoid the transfer of molecules that may change the composition and organoleptic characteristics of the food product and pose a hazard (Serrano et al., 2014) (Fasano and Cirillo, 2018). Regulation (EU) No. 10/2011 defines specific migration limit (SML) as the maximum permitted amount of a given substance released from a material or article into food or food simulants. Much has been published on migration and all authors appear to agree that migration will depend, among other factors, on the size of the particle (small molecules with a low boiling point will migrate more rapidly than larger molecules); the initial concentration of the chemical substance in the plastic; its thickness and crystallinity; the type of food, its fat content and humidity; the storage temperature and time, and the area of contact with the food product (Fassano and Cirillo, 2018). (Hahladakis et al., 2018).

There is no doubt that plastics and their dramatic environmental impact, especially in the ocean, is a cause for great interest and concern. Microplastics (MP), plastics that range between 0.1 and 5000 μ m, and nanoplastics (NP), plastic particles approximately between 0.001 and 0.1 μ m, originating from engineering materials or in the fragmentation of microplastic waste (GESAMP, 2015) have focused most of their studies on their growing presence in the natural environment and their potential for being transferred between trophic levels (Cozar et al., 2014) (Koelman et al., 2015) (da Costa et al., 2016) (EFSA, 2016) (Auta et al., 2017) (Hernández et al., 2017) (Barboza et al., 2018) (Horn et al., 2019). Nano and microplastics are normally discussed separately, but recently some reports have begun to present them together as "NMP" (SAPEA, 2019).

It has been highlighted that plastics make up between 80 and 85 % of all waste in the oceans, and undoubtedly, the increased presence of microplastics in the marine environment entails an increase in its presence in marine organisms (Auta et al., 2017) (Ogunola et al., 2018). Every year, 5 to 13 million tonnes of plastic (1.5 to 4 % of global production) end up in the oceans. Europe generates around 25.8 million tonnes of plastic waste every year, and less then 30 % of it is collected for recycling. 150 000 to 500 000 tonnes of plastic waste find their way to the ocean every year (EC, 2018a). Plastic residue has been detected both at the lowest levels of the food chain, zooplankton, and at the highest levels, invertebrates (crustaceans and molluscs) and vertebrates (different fishes). Crustaceans that feed by filtering ocean water such as mussels and oysters deserve special attention (Cole et al., 2011) (Van Cauwenberghe and Janssen, 2014) (Mathalon and Hill, 2014) (Van Cauwenberghe et al., 2015) (Desforges et al., 2015) (Bråte et al., 2016) (Auta et al., 2017) (Güven et al., 2017) (Jabeen et al., 2017) (Sun et al., 2017) (Barboza et al., 2018) (Ogunola et al., 2018). Even the use of feed made from fish contaminated with microplastics in aquaculture and in rearing chickens and pigs has been identified as another route for MP to access the trophic chain (Bouwmeester et al., 2015) (Lusher et al., 2017).

Although less studied, it has also been pointed out that microplastics pose an emerging risk for the land eco-system, as they are present in farmland (Lv et al., 2019) and soils used in obtaining drinking water as well as in wastewater filtration systems (Eriksen et al., 2013) (Carr et al., 2016) (Souza Machado et al., 2018) (Corradini et al., 2019). The sources of microplastics that are found in land ecosystems are not well known. Nevertheless, it is quite possible that sewage sludge and the use of animal manure as fertilisers in agriculture may introduce a significant quantity of microplastics in the soil (SAPEA, 2019).

Although the biodegradation of plastics (by microbial populations and communities both natural and designed) is beginning to gain ground as a new strategy that may play an important role in plastic degradation (Drzyzga and Prieto, 2019), some authors suggest that plastics are not clearly susceptible to biodegradation, nevertheless they fragment into microplastics and nanoplastics through different processes (Alimba and Faggio, 2019).

With regard to the use of recycled plastics in food contact materials (for example, drinks bottles), the goal of the European strategy for plastic in a circular economy (EC, 2018a) is to give priority to high standards of food safety and at the same time, provide a clear and reliable framework for investment and innovation in circular economy solutions. The European Commission has resolved to swiftly finalise the authorisation procedures for more than a hundred safe recycling processes. At the same time, the European Commission, in cooperation with the European Food Safety Authority (EFSA), will also evaluate the possible authorisation of the safe use of other recycled plastic materials, for example, by better characterising the contaminants.

Nevertheless, the European Commission also highlights that some materials that claim to have biodegradable properties, such as «oxo-degradable» plastic (its use is currently banned in the European Union), do not offer any significant environmental advantage with regard to conventional plastics, while their rapid fragmentation into minuscule pieces is a cause for concern (EC, 2018a).

In spite of the fact that the details of the studies that research the content of microplastics in food are found in the declaration issued by the EFSA's Panel on Contaminants in the Food Chain (2016), there are many authors who consider that, while the environmental impact of plastic waste receives considerable attention from the scientific community, regulators and the society, the impact on human health of contamination due to micro and nanoplastics on food and drinks continues to be

largely unknown (Barboza et al., 2018) (Gallo et al., 2018) (Waring et al., 2018) (Toussaint et al., 2019). Both the Science Advice for Policy by European Academies (SAPEA, 2019) and the Norwegian Scientific Committee for Food and Environment (VKM, 2019) are unanimous in their statements that the currently available information and data does not constitute sufficient basis for characterising the potential toxicity of microplastics in humans. Even the World Health Organisation (WHO), in a press release on 22 August 2019, called not only for an exhaustive evaluation of the presence of microplastics in the environment but also of their effects on people's health (WHO, 2019).

For these reasons, the accumulation of non-biodegradable plastics and their waste (Thompson et al., 2009) (Jambeck et al., 2015) (Shahul et al., 2018) (Alimba and Faggio, 2019), the generation of secondary microplastics (MP) and nanoplastics (NP) (Galloway, 2015) (Rocha-Santos and Duarte, 2015) (Galloway and Lewis, 2016) (Wright and Kelly, 2017) (Revel et al., 2018), the release of hazardous chemicals during their manufacturing and use (Dematteo et al., 2013) (Biryol et al., 2017) (Caporossi and Papaleo, 2017) and the use of recycled plastics (behaviour and migration) and the transition to a system of sustainable plastics (Geueke et al., 2018) (Guillard et al., 2018) (Karmaus et al., 2018) (Milios et al., 2018) (Hatti-Kaul et al., 2019) (Hees et al., 2019) are very active lines of research.

Against this background, this report attempts to review the presence of microplastics in food products and address dietary exposure to plastics that access the trophic chain after polluting the environment.

2. Plastics, Microplastics, Nanoplastics and Plastic Additives

Plastics are organic materials formed by long molecular chains (polymers) that are easy to mould at different pressures and temperatures. Traditionally, they have been synthesised from the chemical by-products of petroleum, although nowadays research is focused on developing plastics from renewable sources such as polylactic acid (PLA) obtained from starch and/or sugarcane, or polyhydroxyalkanoates (PHA) of bacterial origin (Mokhena et al., 2018) (Vatansever et al., 2019) (Zheng et al., 2019).

Plastics may be classified according to different criteria. From the structural point of view we can mention three large groups: thermoplastics, thermostable plastics and elastomers. Of these three large groups, thermoplastics and thermostable plastics are frequently used to manufacture packaging, many of them for food use (PlasticsEurope, 2017). Although elastomers are primarily used in other sectors such as textiles, cars and shoes, they also have applications in the food-based sector and in the design and development of new packaging.

Thermoplastics are those plastics that repeatedly melt when heated and harden when cooled. That is to say, it is possible to reheat them, shape them and cool them repeatedly. Among them we find polyethylene terephthalate (PET), polypropylene (PP), polystyrene (PS), polyethylene (PE), high density polyethylene (HDPE), low density polyethylene (LDPE), expanded polystyrene (EPS), polyvinyl chloride (PVC), polymethyl methacrylate (PMMA), polycarbonate (PC), polyamides (PA) and polysulfone (PSU).

