

Advice 09-2021 of the Scientific Committee established at the FASFC on the evaluation of the FASFC analysis programme for exogenous contaminants: C. Migration from food contact materials (FCM)

Background & Terms of reference

Within the framework of a periodic evaluation of the analysis programme of the Federal Agency for the Safety of the Food Chain (FASFC), the Scientific Committee has been asked to discuss the programming of the analyses with regard to exogenous contaminants in food, in water intended for consumption and water used by operators in the transformation and treatment process of food, in animal feed, and in fertilisers, soil improvers and cultivation substrates. In particular, it is requested (i) to verify whether control results reported between 2010 and 2018 point to possible trends, and (ii) to assess the implementation of the approach generally applied within the FASFC for the programming of analyses (i.e. the control efforts in terms of, inter alia, the chosen "matrix/hazard" combinations and the number of analyses programmed for these combinations) and to identify possible gaps within the analysis programme 2020.

The part 'exogenous contaminants' within the analysis programme comprises a large group of parameters including (heavy) metals and metalloids, persistent organic pollutants, substances which are liable to migrate from materials and articles that come in contact with food as well as radiation and radioactivity. This opinion only covers programmed analyses and control results on migration from food contact materials (FCM).

Method

The programming of the analyses is evaluated on the basis of expert opinion in combination with information from scientific literature and an evaluation of possible trends in the FASFC monitoring results. Possible trends are discussed by means of a trend analysis via logistic regression. The period under consideration concerns 2010-2018, but is -depending on the available data- shorter for a number of 'matrix/hazard' combinations. However, the trend analysis should be considered as a pragmatic tool for the evaluation of the analysis programme. Results of the trend analysis should be interpreted with caution.

Conclusions & Recommendations

The FASFC analysis programme 2020 includes analyses of the overall migration from various plastic FCM, of the release of metals and metalloids from metallic and ceramic materials and of the migration of photoinitiators, of plasticisers, of primary aromatic amines (PAAs), of melamine and formaldehyde, of mineral oil hydrocarbons (MOHs), of bisphenols and analogues (bisphenol A and S, and bisphenol A diglycidyl ether or BADGE) and of ethylbenzene.

Based on the monitoring results reported between 2010 and 2018, main trends observed are a decrease in the percentage of plastic FCM that do not comply with the overall migration limit, an increase in the ESBO (epoxidised soybean oil) content in soy and tomato sauce packed in glass jars with metal lids, and -though not significant- an increase in the amount of melamine, and to a lesser extent of formaldehyde, migrating from articles made of a melamine-formaldehyde resin (often referred to as melamine objects or 'melaware' in short). For most parameters, however, a trend analysis appears to be of little relevance. For instance, the number of quantitative results is too limited or the reporting frequency is very low for the photoinitiators, the plasticisers (except for ESBO), the PAAs, the bisphenols and ethylbenzene.

The release of metals and metalloids from FCM intended for repeated contact with food is assessed with 3 successive tests. To distinguish the results of these 3 successive tests, the individual analysis reports of all samples and each metal or metalloid analysed should have been consulted, which was not feasible in the context of this opinion. With regard to the migration of mineral oil hydrocarbons (MOHs), a trend analysis could not be carried out either because no monitoring results are available for the time period considered.

The Scientific Committee gives following recommendations on the analyses programmed by the FASFS regarding the migration from FCM:

