Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Abstract Report on the National Monitoring 2021

Joint report by the Federal Government and Federal States

Table of content

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This Abstract Report presents a short overview about the findings of the analyses of foods, cosmetic products and commodities carried out in 2021. A full version of the Report on the National Monitoring 2021 is available in German from http://www.bvl.bund.de/monitoring. Abstract Reports on the National Monitoring from previous years can be downloaded from www.bvl.bund.de/monitoring_abstracts.

1 Summary

The Monitoring Programme is a system of repeated representative measurements and evaluations of substances that are unwanted from a health point of view, such as residues of plant protection products, pesticides and veterinary medicinal products, heavy metals, mycotoxins and other contaminants in and on foodstuffs, cosmetics and consumer goods.
Further details about the Monitoring Programme are available from http://www.bvl.bund.de/monitoring_EN. In accordance with the General Administrative Provisions for the Monitoring Programme (AVV Monitoring), the following foodstuffs, cosmetic products and consumer goods were selected from the population's representative market basket for analysis in 2021 (market basket monitoring):

1.1 Food of animal origin

- Butter (mild soured)
- Feta cheese; cheese from sheep's and/or goat's milk, matured in brine
- Hare/rabbit, meat cut
- Chicken eggs
- Carp, freshwater fish
- Beef, meat cut
- Pike perch, freshwater fish

1.2 Food of plant origin

- Apricot
- Aubergine
- Banana, baby banana, cooking banana
- Broccoli
- Breads and small pastries made of wheat/rye
- Chives
- Dill leaf spice
- Pea fresh/deep frozen
- Sweet peppers
- Cereal-based food for infants and young children
- Grapefruit
- Celeriac
- Honeydew melon, musk melon, cantaloupe melon
- Extra virgin olive oil
- Orange juice
- Oregano, wild marjoram, pot marjoram (leaf spice)
- Wild mushrooms
- Farmed mushrooms
- Radish
- Rice (long grain, round grain, basmati, parboiled)
- Rye flour
- Rosemary leaf spice
- Rocket
- Sunflower seeds
- Table grapes red, white
- Tea (*Camellia sinensis*), dried leaves
- Wheat grains, whole wheat flour

Depending on which undesirable substances were to be expected, the foods was analysed for residues of plant protection products, pesticides or contaminants (e.g. dioxins and polychlorinated biphenyls [PCBs], per- and polyfluorinated alkyl substances [PFAS], polycyclic aromatic hydrocarbons [PAHs], elements, mycotoxins and nitrate).

1.3 Cosmetic products

- Elements in eyeliner/eyeliner pencils and toothpaste/gel
- Antimony and other elements in decorative cosmetics with glitter
- Formaldehyde in skin tannings and handwash paste

1.4 Consumer items

- Migration of elements from toys
- Primary aromatic amines and aromatic amides in food-contact items made of paper/cardboard/carton
- Polycyclic aromatic hydrocarbons (PAHs) in consumer articles with skin contact and in toys

In addition to the market basket monitoring, the programme treated the following seven special food safety problems (project monitoring):

Project 1: Aflatoxins and ochratoxin A in rarely consumed cooking oils
Project 2: Determination of lead and other toxic elements in sugar
Project 3: Determination of toxic elements in milk substitute drinks
Project 4: Acrylamide in foodstuffs listed in the Monitoring Recommendation (EU) 2019/1888
Project 5: Triphenylmethane dyes in aquaculture products
Project 6: Polycyclic aromatic hydrocarbons (PAHs) in freekeh
Project 7: Dioxins and PCBs in pork and pork liver from free-range animal keeping

As far as comparisons with results from previous years were possible, these were taken into account in the interpretation of the findings. Yet, the statements and assessments made in this report concerning the presence of substances undesirable from a health point of view solely refer to the products, substances, or groups of substances examined in 2021. It is not possible to estimate the total exposure to certain substances, as only a part of the market basket can be examined per year, while the substances also occur in other products.

Overall, the findings of the 2021 monitoring underline the recommendation of a balanced and varied diet, as this is the most practicable way to minimise the dietary intake of undesirable substances, which is to a certain degree unavoidable.