Thermostable plastics are those plastics that undergo a chemical transformation when they are heated, creating a three-dimensional network, so that after being heated and shaped, it is not possi-

ble to melt them again to reshape them. Among other examples we have polyurethane (PUR), epoxy resins, acrylic resins, non-saturated polyester, vinyl ester, phenolic resins, silicone, melanin resins and phenol-formaldehyde.

Elastomers, due to their great elasticity, offer great opportunities for designing and developing packaging. They are being introduced into new systems such as anti-spill valves, nipple valves for improved suction or seals in order to preserve food better once opened.

Another widespread criterion used to classify plastics is the SPI code system (Society of the Plastics Industry) (ASTM, 2019). It is an international system that lets us distinguish the composition of resins in packages and other plastic products. The different types of plastics are identified with a number from 1 to 7, placed within the recycling symbol. Below is a list of some molecules arranged according to this code:

- 1. PET (polyethylene terephthalate): coded 1, is the most common plastic in food packaging such as water bottles, soft drinks, juices and oils, among others.
- 2. HDPE (high density polyethylene): coded 2, it is a more rigid plastic that can resist heat or cold. It is found in detergent packages, milk bottles, canisters and plastic bags.
- 3. PVC (polyvinyl chloride): coded 3, it is used for tubes, pipes or to make detergent containers.
- 4. LDPE (low density polyethylene): coded 4, it is present in shopping bags, bags for bread, clingfilm and water bottles.
- PP (polypropylene): coded 5, it is used in most yoghurt and sorbet containers, bottle caps, straws, etc.
- 6. PS (polystyrene): coded 6, it is found in disposable cups for hot drinks and meat trays.
- Under code 7 we find "other plastics" obtained by combining two or more of these resins, or from other materials such as PC (polycarbonate) or biodegradable plastics such as PLA (polylactic acid).

The five polymers most commonly used in plastic packaging are PE, PP, PET, PS and PVC (PlasticsEurope, 2016), although others such as PC, PA, acrylics, PLA and PUR are used for more specific packaging applications (PlasticsEurope, 2016) (Selke and Culter, 2016). Recent studies have demonstrated that less common polymers represent less than 10 % of post-consumption plastic packaging waste collected for recycling (Brouwer et al., 2018).

According to the European Chemicals Agency (ECHA, 2019), plastics may decompose into microplastics, extremely small particles of plastic material (their size is generally less than 5 mm), although they can also be manufactured and deliberately added to products for a specific goal.

Microplastics (MP) (0.1-5000 $\mu m)$ may be classified according to their origin as primary or secondary (SAPEA, 2019):

Primary microplastics: they are originally made to have this size. Found in personal hygiene
products such as toothpaste and cosmetic products, as well as in textile fibres (washing
clothes). Spread into the environment from waste water (sewage systems are unable to eliminate them) or through the air (Bouwmeester et al., 2015) (EFSA, 2016) (Auta et al., 2017). These
microplastics added intentionally to products are a relatively small proportion of all plastic in

the oceans. Nevertheless, given that they are relatively easy to prevent and in response to public disquiet, various countries have already adopted measures to restrict their use, while the cosmetics industry has also taken voluntary measures. Various Member States of the European Union are considering or anticipating restrictions (EC, 2018a). Similarly, in line with REACH (Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals) procedures to restrict substances that are a risk for the environment or health, the European Commission has initiated the process to limit the use of deliberately added microplastics, asking the European Chemicals Agency to revise the scientific basis for policy action at the European level (EC, 2018a).

 Secondary microplastics: created from the fragmentation of larger plastics due to exposure to ultraviolet light, low ocean temperatures or mechanical friction. Their marine sources include fishing equipment and sewage from vessels. Their land sources are plastic bags, packaging material and waste from the plastics industry. It is estimated that the emission of secondary microplastics in the marine environment is between 68 500 and 275 000 tonnes per year (EFSA, 2016) (Auta et al., 2017).

Nanoplastics (NP) are defined as plastics with less that 999 nm (Hartmann et al., 2019), that is to say, with dimensions between 0.001 and 0.1 µm. It is possible that NPs detected in food are derived from sources other than food, for example, in processing aids, in water, air or released from machinery, equipment and textiles. It is possible that the quantity of nanoplastics increases during processing and until now, the effects of other processes such as baking and heating, on its content is unknown. Kinetics and the action of nanoplastics in the gastrointestinal tract and other systems is still unknown (Koelman et al., 2015). It is suspected that its capacity for crossing biological barriers and its high surface area has significant implications in bio-accumulation and bio-amplification of other contaminants (Pinto da Costa et al., 2016).

Plastics incorporate different additives that are added intentionally during the process of plastic manufacturing or processing, in order to improve its properties, performance and functionality (Harper, 2006). It is estimated that microplastics may contain on average, 4 % of additives (EFSA, 2016). Migration, release, final destination and environmental impact during its use, elimination and recycling has been reviewed (Halden, 2010) (Hahladakis et al., 2018). Plastic additives, fire retardants, antioxidants, acid collectors, heat and light stabilisers, lubricants, pigments, anti-static agents, sliding compounds and thermal stabilisers are significant owing to their widespread use. Each one of them plays a different role in improving the properties of the plastic product and and are generally classified into four categories (Hansen et al., 2013) (Hahladakis et al., 2018):

- Functional additives:
 - Stabilisers, anti-static agents, flame retardants, plasticisers, lubricants, slip agents, curing agents, foaming agents, biocides, among others.
- Colours.
- Fillers.
- Reinforcements.

The concern about microplastics is also due to its capacity for absorbing organic and inorganic contaminants (polycyclic aromatic hydrocarbons (PAHs), polychlorinated biphenyls (PCBs) and metals, among others) present in the environment and water, and transferring them to the food chain. Concentrations of up to 2750 ng/g of PCB and 24 000 ng/g and PAH have been found in microplastics (EFSA, 2016) (Wright and Kelly, 2017) (Barboza et al., 2018). Even nanoplastics could be efficient vectors of Pb and probably of many other metals (Davranche et al., 2019). The role of microplastics as vectors of pathogenic micro-organisms has also been identified (VKN, 2019).

Plastic materials in contact with food items must comply with the provisions of the Regulation (EU) No. 10/2011 (EU, 2011) and with regard to plastics, the methods of analysis continue to be limited and there is still the need to develop and standardise analytical methods with the goal of identifying, quantifying and assessing their presence in food items. This urgent need to develop and refine analytical methods to identify and characterise nano and microplastics in different matrices has been highlighted by the EFSA (2016), Lusher et al. (2017) and SAPEA (2019). In this line, the recent report on microplastics published by the Norwegian Scientific Committee for Food and Environment (VKM, 2019) recommends an international harmonisation of microplastics sampling, processing of samples, analytical methods and reports for improving quality (QA/QC: Quality Assessment/Quality Control) and comparative studies. The goal of this harmonisation is not necessarily the creation of standards because it would take time to develop and agree upon them.

Likewise, while standardised methods to determine global migration in plastic materials that come in contact with food items follow the guidelines issued by the Regulation, as well as the UNE-EN 1186 norm "Materials and articles in contact with foodstuffs. Plastics" (UNE, 2002), this is not the case of standardised methods of migration for individual substances, given that they are not fully developed.