- With regard to the overall migration analyses, it is recommended that, analyses of rubbers (e.g. rubber rings of lids) should also be provided (possibly thematically) in addition to the analyses of FCM from plastics. Furthermore, attention is drawn to new trends or new materials that are brought onto the market as an alternative to plastics FCM and 'single-use plastics'. Examples are 'biobased' FCM, cardboard straws, cloth bags, etc. It is recommended that analyses of these 'new' materials or alternatives are carried out as well.
- With regard to the analysis of the release of metals and metalloids, the Committee wishes to indicate that the sampling of ceramic materials should largely focus on non-industrially produced (so-called "artisanal") pottery, manufactured on a smaller, local scale or in third countries, for which it can be suspected that the production techniques carry a higher risk of release. This concerns particularly ceramics with coloured glaze and patterns, which is more susceptible to the release of metals and metalloids. As local ceramists are not always well aware of this problem, an information campaign by the FASFC, followed by a random monitoring campaign to check whether the problem (still) exists, is appropriate. In addition, the opinion also points to a number of findings which could be taken into account in the programming, such as the possible release of aluminium from uncoated aluminium objects (e.g. meal trays) in addition to the release from aluminium dishes and foil, and the release of aluminium, arsenic, antimony and nickel from the enamel layer of FCM from enamelled steel and cast iron (e.g. barbecue grill grids).
- Photoinitiators almost immediately form radicals under the influence of UV light and their migration to food is often the result of problems at the level of the industrial process. Given the history, it can be assumed that the European FCM sector should be sufficiently aware of this issue and has taken the necessary measures to avoid such migration from inks and coatings. Therefore, it seems sufficient to programme these analyses thematically rather than annually. The focus could then be on products produced outside Europe, which can be sampled at import or in specialised shops.
- The analyses of plasticisers (this group includes the five phthalates authorised for use in plastic FCM, di-isononyl-1,2-cyclohexanedicarboxylate or DiNCH, and epoxidized soybean oil or ESBO), and semicarbazide or SEM, a degradation product of the blowing agent azodicarbonamide, are currently mainly focused on foodstuffs packed in a glass jar with a metal lid containing a packing or seal made of rather soft PVC. As plasticisers are also used in other applications and may migrate to food products from paper-based FCM (e.g. pizza boxes made of recycled cardboard, recycled paper used to pack fatty foods), it is recommended to program analyses of the migration of phthalates from such packaging, possibly thematically. Operators should be made aware of this issue, which is probably less well known in the field. Following Recommendation (EU) 2019/794, a (possibly temporary) inclusion of phthalates not authorised in plastic FCM in the FASFC analytical programme is considered appropriate. The analysis of plasticisers should mostly focus on products produced outside Europe, which can be sampled upon import or in specialised shops.

The Committee believes that SEM analyses can be dispensed with for the time being.

- Primary aromatic amines (PAAs) are not allowed to migrate from plastic FCM. Recently, the legal detection limit which is used to verify the "absence" of migration, has been lowered for a number of PAAs. The analysis of this parameter therefore remains relevant. Because PAAs can occur in printing inks and may migrate from coloured napkins and printed paper bags (e.g. bread packaging), it is recommended that these matrices should also be included in the analysis programme, at least once, in addition to the analysis of polyamide kitchenware. When polyamide materials are used, not only PAAs but also cyclic polyamide oligomers appear to be able to migrate to food. The analysis of the migration of such oligomers from polyamide kitchen utensils could therefore also be thematically programmed.
 - Concerning the analysis of melamine and formaldehyde, it is noted that in addition to the so-called 'bamboo' plastic objects (which were recently banned) and similar, it remains relevant to continue to sample sufficiently FCM from 'standard' melamine, such as spoons, plates and cups, as well as cooking spoons. For the manufacture of melamine objects, different types of resins with different compositions are used. As these resins are indistinguishable to the naked eye and not all of them are relevant in the context of melamine migration, a preliminary infrared analysis of the composition of the FCM resin is useful.
 - Although analyses of mineral oil hydrocarbons (MOHs) have already been programmed in previous, FASFC monitoring results are not available because a routine analysis allowing clear action to be taken in the event of positive results was not yet fully established. However, there are currently several laboratories accredited for the analysis of MOHs in food (e.g. oils, dry food, infant formulae). The Committee therefore believes that the analysis of MOHs in foodstuffs could be included in the FASFC control programme immediately. The analyses that are foreseen to assess the migration of MOHs from cardboard and paper FCM, are however not very meaningful. This is because the migration of MOHs from FCM not only depends on the type of FCM, but also on the type of food that will be packaged in the FCM in question. For example, fat- and starch-rich products appear to be more sensitive to the uptake of MOHs due to the lipophilic nature of these compounds. In other words, it is more result-oriented to analyse high-risk foods, considering the relevance of the packaging. Moreover, these analyses should not only focus on high-risk foodstuffs packaged in recycled materials without a functional barrier between the packaging and the foodstuff, but also on high-fat bulk products transported in sisal or jute bags or in containers. The analysis programme should also include analyses of follow-on formulae and infant formulae.
 - Currently the bisphenol analogues bisphenol A (BPA), bisphenol A diglycidyl ether (BADGE) and bisphenol S (BPS) are being analysed in plastic FCM (mainly polycarbonate) and cans with internal coating. As polycarbonate FCM are more and more replaced by glass FCM or FCM from other polymers in which no bisphenol analogues are used, the analysis of these parameters is only relevant for epoxy-coated cans.
 - Ethylbenzene is included in the FASFC analysis programme as one of the volatile aromatic components that can migrate from silicone FCM. The amount of migrating volatile organic compounds can be used to check whether the material has been sufficiently tempered. As a precautionary measure, manufacturers sometimes instruct the user to heat the FCM at a high temperature for a long time before the first use. It may be a general consideration for analysing laboratories to take into account such labelling instructions before analysing components migrating from FCM.
- Since ethylbenzene is only one of the possible volatile compounds that may be released and it is not clear to what extent this release is indicative of total migration, these analyses of ethylbenzene seem less relevant. Moreover, the total release of volatile compounds can be more easily verified via weight loss after heating. Consequently, it may be considered to programme these more straightforward analyses by weighing as an alternative to the ethylbenzene analyses.