Including the market basket and project monitoring, the programme examined a total of 9,462 samples of products of German and foreign origin in 2021, including 8,219 samples of foodstuffs, 640 samples of cosmetic products and 603 samples of consumer goods. The findings are presented in the following chapters.

2 Food

2.1 Residues of plant protection products and pesticides

2.1.1 Foodstuffs of animal origin

501 samples of foodstuffs of animal origin were examined for residues of plant protection products and pesticides. Residues were quantifiable in 15.4 % of the 104 butter samples tested, in 18.3 % of the 104 samples of feta cheese (sheep and goat cheese), in 23.5 % of the 170 samples of chicken eggs tested, and in 26.8 % of the 123 samples of beef tested. The levels were all below the maximum levels laid down in Regulation (EC) No 396/2005.
As in the years before, the majority of findings in all products of animal origin tested were residues of ubiquitous, persistent organochlorine compounds.
Overall, the residue levels found do not let a health risk to consumers be expected.

2.1.2 Foodstuffs of plant origin

3,476 samples of foodstuffs of plant origin were examined for residues of plant protection products and pesticides. Product groups with the highest proportions of samples with quantifiable residues were dried dill (leaf spice, 98.9 %), rocket (97.7 %) and table grapes red/white (95.3 %). Product groups with the lowest proportions of samples with quantifiable residues were, on the other hand, rosemary (13.1 %), cereal-based foods for infants (15.2 %), and olive oil (26.3 %).
The highest rate of non-compliant residues occurred in dill (21.8 %).
High rates of non-compliant residues also occurred in tea (*Camellia sinensis*, 8.8 %) and grapefruits (6.5 %).
Six out of the 22 foods and food groups examined did not carry any non-compliant residues , that is, such exceeding established MRLs.
1.6 % (2020: 1.1 %) of samples of products originating in Germany were found with residues of active substances use of which was not authorised in the corresponding crop in Germany in 2021.
One out of 99 samples (1.01 %) of cereal-based infant food examined exceeded the maximum residue level, and 14 samples were found with quantifiable residues.
It is not to be expected that the reported residue levels in cereal-based infant food (for infants aged 0.5 to & 1 year) lead to health impairments.
According to the Federal Institute for Risk Assessment (BfR), human health impairments cannot be ruled out for a total of 46 (1.3 %) out of the 3,476 foods of plant origin examined. All other residue levels measured did not signal any acute health risks to consumers.

2.2 Quaternary ammonium compounds

Quantifiable levels of the quaternary ammonium compounds benzalkonium chloride (BAC) and dialkyl dimethyl ammonium chloride (DDAC) were found in 29 of the 2,420 samples of plant and animal food tested.
BAC levels higher than the maximum level of 0.1 mg/kg were found in one sample of chives (0.43 mg/kg) and one sample of feta cheese (0.51 mg/kg). All other samples had BAC or DDAC levels lower than the respective maximum level.
Processing factors were taken into account, where applicable.

The residue levels found do not give reason to expect a health risk to consumers.
Since the maximum residue levels set in accordance with Regulation (EU) No 396/2005 are considered temporary, the substances BAC and DDAC will continue to be in the focus of monitoring activities in the EU in order to improve the data basis.

2.3 Chlorate

A total of 1,480 food samples of plant and animal origin were examined for chlorate. 232 of the samples had quantifiable residues of chlorate. The highest proportions of samples with quantifiable chlorate residues were found in peas (54 %), dill (43 %) and orange juice (42 %). The specific maximum residue levels in force since 28 June 2020 (Regulation (EU) 2020/749) were exceeded in 2 samples of orange juice and one sample each of farmed mushrooms, chives, and chicken eggs. Five of the 86 samples of cereal-based foods for infants were also found to exceed the applicable maximum residue level.
The residue levels found do not give reason to expect a health risk to consumers. Neither should health problems be expected as a result of the intake calculated on the basis of reported chlorate residue findings in cereal-based food for infants, according to the BfR.