3. Toxicological data and effects on the health of plastics

Regarding toxicokinetics, the mechanisms of action, toxicity and possible effects of plastics and its fragments (micro and nanoplastics), there exists, in general, very little information and especially, very few studies on humans. On the other hand, some special monomers or plastic additives have received more attention and are even regulated with regard to their presence in food items and intake limits. For example, Regulation (EU) 2018/213 regulates the use of Bisphenol A in varnishes and coatings intended to come into contact with food (EU, 2018) modifying Regulation (EU) No. 10/2011 (EU, 2011).

The rate of absorption of different plastic polymers throughout the digestive tract is still unknown, and the current information on its distribution, target tissues, metabolism and elimination, is still limited. Although the small size of microplastics favours their translocation through the gastrointestinal membranes through mechanisms similar to endocytosis and their distribution in tissues and organs, it is suspected that the absorption of microplastics is limited ($\leq 0.3 \%$) and that only the smallest fraction (size <1.5 µm) is capable of dispersing itself in the organism (EFSA, 2016) (Alimba and Faggio, 2019). A recent study on human faeces has demonstrated its elimination through faeces with a median of 20 microplastics (50 to 500 µm in size) per 10 g of human faeces, detecting up to nine new types of plastic, of which polypropylene (PP) and polyethylene terephthalate (PET) were the most abundant (Schwabl et al., 2019).

With regard to the mechanisms of action there are doubts about its similarity with those observed in animals where microplastics have been linked to various molecular and cellular alterations (Avio et al., 2015) (Alimba and Fagio, 2019).

Microplastic particles smaller than 150 µm are known for an inherent capacity for inducing intestinal blockage or tissue abrasion, resulting in lesions to the intestinal wall, morbidity and mortality (Peda et al., 2016) (Rodríguez-Seijo et al., 2017) (Alimba and Faggio, 2019). A recent experimental study shows that ingested polystyrene (PS) microplastics, apart from reducing intestinal mucous secretions and altering the functioning of the intestinal wall, are able to disrupt the diversity of gut microbiota and give rise to changes in the metabolism (Jin et al., 2019). At the same time, it cannot be neglected that exposure to micro and nanoplastics may increasingly affect patients with underlying pathologies that may augment intestinal permeability or disrupt the blood-brain barrier (Waring et al., 2018).

Gastrointestinal absorption, transportation in the intestinal epithelium and response to oxidative stress as a potential consequence of exposure to microplastics have been studied both *in vitro* and *in vivo*. *In vivo* data demonstrate the absence of histologically detectable lesions and inflammatory responses as microplastics do not seem to interfere with the differentiation and activation of the human macrophage model (Stock et al., 2019). According to these authors, oral exposure to polystyrene microplastic particles does not pose significant health risks to mammals (Stock et al., 2019).

Some toxic effects of microplastics in marine mammals are increased mortality, reduced body mass or metabolism, behavioural and fertility changes, neurotoxicity and oxidative stress (Barboza et al., 2018) (Guzzetti et al., 2018) (Wang et al., 2019). Likewise, it seems that microplastics increase the dysregulation of gene expression required for the control of oxidative stress and activating the expression of nuclear factor E2-related factor (Nrf) signaling pathway in marine vertebrates and invertebrates. These alterations may be responsible for microplastics induction of oxidative stress, immunological responses, genomic instability, disruption of endocrine system, neurotoxicity, reproductive abnormities, embryotoxicity and trans-generational toxicity (Alimba and Faggio, 2019).

It is unknown whether ingested microplastics may disintegrate into nanoplastics in the gastrointestinal tract but, with regard to the toxicity of nanoplastics, many conclusions on its effects are based on general knowledge about microparticles. They have the demonstrated capacity to affect the reproductive system and cross the blood-brain barrier, affecting the central nervous system (Waring et al., 2018). Some engineering nanomaterials have displayed toxic effects, nevertheless, data on toxicity for nanoplastics for the characterisation of human risk is lacking, and it is still not possible to extrapolate data from one nanomaterial to another. Existing data on NP are limited and most experimental designs on animals do not allow the building of a dose-response relationship. Besides, the few studies that have been published use synthesised nanoparticles, mostly nano-sized polystyrene, and it is unknown if these are truly representative of nanoplastics in the environment (SAPEA, 2019).

In 2016, the EFSA report on the presence of micro and nanoplastics in food items suggested that there was not enough data on toxicity or toxicokinetics at that moment for evaluating the risk to

humans (EFSA, 2016). Currently, although limited, the available toxicological information on some plastics and monomers or plastic additives is more extensive. Below, a summary of relevant toxico-logical information on oral exposure is presented:

- Acute, chronic toxicity and repeated dose toxicity:
 - HDPE (High density polyethylene): rat> 5000 mg/kg (MSDS, 2008), rat= 4000 mg/kg (MSDS, 2018a).
 - PVC: rat> 2000 mg/kg (MSDS, 2018b).
 - PP (Polypropylene): NOAEL (No Observed Adverse Effect Level)= 8 g/kg (mouse) (MSDS, 2006).
 - PS (Polystyrene) (Eltemsah and Bøhn, 2019):
 - acute exposure: not extremely toxic for *Daphnia magna* at 48 hours but causes additional mortality at 120 hours, juveniles being 50 % more sensitive than adults.
 - chronic exposure: Daphnia magna juveniles show greater sensitivity and a slight increase in mortality is observed, along with decreased growth and stimulated early reproduction at the cost of later reproduction. Both the growth rate of Daphnia magna mothers and the size of the newborns decrease when microplastic dosage is increased.
 - Monomers or plastic additives (Table 1):
 - Bisphenol A: LD₅₀ oral> 2000-5000 mg/kg (rat). Toxicity due to repeated dose: LOAEL (Lowest Observed Adverse Effect Level) (oral)= 600 mg/kg b.w./day (rat) (MSDS, 2019a).
 - Bisphenol S: LD₅₀ oral= 2830 mg/kg (rat) (MSDS, 2019b).
 - BBP (Benzyl Butyl Phthalate) LD₅₀ oral= 2330 mg/kg (rat) ,> 10 000 mg/kg (rabbit). LC₅₀ in rats is> 6.7 mg/l/4 hours (MSDS, 2016). NOAEL= 50 mg BBP/kg b.w./day (EFSA, 2019).
 - Phthalic acid: LD_{50} oral= 7900 mg/kg (rat) (MSDS, 2018c).
 - DEHP (Bis(2-ethylhexyl) phthalate): NOAEL= 4.8 mg DEHP/kg b.w./day (EFSA, 2019).
 - DBP (Dibutyl phthalate): LOAEL= 2 mg DBP/kg b.w./day (EFSA, 2019).
 - DINP (Diisononyl phthalate): NOAEL= 15 mg DINP/kg b.w./day (EFSA, 2019).

Table 1. Available toxicological data for some monomers or plastic additives								
	Bisphenol A (BPA) (80-05-7)	Bisphenol S (80-09-1)	Bis(2-ethylhexyl) phthalate (DEHP) (117-81-7)	Benzyl Butyl Phthalate (BBP) (85-68-7)	Phthalic acid (88-99-3)			
LD ₅₀ oral	>2000-5000 mg/kg Male and female rats	2830 mg/kg (rat)	Not classified as acute toxicity	2330 mg/kg (rat) > 10 000 mg/kg (rabbit) LC_{50} (rat) > 6.7 mg/l/4 hours	7900 mg/kg (rat)			
Mutagenicity	Ames test: negative Test on mouse germ cells: negative	Ames test: negative Mutagenicity (micronucleus test) in mouse: negative	Not classified as mutagen in germ cells	Not classified	In vitro genotoxicity Salmonella typhimurium Ames test: negative			

- Carcinogenicity: PVC is classified in Group 3 (not classifiable as to its carcinogenicity to humans) by the International Agency for Research on Cancer (IARC, 1987).
- Toxicity for reproduction: there is little data. There does not seem to be effects of high density
 polyethylene (HDPE), although it has not been tested and its evaluation has been made on the
 basis of the properties of its individual components. PVC and PS have not been classified and
 for low density polyethylene (LDPE) and PP, no effects are known. With regard to monomers or
 plastic additives, BPA, BPS and phthalic acid, there is no available data. Nevertheless, DEHP
 and BBP can damage the foetus and may impair fertility.
- Mutagenicity: PVC, PS and LDPE have not been classified for mutagenic and genotoxic toxicity. For HDPE, the chemical structure does not display signs of mutagenicity and in vitro genetic toxicity has not been registered although the product has not been tested and the evaluation has been made on the basis of the properties of its individual components. For the rest of the aforementioned plastics, no data is available in this regard.
- Teratogenicity: There is very little information available on teratogenicity. It is only known that HDPE does not have this effect. With regard to monomers or plastic additives there is no available information.