In general, the most relevant parameters with regard to migration from FCM and for which legal specifications apply, are included in the analysis programme. However, it concerns only a fraction of the substances that may migrate from FCM into food. For example, the EU list of substances permitted in plastic FCM alone (Annex I of Regulation (EU) No 10/2011) contains already about one thousand substances. In order to have some idea of the migration of these substances it is recommended to include occasionally or thematically a number of substances from this EU list in the analysis programme. Relevant substances are molecules with a low specific migration limit (SML) or an SML equal to the detection limit.

Additionally, attention is drawn to the possible migration of poly- and perfluor alkyl compounds (PFAS). In the analysis programme for exogenous contaminants, the occurrence of these compounds as persistent organic pollutants or environmental contaminants in foodstuffs (being the principal contamination route) is examined, but not specifically their occurrence as a result of migration from FCM. The Scientific Committee suggests programming thematic analyses of PFAS migration from coated, grease or moisture resistant paper and cardboard FCM, such as for example packaging for fast food, butter, takeaway and bakery products or microwave popcorn bags.

It is advisable to monitor the situation on the ground critically and regularly. It is indeed very changeable, due to changes in regulations, in the supply chain or due to pressure from consumers. As a result, producers are switching to alternative substances or materials (e.g. replacement of BPA). In addition, there are new trends and new or alternative materials are used, which is driven, among other things, by the ban on single-use plastics and the pursuit of a circular economy.

Given the complexity of monitoring migrating components from FCM (among others, because of different types of FCM, starting substances, added substances, etc.), the monitoring should be as targeted as possible. Therefore, it is recommended to provide targeted campaigns in the analysis programme. These allow identifying potential problems and raising awareness among the operators or sector concerned.

A more targeted control also implies a more targeted sampling. This can be pursued by giving an as accurate as possible description of the sample to be collected in the analysis programme, by consulting the FCM's DoC ('Declaration of Compliance') when sampling, and by deploying controllers or inspectors in the field who have been specifically trained in FCM matters.

Finally, with the aim of a better valorisation and processing of monitoring results, it is recommended to identify clearly the individual analytical results of the 3 consecutive migration tests performed for metals and metalloids on FCM intended for repeated contact with food in the general FASFC database. Similar to previous opinions in which the analytical programme was evaluated on the basis of an analysis of control results, it is also recommended to implement additional automatic quality control at data entry and to ensure consistency of units.

The full text is available on this website in dutch and in french.