2.4 Perchlorate

The 1,450 foodstuffs of plant and animal origin sampled had low perchlorate levels. Only in cereal-based infant food, 4 of the 86 samples tested (4.7 %) exceeded the legal maximum residue level.
Given the minimisation requirement laid down in Article 2 of Regulation (EEC) No 315/93, every effort should continue to be made to minimise the perchlorate content in foodstuffs, in accordance with the ALARA principle.

2.5 Dioxins and polychlorinated biphenyls (PCB)

Levels of the sum parameters for dioxins (WHO-PCDD/F-TEQ) and for dioxins and dioxin-like PCB (WHO-PCDD/F-PCB-TEQ), as well as the sum parameter for non-dl PCB were inconspicuous in the tested samples of muscle meat of hare/rabbit, pike perch, and carp, and in dried oregano (leaf spice). Chicken eggs were also inconspicuous, except for some single samples.

Project 07: Dioxins and PCBs in pork and pork liver from free range animal keeping
Against the background of the current discussion on the reduction of EU established maximum levels for dioxins and dl-PCBs, the programme collected data on the contamination of pig meat and pig liver originating from free-range farming Free-range pigs eat soil particles with their feed, which is why there is an enhanced risk of dioxin and PCB contamination.
In pork, 4.7 % of the 64 samples exceeded the legal maximum level for the sum of dioxins and dl-PCBs, with 3.1 % of the samples at the same time exceeding the maximum level for dioxins alone. In pork liver, 38.7 % of the 62 samples exceeded the maximum level for dioxins. 26.6 % of these samples at the same time exceeded the maximum level for the sum of dioxins and dl-PCBs. The residues of non-dl PCBs exceeded the respective maximum levels in the meat and liver of one single animal. We found a statistically significant correlation between the findings in meat and liver.

The findings of this project monitoring of dioxins and PCBs in pig meat and pig liver from free-range animal keeping confirm evidence from previous studies showing that there is a risk of increased dioxin and PCB levels in foodstuffs originating from animals kept in extensive farming. The holding management of pigs in free-range farming varies greatly in terms of time of pasturing, feeding, fattening period and other factors. The impact of these risk factors on dioxin or PCB contamination or other operational risks could not be investigated in the context of this project, and further research should be carried out in order to develop strategies and recommendations for animal keeping to the end of reducing contamination. All possible measures of Good Agricultural Practice should be taken to minimise the intake of soil with feed, in order to reduce the transfer of these contaminants to the pigs.

2.6 Per- and polyfluorinated alkyl substances (PFAS)

With regard to the sum of the 4 single substances PFOS, PFOA, PFHxS and PFNA (PFAS-4), we expect that maximum levels will be established for some foods in 2022. Sixty samples of carp and 76 samples of wild mushrooms (peppers and porcini mushrooms) were tested for the above-mentioned 4 single PFAS, among others, and were found with only low levels of these substances.
PFAS levels in 133 samples of chicken eggs tested were slightly higher than in a prior test in 2017. This held mainly for the samples from free-range farming. A possible explanation for the higher levels in samples from extensive farming is that these 4 PFAS, as well as dioxins, dl- and ndl-PCB constitute persistent halogenated contaminants that are ubiquitous in the environment.
Some of the 53 pike perch samples tested showed conspicuous total levels up to a maximum of 18.6 µg/kg. According to the BfR, the sum levels of the 4 single substances PFOS, PFOA, PFNA and PFHxS in pike perch are lower than those evaluated by the BfR with regard to the food group ‘Other freshwater fish’ in their recent opinion on PFAS in foodstuffs. Fish is regarded as a source of exposure that can considerably contribute to the dietary intake of PFOS, PFOA, PFNA and PFHxS.