With regard to monomers or plastic additives (bisphenols and phthalates, mainly), the toxicity of Bisphenol A (BPA) has been extensively researched and EFSA has recently published (EFSA, 2019) a scientific opinion updating the risk assessment of some phthalates. Since 2009, the French *Agence Nationale de S*écurité *Sanitaire de l'alimentation, de l'environnement et du travail* (ANSES, 2013) recognises four adverse effects of BPA: disruptions to neurobehavioural development, disruptions in the female reproductive system, metabolic changes and obesity and effects on the mammary gland. A highlight is the ANSES validation of meaningful *in vitro* and *in vivo* data that demonstrate changes in learning and memory through estrogenic alterations. By means of these studies on animals it is extrapolated that exposure to BPA may alter cognitive capacity in humans, through similar mechanisms. The 2015 EFSA Opinion Panel pointed out that the initial classification of the probability of the mentioned effects of BPA are only applicable to hazard identification and not to assessing the risk of human exposure to BPA (EFSA, 2015). Given the relevance of this component in plastics, the EFSA committed to starting a new risk assessment for BPA in 2018, using a new and transparent assessment and hazard algorithm and protocol, and including cross-sectional human studies and single measurement studies (EFSA, 2017).

Information on other bisphenols is very limited, but it is suspected that the qualitative effects in endocrine receptors are found in the range of BPA. Bisphenol S, for example, is believed to have the potential to produce oxidative stress, induce obesity or, in animal-based studies with zebrafishes, hyperactivity. In general, the potential health hazards appear to be within the same order of magnitude as BPA (Wu et al., 2018).

Phthalates have also been classified as endocrine disrupting chemicals, and diet has been identified as the main exposure route for human beings. Experimental studies on animals have demonstrated deformities in the masculine reproductive system and feminisation (Foster, 2006). Other studies suggest an effect on the thyroid axis and immune response.

Apart from the toxicological data there are many studies on the potential health effects from exposure to very low levels of monomer components, additives, or their combinations used in plastics, that often manifest at later stages. Special mention must be made here of the effects of endocrine disruption caused by bisphenols and phthalates. Academic studies (especially epidemiological and experimental studies on laboratory animals) make plausible many of the effects detailed below, while the lack of toxicological tests for these postulates has given rise to a certain controversy in scientific literature and differing assessments by the risk assessment agencies.

It has been deemed necessary to mention these effects and the related controversy on bisphenols and phthalates in this report, as there is a high degree of social concern, as noted by the European Commission (EC, 2018b). Therefore, this section especially discusses their adverse health effects that do not conclusively fulfil the necessary criteria in different risk assessments, but are noted as being important in academic (epidemiological and experimental) studies.

Bisphenol A (BPA)

In the EFSA report (2015), a hazard identification protocol was applied to BPA, in which other large groups of possible adverse effects such as effects on reproduction and development, neurological effects, neurobehavioural and neuroendocrinological effects, immunological effects, cardiovascular effects, metabolic effects, genotoxicity, carcinogenicity, proliferative changes and morphological changes potentially linked to carcinogenesis did not reach sufficient criteria to be characterised as hazards (Table 2).

The following possible adverse effects of BPA on health were not characterised as hazards in the latest EFSA opinion (2015) as they did not fulfil the criteria and therefore, were only evaluated with a risk identification of "less than likely":

- BPA endocrine disruption: BPA is classified as a weak estrogen mimic when it unites with the ERβ and ERαβ estrogen receptor, although when compared to estradiol, the affinity is 10 000 times lower (Kuiper et al., 1998) (Halden, 2010). The capacity of BPA to affect thyroid homeostatis has also been demonstrated. The effects of low doses are measured through endocrine signalling pathways that have evolved to act as powerful amplifiers (Welshons et al., 2003), causing important effects in response to very low doses. Nevertheless, there is no general consensus on its classification as an endocrine disruptor, as it does not fulfil the three criteria of: endocrine activity, adversity and causality between endocrine activity and its effects.
- BPA studies on animals have postulated adverse effects at different doses, on many occasions much lower than the BMDL₁₀ (Benchmark dose level) of 8960 μg/kg b.w./day (EFSA, 2015): among which are described growth, hormonal, chromosomal, immunological and behavioural alterations (Halden, 2010).
- Epidemiological studies (without being able to draw conclusions on causality) have encountered links between BPA levels in women and obesity, endometrial hyperplasia, recurring abortions and polycystic ovary syndrome. The levels found in human blood fall within or above the concentrations for which *in vitro* alterations of human tissue function have been demonstrated.

Table 2. BPA risk assessment algorithm acc	ording to the EFSA report (2015		
	Classification for hazard identification	Most important reasons for the classification	Does the algorithm follow hazard characterisation
General toxicity	Probable	NOAEL identification	Yes
Effects on reproduction and development	Equally probable and unlikely	Contradictory and variable studies Biological relevance of murine model studies A causal relationship could not be established	No
Neurological, neurobehavioural and neuroendocrinological effects	Equally probable and unlikely	Inconsistent epidemiologial associations Incomplete methodology of animal studies A causal relationship could not be established	No
Immunological effects	Equally probable and unlikely	Studies with methodological limitations A causal relationship could not be established	No
Cardiovascular effects	Equally probable and unlikely	Non useful cross-sectional studies A causal relationship could not be established	No
Metabolic effects	Equally probable and unlikely	Most studies are cross-sectional and inconsistent A causal relationship could not be established	No
Genotoxicity	Not probable	Studies support that BPA is not mutagenic	No
Carcinogenicity	Improbable to equally probable and unlikely	Weakness of murine model studies. Lack of convincing epidemiological studies	No. Also not included in the uncertainty assessment
Proliferative and morphological changes potentially linked to carcinogenesis	Probable	New studies provide proof of BPA effects on the proliferation and differentiation of various tissues	Yes
Mechanistic studies		Studies support the effect of BPA on hormonal homeostasis, genetic expression, cytogenetic and epigenetic effects But no effect contributes significantly to the comprehension of potential effects on humans	ı

There are studies that demonstrate adverse effects only at low doses and not at high doses, reflected in an inverted U dose-response curve: changes in the expression of receptors or neuroendocrine feedback systems (Vom Saal y Hughes, 2005). The window of exposure when the most serious and the most numerous adverse effects are observed, correspond to embryo development in exposed pregnant women.

There is a possibility that BPA may be linked to prostate cancer (Di Donato et al., 2017), as it may produce a pro-inflammatory effect, while an oestrogen stimulation in adult males may be potentially responsible for prostatic hyperplasia.

With regard to possible immuno-toxic effects, there are animal studies that display a dose-response effect in allergic lung inflammation, while other studies are contradictory (Kimber, 2017). Experimental evidence postulates immunological mechanisms such as the Th2 immune pathway activation or increased production of cytokines such as IL-4 (Xie et al., 2016) and the degranulation of mast cells (Robinson y Miller, 2015). Cohort studies that attempt to shed light on the possible role of BPA and the appearance of asthma have not helped to clarify the role of BPA, as there are many uncertainties and a causal relationship between BPA and immunological effects in human beings has not been established.

Phthalates

The controversy on the endocrine disruption of phthalates is based on epidemiological studies that show a link between levels of different metabolites of phthalates in maternal urine and reduced anogenital distance in male infants (Swan et al., 2005). In 2009, the lack of sufficient epidemiological studies necessary to establish causal relationships and the relevance of co-exposure with other possible endocrine disruptors was highlighted (Meeker et al., 2009). Subsequently, prenatal exposure has been linked to hormonal levels in infants and neurobehavioural disorder in children, as well as altered gestation times (Serrano et al., 2014). In the adult population, exposure is linked to markers of testicular function in males, endometriosis in women and premature thelarche (Serrano et al., 2014). Other studies reviewed by Serrano et al. (2014) suggest an effect on the thyroid axis and immune response. DINP as a substitute for DEHP has been declared a carcinogen in California (CalEPA, 2017). A link between phthalates and asthma has also been postulated, but the studies are not conclusive. Similar to bisphenols, it has been demonstrated that phthalates can induce a Th2 immune response, mast cell degranulation or IL-4 or TNF- α cytokines. Besides, the risk of suffering asthma in infancy is higher in mothers who have high concentrations of BBP and DnBP (Robinson and Miller, 2015).

EFSA is currently reviewing the presence and effects of phthalates in materials that enter into contact with food items even though the group tolerable daily intake (TDI) of 50 µg/kg b.w./day established for four of these substances (dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), bis(2-ethylhexyl) phthalate (DEHP) and diisononyl phthalate (DINP)) is maintained. A recent opinion of the EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) has been published (EFSA, 2019), estimating the dietary exposure in Europeas will be mentioned later.

4. Plastics in food items

There is undoubtedly a growing concern and awareness regarding the presence of plastics in food items both among civilians and the scientific community. There are numerous global and local initiatives that attempt to solve this problem at the individual and collective level.

Based on food groups, the available data on microplastic levels are primarily from fish, molluscs and crustaceans (Table 3) but also from other food items such as table salt, honey and beer (Table 4) and drinking water (Table 5). Nevertheless, these data are scarce, especially with regard to non-marine foodstuffs, and there is no consensus in the available bibliography on the concentrations detected owing to the lack of harmonisation and validation of the methodologies, and especially in comparative studies. Overall, this means that there is no complete and balanced vision on the presence of microplastics in food items and drinking water (SAPEA, 2019). Additionally, the information on the presence of nanoplastics in food items is practically non-existent.

The size of microplastic particles present in food items is quite variable, as shown in Tables 3-5. Although the microplastic size ranges between 0.1 and 5000 µm, in some cases, microplastic particles larger than 5000 µm, occasionally reaching 9000 µm have been detected (Liebezeit and Liebezeit, 2013) (Renzi et al., 2018). Another aspect to take into account is the morphology of microplastic particles in food items and water. The presence of fibres, fragments, films, filaments, granules have been described (Neves et al., 2015) (Renzi and Blašković, 2018). For uniformity, Hartmann et al. (2019) propose the classification of particles into five types according to their morphology and structure: spheres, cylinders, fragments, films and fibres.

Below is a review of the references on the presence of plastics in different food groups.

4.1 Plastics in seafood

In studies where the content of microplastics has been determined in seafood, the data is grouped in different units, such as number of particles/marine organism or number of particles/g wet weight. This differing nomenclature makes it difficult to compare results and studies (Table 3).

The presence of microplastics has been observed in fish, crustacean and mollusc species meant for human consumption. They have especially been observed in the stomach and gastrointestinal tract, as well as in the liver and gills (Neves et al., 2015) (Barboza et al., 2018). Generally, the consumer discards the stomach and intestines of fish, and therefore, the plastic contamination of these tissues does not pose a significant risk to the population. Nevertheless, in the case of crustaceans, molluscs and some species of small fishes (anchovies and sardines, for example), the entire product including the digestive tract, is usually consumed, for which reason the microplastics contamination of these tissues must be taken into consideration when assessing dietary exposure (EFSA, 2016) (Barboza et al., 2018) (Waring et al., 2018). Some studies, nevertheless, indicate the presence of microplastics in the muscles of fishes and crustaceans (edible tissue) therefore, they must be considered as clear dietary sources of microplastics for consumers (Akhbarizadeh et al., 2018) (Abassi et al., 2018).

Neves et al. (2015) examined the contents of the digestive tract of 26 species of commercial fish in the Portuguese coast. 73 microplastics were detected, 48 (65.8 %) fibres and 25 (34.2 %) frag-

ments. The most commonly-present polymers were polypropylene (PP) and polyethylene (PE). The presence of microplastics was detected in 17 species (19.8 % of the fish studied) of which 32.7 % had ingested more than one microplastic. The average amount of microplastics ingested was 0.27 \pm 0.63 per fish (n= 263). The *Scomber japonicus* species (chub mackerel) registered the highest average of ingested microplastics, which suggests its potential as an indicator species (Table 3).

Bessa et al. (2018) analysed the presence of microplastics in the gastrointestinal tract of commercial fishes such as sea bass (*Dicentrarchus labrax*), sea bream (*Diplodus vulgaris*) and flounder (*Platichthys flesus*) in the Mondego estuary (Portugal), detecting an average content of 1.67 \pm 0.27 microplastics/fish with a significantly large quantity of ingested microplastics for *D. vulgaris* (73 %). The main polymers were polyester (PES), polypropylene (PP) and rayon (semi-synthetic fibre) (Table 3).

Pellini et al. (2018) characterised microplastics in the gastrointestinal tract of *Solea* in the Adriatic Sea, observing that 95 % of sampled fish contained microplastics. Additionally, more than one microplastic element was detected in more than 80 % of the specimens examined. The most commonly found polymers were polyvinyl chloride (PVC), polypropylene (PP), polyethylene (PE), polyester (PES) and polyamide (PA), 72 % as fragments and 28 % as fibres. The average number of ingested microplastics was 1.73 ± 0.05 microplastics/fish in 2014 and 1.64 ± 0.1 microplastics/fish in 2015 (Table 3).

Van Cauwenberghe and Janssen (2014) studied the presence of microplastics in commercially farmed bivalves, observing a plastic presence of 0.36 ± 0.07 particles/g w.w. (wet weight) in *Mytilus edulis* and 0.47 ± 0.16 particles/g w.w. in *Crassostrea gigas* (Table 3).

Microplastic contamination in mussels collected around the coast of Scotland (United Kingdom) has been studied by Catarino et al. (2018) who have observed the average number of microplastics, based on weight, as 0.086 \pm 0.031/g w.w. (3.5 \pm 1.29 per mussel) in *Modiolus modiolus* and 3.0 \pm 0.9 MP/g w.w. (3.2 \pm 0.52 per mussel) in *Mytilus* spp. (Table 3).

Cho et al. (2019) studied the average concentration of microplastics in the four most consumed species of bivalves in South Korea. Oysters (*Crassostrea gigas*), mussels (*Mytilus edulis*), clams (*Tapes philippinarum*) and scallops (*Patinopecten yessoensis*) showed an average concentration of 0.15 ± 0.20 particles/g and 0.97 ± 0.74 particles/individual. Fragments and particles smaller than 300 µm were the predominant form and size, representing 76 % and 65 % of the total quantity of microplastics, respectively. Polyethylene (PE), polypropylene (PP), polystyrene (PS) and polyester were the main types of polymers (Table 3).