2.7 Polycyclic aromatic hydrocarbons (PAH)

Wild mushrooms were tested for PAH for the first time in the framework of the Monitoring Programme. In the 73 samples tested, both the benzo[*a*]pyrene content and the sum content of PAH-4 substances were at very low levels. As dried oregano (leaf spice) of certain areas of origin had been conspicuous with increased PAH levels in risk-based examinations in the past, it was now included in the Monitoring Programme. Here, only one of the 95 samples examined was found to exceed the legal maximum level for benzo[*a*]pyrene and the sum of PAH-4 substances.
PAH levels (90th percentile) detected in 69 samples of dried tea leaves (black tea) were higher than in the monitoring of 2015. The European Commission has so far assumed that only a minute portion of these contaminants was extracted from tea leaves to the infusion, and has therefore not yet required maximum residue levels for PAH in tea leaves (black tea and herbal tea). Against the background of more recent research findings, this assumption is now under discussion, and regulatory action at EU level is being considered in this context. The relevant expert group at the European Commission has begun discussions of that matter.

Project 06: Polycyclic aromatic hydrocarbons (PAHs) in Freekeh
Freekeh is durum wheat harvested unripe, and dried and roasted over open fire. While producing Freekeh, polycyclic aromatic hydrocarbons (PAH) may be formed during the roasting process due to incomplete burning of organic material.

Under this project, 88 freekeh samples were tested and, with an average of 80.4 µg/kg, were shown to have significantly higher PAH-4 levels than, for example, green spelt, which is produced by a roughly similar process (cf. Monitoring 2016).
On principle, exposure to PAH-4 substance should be minimised as far as reasonably achievable (ALARA principle) because of their genotoxic and carcinogenic properties. The manufacturing process should be adapted to the end of reducing the contamination with PAH.

2.8 Mycotoxins

2.8.1 Aflatoxins B1, B2, G1, G2

85 samples of dried dill (leaf spice) and 106 samples of sunflower seeds were analysed and found with very low levels of aflatoxin B1 and of the B1, B2, G1, and G2 aflatoxin sum parameter.
In 125 rice samples tested, only few samples were found with quantifiable aflatoxin concentrations, with one (in a sample of unknown origin) exceeding the legal maximum level. The spices oregano and rosemary, which were also examined for aflatoxins in the framework of this programme, did not contain quantifiable aflatoxin amounts.

2.8.2 Ochratoxin A (OTA)

Foodstuffs examined were wheat grains, rye flour, rice, sunflower seeds, and dried dill (leaf spice). They were found with only low levels of ochratoxin A (OTA). Only one sample each out of 115 wheat grain samples and 126 rice samples tested exceeded the legal maximum level for OTA. All findings in spice samples of oregano and rosemary were below the limit of determination for ochratoxin A.

2.8.3 Deoxynivalenol (DON)

Analyses of wheat grains and rye flour for deoxynivalenol (DON) did not produce conspicuous findings. Samples which had DON findings > 100 µg/kg were additionally tested for the modified forms DON-3-glucoside, 3-acteyl-DON and 15-acteyl-DON. While 15-acetyl-DON was not quantifiable in any sample, the other two modified forms were actually quantified in some samples, but at significantly lower levels compared to DON. Low DON levels might possibly be explained by the fact that the weather in Europe was predominantly dry over the last 3 years, which might have had an impact on the spread of *Fusarium* fungi and thus DON levels in the cereals examined.

2.8.4 T-2 toxin, HT-2 toxin

In the 86 samples of wheat grains and 106 samples of rye flour no levels of T-2 and HT-2 toxin were quantifiable. This might possibly be explained by the fact that the weather in Europe was predominantly dry over the last 3 years, which might have had an impact on the spread of *Fusarium* fungi, leading to lower fungal toxin levels in the cereals examined.

2.8.5 Zearalenone (ZEN)

The 115 wheat grain samples tested for the *Fusarium* toxin zearalenone showed only low levels. As it has been observed with the other *Fusarium* toxin studies in this monitoring, we may assume that there is a relation with weather influences.