Renzi et al. (2018) analysed not only the microplastic content but also their type and form. Microplastics recovered in farmed and wild mussels (*Mytilus galloprovincialis*) in different Italian cities were primarily filaments with a maximum length of 750-6000 µm (average values of 1150-2290 µm) and did not present significant differences between farmed and wild populations. Consuming raw mussels could lead to median microplastic intakes of 6.2 to 7.2 particles/g w.w. (Table 3).

It is possible that food processing affects the overall content of plastics and derivatives, and also their profiles. Similarly, lower levels of microplastics (-14 %) were detected in mussels that were

boiled, in comparison to raw mussels. Meanwhile, the microplastics detected in the cooking water showed a smaller size than microplastics in raw mussels when characterised (Renzi et al., 2018).

Microplastic content (synthetic fibres of 200-1000 μ m) in shallow-water shrimps in the Channel area and the southern section of the North Sea were determined at 0.68 ± 0.55 microplástics/g w.w. (1.23 ± 0.99 microplastics/shrimps). Microplastics were detected in 63 % of analysed shrimps (Devriese et al., 2015) (Table 3).

Table 3. Presence of microplastics in seafood								
Food item	Content in microplastics	Particle size	Particle type	Polymers found	Location	Source		
Fish: 26 species	0.27 ± 0.63 particles/fish	217-4810 µm	Fibres: 65.8 % Fragments: 34.2 %	PP, PE	Portuguese coast	Neves et al. (2015)		
Fish: Dicentrarchus labrax Diplodus vulgaris Platichthys flesus	1.67 ± 0.27 particles/fish	<1000-5000 μm	Fibres Fragments	PES, PP	Portugal, Mondego Estuary	Bessa et al. (2018)		
Fish	2014: 1.73 ± 0.05 particles/fish 2015: 1.64 ± 0.1 particles/fish	<100-500 µm	Fragments: 78 % Fibres: 28 %	PVC, PP, PE, PES, PA	Adriatic Sea	Pellini et al. (2018)		
Molluscs Mytilus edulis Crassostrea gigas	0.36 ± 0.07 particles/g w.w. 0.47 ± 0.16 particles/g w.w.	5-25 µm	Not specified	Not specified	-	Cauwenberghe and Janssen (2014)		
<i>Mytilus</i> spp.	3.0 ± 0.9 particles/g w.w. 3.2 ± 0.52 particles/mussel	Not specified	Fibres	Not specified	Coast of Scotland	Catarino et al. (2018)		
Bivalve molluscs Crassostrea gigas Mytilus edulis Tapes philippinarum Patinopecten yessoensis	0.15 ± 0.20 particles/g 0.97 ± 0.74 particles/ individual	43-4720 μm 65 % <300 μm	Fragments: 78 % Fibres: 23 %	PE, PP. PS, PES	South Korea	Cho et al. (2019)		
<i>Mytilus</i> galloprovincialis farmed and wild species	6.2-7.2 particles/g w.w.	750-6000 µm (average values 1150- 2290 µm)	Filaments	Not specified	ltaly	Renzi et al. (2018)		
Crangon crangon	0.68 ± 0.55 particles/g w.w.	200-1000 µm	Fibres	Not specified	Shallow areas in the Channel area and southern section of Northern Sea	Devriese et al. (2015)		

4.2 Plastics in non-marine food items

Although most scientific articles focus primarily on the marine environment, there are increasingly more studies on the presence of plastics in other food sources. Some non-marine food items where the presence of microplastics has been analysed are salt, beer, honey, sugar and water, among others. It must be pointed out that for these food items, there are no standard analytical methods nor consensus in the definition and description of microplastics to be determined, nor in the expression of results, therefore, an adequate comparison between studies is not currently possible.

4.2.1 Plastics in table salt

Most studies on microplastics in commercial table salts have not been able to determine their exact origin or levels, due to methodological limitations (Table 4). Until now, comparative data is scarce and knowledge is lacking on the possible causes of the different levels detected in this food (Iñiguez et al., 2017).

In 2015, Yang et al. (2015) highlighted the presence of microplastics in sea salt, at levels between 550 and 681 particles/kg. These authors detected between 7 and 204 particles/kg in rock salt and between 43 and 364 particles in salt from lakes. The microplastics detected were polyethylene (PE), cellophane and polyethylene terephthalate (PET). Later, the EFSA (2016) published a microplastic content between 7 and 680 particles/kg, reflecting the disparity in data between the reviewed publications.

In 2017, microplastics of more than 149 µm were analysed in 17 brands of salt in 8 different countries, with observed levels between 0 and 10 particles/kg of salt. Of the 72 detected particles, 41.6 % were plastic polymers of which the most common were polypropylene (PP) (40 %) and poly-ethylene (PE) (33.3 %). Fragments were the most common form of microplastics (63.8 %), followed by filaments (25.6 %) and films (10.6 %) The low level of ingestion of the anthropogenic particles of salt (a maximum of 37 particles/person/year) ensures that the health impact is negligible (Karami et al., 2017).

In Spain, the microplastic content detected in 21 different samples of commercial table salts was 50-280 MP/kg of salt, with polyethylene terephthalate (PET) being the most frequently found, followed by polypropylene (PP) and polyethylene (PE) (Iñiguez et al., 2017). Marine table salts presented microplastic values between 1.57 and 8.23 particles/g (Italy) and 27.13 and 31.68 particles/g (Croatia). The size of microplastics ranged between 4-2100 µm (Italy) and 15-4628 µm (Croatia) (Renzi and Blašković, 2018). Microplastic content in 16 brands of Turkish table salts was analysed, with a detected content of 16-84 MP/kg in sea salt, 8-102 MP/kg in salt from lakes and 9-16 MP/kg in rock salt. The most common plastic polymers were polyethylene (22.9 %) and polypropylene (19.2 %). With regard to this contamination and given the consumption of salt/year in Turkey, MP exposure was estimated at 249-302, 203-247, and 64-78 MP/year from the dietary intake of sea, lake or rock salt, respectively (Gündoğdu, 2018).

Kim et al. (2018) analysed a total of 39 different brands of salt, including 28 brands of sea salt from 16 regions in 6 continents. A wide range of microplastics (particles/kg of salt) was found: 0-1674 particles/kg (excluding an atypical value of 13 629 particles/kg) in sea salts, 0-148 particles/kg in

rock salt, and 28-462 particles/kg in salt from lakes. The relatively high content of microplastics was identified in sea salts produced in Asiatic regions.

Recently, Lee et al. (2019) reported the presence of microplastics in commercial table salts in Taiwan (9.77 particles MP/kg). The identified polymers were, in descending order of abundance, polypropylene (PP), polyethylene (PE) and polystyrene (PS), polyester (PES), polyethylenimine (PEI), polyethylene terephthalate (PET) and polyoxymethylene (POM). The same authors carried out a global review of the presence of microplastics in table salts from all over the world. 94 % of the products analysed contained microplastics. 3 (PET, PP and PE) out of a total of 27 types of polymers detected constituted most of the particles. The analysed table salts contained on average 140.2 microplastic particles/kg (Lee et al., 2019).

It is generally accepted that microplastic concentrations found in salt samples are lower than those found in other marine sources such as fish, crustaceans and molluscs. Nevertheless, it must be remembered that salt is consumed as a condiment on a daily basis, which may involve a longterm exposure for the people in general, in addition to that produced by other means involving food consumption.

4.2.2 Plastics in honey

While the reported average content of microplastics in honey is 166 fibres/kg and 9 fragments/kg, in the case of sugar, 217 fibres/kg and 32 fragments/kg have been observed (Liebezeit and Liebezeit, 2013). Nevertheless, in samples of Swiss honey, indications of significant microplastic contamination have not been found (Múhlschlegel et al., 2017) (Table 4).