Project 01: Aflatoxins and ochratoxin A in rarely consumed cooking oils

This project intended to examine rarely consumed edible oils for which literature shows data about mycotoxin contaminations, or for which earlier Monitoring Programmes produced data about

contaminations of the underlying raw materials. The aim is to close existing data gaps in exposure assessment by complementing the monitoring of frequently consumed edible oils, which have already regularly been subject to the market basket monitoring.
The project examined a total of 44 samples of pumpkin seed oil (14 samples cold-pressed and 30 samples conventional) and 60 samples of linseed oil (cold pressed) for aflatoxins and ochratoxin A.
Aflatoxins were detectable only in few samples. Concentrations did not exceed the limit of determination in any sample, which means levels of aflatoxins were very low, and applicable maximum levels were not exceeded.
The test result for ochratoxin A in pumpkin seed oil was comparable to the results found about aflatoxins. In linseed oil, ochratoxin A was detectable in 28.3% of the 60 samples tested. Therefore, it is recommended to continue the studies of ochratoxin A in linseed oil (cold-pressed) in order to strengthen the data base and better be able to estimate the contribution of linseed oil to the overall exposure to ochratoxin A.

2.8.6 Ergot alkaloids

The testing of rye flour for ergot alkaloids confirmed the results of earlier years. Though the maximum value observed in the 69 rye flour samples examined was lower compared with the 2016 studies (2021: 954 µg/kg and 2016: 1.803 µg/kg), the mean level (median) of the ergot alkaloid sum content was significantly higher than in 2016 (2021: 51.4 µg/kg and 2016: 15.0 µg/kg). Compared to that, ergot alkaloid levels were lower in the 62 samples of bread and small pastries with or without rye. Occurrence of single samples with higher concentrations and statistically unequal distribution of concentration values in processed cereal products is a frequently observed characteristic of these agricultural contaminants.
31 samples of wheat grains which were also examined showed low levels of ergot alkaloids, in total.

2.8.7 Alternaria toxins

Examination of sunflower seeds for *Alternaria* toxins (86 samples) was newly included in the Monitoring Programme in 2021. Concentrations of tenuazonic acid (median: 114 µg/kg) were clearly higher than those of other *Alternaria* toxins in the current parameter spectrum. Alternariol was not quantifiable in any of the 86 samples tested.
Although the lack of toxicological data makes health assessment of *Alternaria* toxins highly uncertain, from today's point of view, we should make further efforts to minimise *Alternaria* toxins' currently wide spread in foodstuffs for reasons of precautionary consumer protection.

2.9 Elements

Test results showed in the majority low levels of elements analysed (lead, cadmium, arsenic, aluminium, and nickel, as well as, in selected samples, mercury, chromium, thallium, copper, selenium, manganese and zinc). Element levels found were in the majority comparable with, or lower than in previous years' programmes. Lead and cadmium did not, or only in very single cases, exceed the maximum levels laid down in Regulation (EC) No 1881/2006 in almost all product groups examined.
In cereal-based infant foods, there was only one cadmium level exceeding the legal maximum level. Such low rate of non-compliance is welcome, in view of infants' and young children's enhanced sensitivity to lead and cadmium.
High levels of elements were found only in a few single cases in certain substance-matrix combinations. Leaf spices in particular were conspicuous with regard to almost all elements. However, health

impairment may be considered as rather unlikely, since spices are usually consumed only in small amounts.
Dried tea leaves were also conspicuous. These showed comparatively very high levels of all elements tested for. However, analysis of the watery infusion of these tea leaves also showed that only a very small portion of the elements migrates to the infusion.
Comparatively high levels of cadmium and aluminium as well as samples not complying with the maximum levels for mercury and copper were found in wild mushrooms. As wild mushrooms accumulate heavy metals and elements from the soil to a higher degree, one has to expect higher element levels here.
As regards food of animal origin, 2 (2.4 %) out of 85 samples of rabbit meat did not comply with the legal maximum level for lead. Furthermore, the predatory fish pike perch was found with comparatively enhanced levels of mercury and arsenic.

Project 02: Determination of lead and other toxic elements in sugar
Sugar had so far not yet been analysed for the heavy metal lead or other toxic elements under the Monitoring Programme. So this project was designed to raise basic data on the occurrence of lead and other toxic heavy metals or elements in this food, in order to gain further information for the purpose of risk and exposure assessment.
Element contents in the 74 samples of white sugar and 88 samples of brown sugar tested can be considered as low. In 41 samples of molasses/sugar beet syrup, nearly all element levels were significantly higher than in white and brown sugar, in particular those of aluminium and lead. This is probably owing to the production process of molasses/sugar beet syrup, in which molasses is boiled several times. This can lead to enhancing the concentration of elements in the remaining molasses, which explains the higher element levels. Further minimisation strategies should be considered here in order to reduce element contents as much as reasonably achievable (ALARA principle).
The data collected in this project, namely those on molasses and sugar beet syrup, can serve as an important decision-making basis for further discussions on the introduction of maximum levels at the European and international level. The Codex Alimentarius Committee on Contaminants in Food (CCCF) has already proposed maximum levels for lead in sugar that have been met both by the white and brown sugar samples examined.

Project 03: Determination of toxic elements in milk substitute drinks
Milk substitute drinks based on oats, almond, rice or soya play an important role in people’s dietary habits today.
Apart from soy drinks, milk substitute drinks have not yet been subject to the Monitoring Programme as regards toxic elements. So this project was designed to raise basic data on the occurrence of toxic heavy metals and other elements in these milk substitute drinks, in order to gain further information for the purpose of risk and exposure assessment.
Element contents were at a very low level in all 331 samples of milk substitute drinks. Namely, lead and cadmium were quantifiable only at extremely low levels in all drinks. The low levels might be explained by the fact that oats, almonds, rice, or soy usually make up only a small portion of the drinks (about 2 % to 15 %, depending on the base ingredient).
The data collected in this project can serve as an important decision-making basis for further discussions on the introduction of maximum levels at the European level.

2.10 Nitrate

Nitrate contents in the two foods examined – chives (101 samples) and celeriac (147 samples examined) – are considered as comparatively low. Although the actual maximum content found in chives was high, consumers should not reduce their consumption of vegetables, but should pay attention to a varied vegetable diet, according to the BfR's FAQ sheet on nitrate and nitrite in foodstuffs.

2.11 Acrylamide

Project 04: Acrylamide in foods listed in Monitoring Recommendation (EU) 2019/1888

Acrylamide is produced in particular when baking, frying or frying food and potentially increases the cancer risk of consumers of all ages. Therefore, 425 samples of foods with so far insufficient data basis concerning the content of acrylamide were analysed in this project.

Except *pumpernickel* bread, all foods studied — rice waffles, hash browns, potato pancakes, (blackened) olives, and vegetable chips — can contribute significantly to acrylamide intake, depending on consumption habits.

As one cannot define intake amounts of mutagenic or carcinogenic substances which would be safe for health, acrylamide contents must be minimised according to the ALARA principle.

There is definitely need for action regarding minimisation measures in vegetable chips and blackened olives. Guidance values should be established for acrylamide in other product groups, too. In addition, further product groups should be examined that are not at first sight recognisable as predestined for acrylamide formation during the production process.

2.12 Pharmacological active substances

Project 05: Triphenylmethane dyes in aquaculture products

Triphenylmethane dyes (TPMD) are not authorised for use in food-producing animals due to their suspected adverse health effects. But as use is permitted in the pet sector/hobby fish keeping and in industry in Third Countries, this project was designed to examine the residue situation in aquaculture products available on the German market, regardless of their origin.

Residues of TPMD were detected in 2 out of 293 samples tested at levels higher than the current reference point for action (RPA). The nature and frequency of detectable TPMD residues are consistent with the residues found in the National Residue Control Plan (NRCP). The positive rate of 0.68 % in this Monitoring Project is comparable with the positive rate for triphenylmethane dyes found in Germany's NRCP in 2020 (0.66 %).

3 Cosmetic products

3.1 Elements in toothpaste/gel and eyeliner/eye pencil

Regulation (EC) No 1223/2009 provides that cosmetic products must not contain various heavy metals and their compounds. Based on data developed in the period from 2010 to 2012, we were able to derive orientation values for arsenic, lead, cadmium, antimony and mercury in various cosmetic products. To exceed these levels is technically avoidable.