4.2.3 Plastics in Beer

Plastic contamination in beer may be due to particles present in the air, the materials used in the process, contamination of raw materials or impurities in the packaging surface (Liebezeit and Liebezeit, 2014) (Kosuth et al., 2018). The following quantities of fibres, fragments and granules per litre have been detected: 25, 33 and 17, respectively (Liebezeit and Liebezeit, 2014) in a sample of 24 commercially sold German beer brands. Later, Kosuth et al. (2018) detected the presence of 0-14.3 MP particles/l in beers with fibre and fragment sizes ranging between 100 and 5000 µm (Table 4).

Table 4. Presence of plastics in non-marine food items							
Food item	Content in microplastics	Particle size	Particle type	Polymers found	Location	Source	
Table salt	50-280 particles/kg	10-3500 µm	Fibres	PET, PP, PE	Spain	lñiguez et al. (2017)	
Sea salt	550-681 particles/kg						
Rock salt	7-204 particles/kg	45-4300 μm	Fragments Fibres Pollets	PE, PET, cellophane	China	Yang et al. (2015)	
Salt from lakes	43-364 particles/kg		renets				

Table 4. Presence of plastics in non-marine food items							
Food item	Content in microplastics	Particle size	Particle type	Polymers found	Location	Source	
Sea salt	0-1674 particles/kg	47 % <50 μm					
Rock salt	0-148 particles/kg	61 % <50 µm	Not specified	PE, PET, PP	16 countries/ regions in 6	Kim et al. (2018)	
Salt from lakes	28-462 particles/kg	55 % <50 µm			continents	(2010)	
Sea salt	1.57-8.23 particles/g	4-2100 µm	Fragments Fibres Granules Films Foams	Not specified	Italy	Renzi and Blašković (2018)	
Sea salt	27.13-31.68 particles/g	15-4628 µm	Fragments Fibres Granules Films Foams	Not specified	Croatia	Renzi and Blašković (2018)	
Sea salt	16-84 particles/kg						
Salt from lakes	8-102 particles/kg	-	-	PE, PP	Turkey	Gündoğdu (2018)	
Rock salt	9-16 particles/kg						
Salt	0-10 particles/kg	160-980 μm	Fragments: 63.8 % Filaments: 25.6 % Films: 10.6 %	PP, PE	Australia, France, Iran, Japan, Malaysia, New Zealand, Portugal, South Africa	Karami et al. (2017)	
Table salts	9.77 particles/kg	1-1500 µm	Fragments: 93 % Fibres: 7 %	PP, PE, PS, PES, PEI, PET, POM	Taiwan	Lee et al. (2019)	
Table salts	Average 140.2 particles/kg	-	-	PET, PP, PE	Global	Lee et al. (2019)	
Salt	46.7-806 particles/kg	100-5000 µm	Fibres Fragments	Not specified	United States	Kosuth et al. (2018)	
Honey	166 fibres/kg 9 fragments/kg	Fibres: 40-9000 µm Fragments: 10-20 µm	Fibres Fragments	Not specified	Germany, France, Italy, Spain, Mexico	Liebezeit and Liebezeit (2013)	
Sugar	217 fibres/kg 32 fragments/kg	Not specified	Fibres Fragments	Not specified	Local market Germany	Liebezeit and Liebezeit (2013)	
Beer	23 fibres/l 33 fragments/l 17 granules/l	Not specified	Fibres Fragments Granules	Not specified	Germany	Liebezeit and Liebezeit (2014)	
Beer	0-14.3 particles/l	100-5000 μm	Fibres Fragments	Not specified	United States	Kosuth et al. (2018)	

4.2.4 Plastics in drinking water

The scientific data on the presence of microplastics in drinking water is very recent. The first scientific articles were published from 2017-2018 onwards. The published studies provide data on microplastic concentrations in drinking water (tap water, bottled water) or in freshwater sources, that is to say surface and groundwater bodies as well as (indirectly) sewage. In general, it is accepted that most microplastics (78-98 %) in water are within the range of 1-5 μ m (Novotna et al., 2019), although reported microplastic concentrations vary widely based on types/sources of water.

In studies on treated and untreated water, different concentrations of microplastics have been detected. For example, particles sized 1-10 μ m and >10 μ m were identified in water samples from three different urban zones in the Czech Republic with microplastic concentrations ranging between 1383-4464 particles/l in untreated water and 243-684 particles/l in treated water. Fractions with the smallest particle size (ranges 1-5 μ m and 5-10 μ m) predominating in untreated water samples as well as in treated water, with 95 % of particles less than 10 μ m in size (Pivokonski et al., 2018). These concentrations differ with the results found in German untreated and treated waters, where a maximum concentration of 7 particles/m³ (size range 50-150 μ m) in untreated waters (Mintening et al., 2019). Other authors have reported average particle concentrations of 3633 particles/l in bottled water (0ßmann et al., 2018), between 1812 and 3605 particles/l in untreated water, and between 338 and 628 particles/l in treated water (Pivokonski et al., 2018). Oßmann et al. (2018) reported an extremely high number of microplastics with a range of 2649 ± 2857 MP/l in single-use plastic bottled waters and up to 6292 ± 10.521 MP/l in glass bottled waters.

A review integrating the available information on microplastic concentrations in different types of water from different areas has been recently published (Eerkes-Medrano et al., 2019). The main conclusion of this study, one of the few that compares values, highlights the notable variation in microplastic concentrations, particle sizes and particle typesand the studied sources of water.

Generally, the detected particles are primarily fibres and fragments, with a greatly varied particle composition, including polymers such as polyamide (PA), polyacrylamide (PAM), polybutylacrylate (PBA), polyethylene (PE), polyethylene terephthalate (PET), poly(methyl methacrylate) (PMMA), polypropylene (PP), polyester (PES), polystyrene (PS), polytrimethylene terephthalate (PTT), polyvinyl chloride (PVC) (Eerkes-Medrano et al., 2019).

Koelmans et al. (2019) evaluated the quality of 50 studies on microplastics in specific types of waters from different locations (Asia, Australia, Europe and North America), and observed that sampling methods, isolation, purification and identification of microplastics vary enormously between studies. The order of polymers detected at a global level in these studies is PE≈PP> PS> PVC> PET, which probably reflects the global plastic demand and a greater trend of sedimentation in PVC and PET due to their greater densities. Fragments, fibres, film, foam and pellets were the most frequently observed forms (Koelmans et al., 2019).

In freshwater and drinking water, the detected microplastic concentration (expressed in number of particles) spans ten orders of magnitude (1 x 10⁻² to 10⁸ /m³). In general, concentrations are higher in bottled water than in tap water. Nevertheless, these results must be interpreted with caution,

given the relatively very low number of bottles studied; bottled water (n= 3), treated tap water (n= 2), and untreated tap water (n= 2) (Koelmans et al., 2019).

According to Welle and Franz (2018), the exposure estimates based on the quantities of microplastics found in mineral water and the assumption of total mass transfer of small molecules like additives and oligomers present in the plastic would not raise a safety concern.

Table 5. Presence of plastics in drinking water							
Food item	Content in microplastics	Particle size	Particle type	Polymers found	Location	Source	
Untreated water Treated water	1383-4464 particles/l in untreated water 243-684 particles/l in treated water	1-10 μm >10 μm	Fibres Fragments	PET, PP, PE	Czech Republic, urban zones	Pivokonski et al. (2018)	
Bottled water Water in single-use plastic bottles Water in glass bottles	3633 particles/l 2649 ± 2857 particles/l 6292 ± 10.521 particles/l	90 % <5 μm	Not specified	PE, PET, PP	Germany	Oßmann et al. (2018)	
Untreated water	0.007 particles/l	50-150 μm	Fibres	PE, PA, PS, PVC	Germany	Mintening et al. (2019)	
Bottled water Tap water	0.00001-100 000 particles/l	1->5000 µm	Fragments Fibres Film Foam Pellets	PE,PP, PS, PVC, PET	Asia, Europe, Europe and North America	Koelmans et al. (2019)	

5. Dietary exposure to plastics

In the absence of studies on total dietary exposure to plastics in human beings, some estimations on dietary exposure from certain food groups identify seafood as the main source of dietary exposure for humans to plastics that pollute the environment and access the food web. Many authors agree that the risk derived from the dietary intake of plastics and derivatives is minimal in comparison to exposure to these substances by other means, specifically, by inhaling (Santillo et al., 2017) (Barboza et al., 2018) (Catarino et al., 2018) (Rist et al., 2018).