89.5 % of the 124 toothpaste/gel samples tested and 87.8 % of the 72 eyeliner/eye pencil samples contained elements at levels below these orientation values. Regarding the toothpaste/gel samples, findings in comparison to 2012 were that levels of the listed elements increased in the central trend (medians), while the majority of contamination levels (90th percentiles) were lower or the same as in 2012.

Findings in eyeliner/eye pencil samples looked similar: medium levels (medians) increased with the above elements, except with lead, while the majority of element levels (90th percentile) declined. In general, we can say that the entry of elements as contaminants in cosmetic products should be as low as technically possible.

3.2 Elements in decorative cosmetics with glitter

Lip cosmetics with glitter were examined for content of elements in 2019. In 2021, the following matrices were added to the programme: eyeshadow, skin make-up preparations (both powders and creams), blush, colour make-up, glitter effect spray and camouflage with glitter. Antimony trioxide is often used as a catalyst in the production of the polyethylene terephthalate (PET) or polybutylene terephthalate (PBT) used for the glitter effect. One aim of investigations was therefore to find out whether the use of terephthalates has an influence on the antimony content in these matrices, too.

Heavy metal contents of 83.5 % of the 258 samples of decorative glitter cosmetics examined were below the orientation values for technical avoidability of arsenic, antimony, lead, cadmium and mercury. The analytic findings confirmed that use of terephthalates can lead to higher antimony levels in cosmetic products. Eyeshadow was the major test matrix. Compared to findings in the Monitoring Programmes of 2012 and 2018, levels of the elements arsenic, antimony, lead, cadmium and mercury were approximately equal or lower. As these substances are prohibited in cosmetic products, heavy metal contents should continue to be lowered by responsible raw material selection and good manufacturing practice.

The studies carried out in 2018, 2019, 2020 and 2021 using standardised measurement methods should provide a sufficient data basis to also derive guidance values for technically avoidable levels of the element nickel in the various product groups.

3.3 Formaldehyde in skin tanning products and hand wash pastes

Formaldehyde was used in the past as a preservative in cosmetic products, as it effectively kills bacteria. Commission Regulation (EU) 2019/831 of 22 May 2019 prohibited the use of formaldehyde in cosmetic products because of its classification as a category-1B carcinogen. However, formaldehyde may be present in cosmetic products. The focus in 2021 was therefore on skin tanning products, where dihydroxyacetone (DHA) is often used as an active ingredient for tanning. Due to its chemical structure, DHA can split off formaldehyde. Hand wash pastes were examined on the other hand, because hand

wash pastes often contain wood particles intended to support the cleaning action. As formaldehyde may be contained as an adhesive component in wooden materials, the wood particles may bring formaldehyde into the wash paste.
Another source of entry of formaldehyde which should also be taken account of in both product groups are formaldehyde-separating preservatives, such as DMDM-hydantoin, diazolidinyl urea, imidazolidinyl urea, 2-bromo-2-nitropropane-1,3-diol and 5-bromo-5-nitro-1,3-dioxane. For these substances, maximum concentrations and labelling requirements are laid down in the EU Cosmetics Regulation.

Formaldehyde was detected in quantifiable, though very small amounts in 50.8 % of the 128 samples of skin tanning agents and in 4.88 % of the 123 samples hand wash paste examined. As it was expected, use of the formaldehyde separators 2-bromo-2-nitropropane-1,3-diol or DMDM-hydantoin resulted in higher formaldehyde levels in the products tested. The degree of dependence between this effect and the amount of formaldehyde separator used in the product was not considered here.
Formaldehyde levels reached up to 0.011 % in skin tanning agents, and up to 0.021 % in hand wash pastes. Overall, these concentrations are considered as very low.