Toussaint et al. (2019) have analysed publications from 2010 that document the presence of micro and nanoplastics in animals and animal products, in order to understand exposure in human beings. These authors state that, beyond a few estimations and comparisons, there is no precise data available to evaluate the exact exposure of human beings to micro and nanoplastics through diet, mainly due to the inexistence of standardised methods for analysis.

In spite of this and as it has been described in the previous section, the scientific community seems to agreed that molluscs and crustaceans are the main contributing to the total intake of

microplastics in humans based on the many studies published on the levels of microplastics in molluscs (Van Cauwenberghe and Janssen, 2014) (Catarino et al., 2018) (Li et al., 2018, 2019) (Cho et al., 2019) and in drinking water (Eekes-Medrano et al., 2019) (Mintenig et al., 2019) (Novotna et al., 2019).

Thus, while in 2014, Van Cauwenberghe and Janssen estimated the annual dietary exposure from molluscs and crustaceans for European consumers at 11 000 microplastics/year, in 2019, Cho et al. calculated the annual intake of microplastics from seafood for the Korean population at 212 microplastics/year which is a very low estimate in comparison to that made by Van Cauwenberghe and Janssen (2014) from the same food group, but in the same order of magnitude as that published by Catarino et al. (2018) in the United Kingdom. These authors estimated the microplastic ingestion from consuming mussels at 123 particles/person/year in the United Kingdom. At the same time, they considered that this exposure may increase up to 4620 particles/person/year in countries with a greater consumption of molluscs and crustaceans. Considering exclusively the consumption of shrimps, the exposure to MP from this food group was estimated to be 175 particles (200-1000 µm)/ person/year (Devriese et al., 2015).

Another food item identified as a vehicle for plastics and derivatives in the diet is salt. According to Lee et al. (2019) table salts contain an average of 140.2 microplastic particles/kg. Therefore, assuming an average annual salt consumption of 3.75 kg/year, the annual intake of microplastics from salt could be estimated at a few hundreds (525.75 microplastic particles/year). Assuming the concentration of plastics in table salt marketed in Spain (50-280 particles/kg, Table 4) published by Iñiguez et al. (2017) and considering that the consumption of table salt in Spain has been estimated in 0.29 g/day (0.105 kg/year) by the Spanish dietary survey ENALIA 2 (AESAN, 2019), the adult Spanish population aged between 18 and 75 years would be exposed to 5.25-29.4 plastic particles/year by consuming table salt.

This same year, Cox et al. (2019) have evaluated the number of microplastic particles in common foodstuffs included in the American diet and have estimated the annual microplastic ingestion to be between 39 000 and 52 000 particles, depending on age and sex. These estimates rise to between 74 000 and 121 000 particles/year when inhalation is considered. These authors state that persons who comply with the daily recommended water intake only through bottled water sources may be ingesting an additional 90 000 microplastics every year, in comparison with 4000 microplastics/year for those who only drink tap water (Cox et al., 2019).

Until now, no risk assessments or exposure estimates have been made of nanoplastics as it is unknown what the concentrations are in environmental compartments or components of the human diet (SAPEA, 2019). Currently, the scientific community appears to agree that due to the limited data of acceptable quality on levels of plastics and their derivatives, micro and nanoplastics in food items, the risk characterisation and evaluation of dietary exposure to micro and nanoplastics in human beings cannot be satisfactorily concluded.

With regard to dietary exposure to monomers and plastic additives, the estimation of dietary exposure to BPA was highest for infants and small children (up to 0.875 μ g/kg b.w./day) although it is less than the tolerable daily intake (TDI) of 4 μ g/kg b.w./day (EFSA, 2015). As said before, for phthalates, the group tolerable daily intake (TDI) established by the EFSA at 50 μ g/kg b.w./day for

four substances (dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), bis(2-ethylhexyl) phthalate (DEHP) and diisononyl phthalate (DINP)) is still maintained. For diisodecyl phthalate (DIDP), an individual TDI of 150 µg/kg b.w./day based on hepatic toxicity is proposed. For European consumers, the EFSA estimated in 2005 the combined dietary exposure of DBP, BBP, DEHP and DINP at less than a fourth part of the group TDI. For DIDP, the dietary exposure was approximately 1500 times lower than the individual TDI (EFSA, 2005a, b). Nevertheless, a recent Scientific Opinion of the EFSA (2019) has reevaluated the dietary exposure of some phthalates in Europe. The estimated average values (minmax) and the P95 (min-max) in µg/kg b.w./day are: DBP average (0.042-0.769) and P95 (0.099-1.503); BBP average (0.0232-4.270) and P95 (0.021-0.442); DEHP average (0.001-0.057) and P95 (0.008-0.095). These intakes imply a contribution of 1.8 to 14 % of the group TDI although in extreme consumers (P95) dietary exposure reache between 3 and 23 % of the group TDA (EFSA, 2019).

Conclusions of the Scientific Committee

The contamination, bioaccumulation and biomagnification due to plastics and their derivatives, monomers and additives, is a cause of growing concern, not only because of their potential adverse consequences for the environmental health and the diversity conservation, but also due to their capacity to access the trophic chain and consequently, to affect human health after dietary exposure.

Data on microplastic levels in food items are sourced primarily from fish, molluscs and crustaceans. Of the non-marine food items studied, significant studies have been made on drinking water and salt, among others. Nevertheless, quality data on the presence of microplastics in food continue to be scarce, especially for non-marine items. Information on the presence of nanoplastics is practically non-existent.

In the absence of studies on total dietary exposure to plastics in human beings, some estimations on dietary exposure identify seafood as the main dietary source for plastics that pollute the environment and access the trophic chain.

The determination of plastic polymers does not only require standardised methods of analysis that allow reproducibility and the comparison of results along with their monitorisation, but also consensus on the definition, description and expression of the results.

Micro and nanoplastics have the potential to be transferred between trophic levels and therefore, the risk characterisation and evaluation of dietary exposure to them constitutes a current challenge for the food safety along with the study of the microplastic degradation to nanoplastics, the impact of food processing and the role of microplastics as a vector for other organic and inorganic contaminants and pathogenic microorganisms.

With the currently available information and data, there is not sufficient basis to characterise the potential toxicity of microplastics in human beings. The potential effects of microplastics on the health of consumers are still unknown and require further research. The lack of extensive knowledge on the toxicokinetics and toxicodynamics of these contaminants and their effects on health prevent making a solid risk characterisation although many authors anticipate that the risk derived from dietary exposure to plastics and derivatives is low. In spite of this, the publication of experimental and epidemiological studies that link prolonged exposure to very small doses with adverse effects maintains this growing preoccupation within the scientific community regarding the dietary exposure to plastics and its additives.

This Comittee concludes that the total dietary exposure to plastics, microplastics and nanoplastics cannot be performed yet and, thus, the risk assessment cannot be concluded, although it suggests that future research on these food contaminants may provide innovative solutions for the implementation of measures that mitigate/minimise human dietary exposure, and at the same time, regulate the maximum levels of their main molecules in foods.

The global commitment to reduce, reuse, recycle plastic materials constitute the best tool to mitigate the environmental and health impact of these contaminants.

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