4 Consumer items

4.1 Element release from toys

Coloured dry, brittle, dusty or moldable toy materials, liquid and adhesive materials, or scrapable toy materials may contain heavy metal-containing colour pigments and heavy metal-containing fillers. The monitoring in 2021 placed the focus on measuring the release of elements from finger paints, colour pencils and wax crayons placed on the market as toys. Examinations focussed in particular on toys intended for young children under 3 years of age, because of the higher probability in this consumer group that toys might be swallowed, due to mouthing behaviour (taking objects into the mouth). The release of heavy metals or elements was analysed under conditions of use as specified by industrial standard DIN EN 71-3:2019+A1:2021, which simulates the release after swallowing of toy material. Coloured pencil leads and finger paints were already subject of investigation in 2011. Since that time, migration limits have been – sometimes significantly – reduced.
As determination limits for the quantification of element releases differed sometimes significantly in the monitorings of 2011 and 2021, statistical key figures could be meaningfully compared only to limited extent. Apart from that, determination limits in 2011 were partly higher than current migration limit values.

Element release in 90.8 % of a total of 502 toy samples was lower than the migration limits set out in Directive 2009/48/EC for aluminium, lead, cadmium, arsenic, antimony, barium, boron, cobalt, copper, manganese, nickel, mercury, selenium, strontium, zinc and tin. The release of lead in the tested finger paints was striking, with 30.4 % of the samples exceeding the migration limit value. As there is no toxicological threshold value for negative effects on brain development, the BfR holds that children's intake of lead should be minimised as far as possible across all sources, including finger paints. Migration limit values for all other elements were by far not reached – apart from a few exceptions – which shows that even significantly lower values are technologically feasible with good manufacturing practice.

4.2 Primary aromatic amines and aromatic amides in food contact items made of paper/cardboard/carton

Primary aromatic amines (PAA) and aromatic amides can transition from dyed or printed food contact products made of paper, carton or cardboard to the food in contact. Numerous PAA are classified as carcinogens in Regulation (EC) No 1272/2008. In accordance with the BfR Recommendation XXXVI and BfR Opinion No 037/2019, there are guidance values/detection limits for the sum of PAA (10 µg/kg), for PAA classified as category-1A and 1B carcinogens according to Regulation (EC) No 1272/2008 (2 µg/kg), and for the aromatic amides naphthol AS, N-acetoacetyl-m-xylidin (NAAX) and N-(2,4-dimethylphenyl) acetamide (NDPA) (each 10 µg/kg). The aim of the monitoring tests was to obtain data on the real situation on the market, and to be able to assess the exposure to PAA and aromatic amides and evaluate it under health aspects.

Subject to testing were only coloured or printed papers/cardboards/cartons. Depending on the sampled material's purpose of use, PAA transition was measured in either cold water or hot water extract.

With a few exceptions (6 out of 177 samples, 3.4 %), all paper/cardboard/carton samples complied with the above reference values. However, these few samples with migration exceeding the detection limits at the same time show that coloured or colour-printed food contact items made of paper/paperboard/carton can still release relevant amounts of PAA or aromatic amides. In principle, the BfR advises not to use printed paper packaging or printed table napkins (namely, with colour range yellow — orange — red) for long-term storage of food in households.

4.3 Polycyclic aromatic hydrocarbons (PAHs) in consumer articles with skin contact and in toys

Regulation (EC) No 1907/2006 (REACH Regulation) provides for Europe-wide concentration limits on 8 polycyclic aromatic hydrocarbons (PAHs) classified as carcinogenic, which may be part of plastic or rubber elements in toys and consumer products intended for prolonged or repeated skin contact. Yet there are discussions as to whether it would be possible and useful to supplement or even replace existing concentration limits by migration limits.

After PAH levels in products as named above, and migration to contact objects were analysed in the 2017 Monitoring Programme, such studies were to be repeated at intervals of 4 years. Therefore, 53 toys and 236 body contact materials were analysed for levels of the 8 PAHs regulated under the REACH Regulation. In addition, concentrations of further, unregulated PAHs were analysed on a voluntary basis.

The limit values for the 8 PAHs were met by 99.7 % of the samples tested. Only one handle of a rubber hammer exceeded the limit value. Compared to the 2017 monitoring tests, there were fewer findings exceeding the limit values, a lower percentage of samples with quantifiable PAH levels, lower maximum findings and lower median values of regulated PAHs. The maximum values of unregulated PAHs were also clearly lower than in 2017, in the majority.