

No. 2 – April 2020

News from the BfR

Amongst others, the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung (BfR)) published the following:

- Food supplements with red yeast rice: due to significant health safety concerns, the BfR recommends not to consume food supplements that contain red yeast rice or only after medical consultation. The background is the unclear safety evaluation of the cholesterol-lowering constituent monacolin K (Statement No. 003/2020 dated 15 January 2020; in German: <https://www.bfr.bund.de/cm/343/cholesterinsenkung-mit-folgen-nahrungsergaenzungsmittel-mit-rotschimmelreis-nur-nach-aerztlicher-ruecksprache-einnehmen.pdf>).

- STEC in flour: on account of the fact that, in Germany in 2018, shiga toxin-producing *Escherichia coli* (STEC) were consistently detected in flour samples (wheat, spelt, rye), the BfR provides information on the sources, risks and preventive actions (Statement No. 0004/2020 dated 20 January 2020; in German: <https://www.bfr.bund.de/cm/343/escherichia-coli-in-mehl-quellen-risiken-und-vorbeugung.pdf>).

- Poultry plague: the virus transmission (H5N8) through the consumption of food from poultry is unlikely (Communication No. 0009/2020 dated 30 January 2020; in German: <https://www.bfr.bund.de/cm/343/aktueller-gefluegelpest-fall-in-deutschland-virusuebertragung-h5n8-durch-den-verzehr-von-lebensmitteln-vom-gefluegel-ist-unwahrscheinlich.pdf>).

- Coronavirus – FAQ: the BfR updated the questions and answers regarding the new coronavirus (SARS-CoV-2). According to the current state of knowledge it is considered to be unlikely that imported goods (such as foods, articles of daily use, toys etc.) can be the source of an infection with the new coronavirus. (https://www.bfr.bund.de/en/can_the_new_type_of_coronavirus_be_transmitted_via_food_and_objects_-244090.html) – the questions and answers are continuously updated by the BfR on this website as new findings are made).

For further information, please refer to www.bfr.bund.de.

Modifications Regarding Pesticides

- Chlorpyrifos-methyl, chlorpyrifos and thiacloprid approvals not renewed:

with the Implementing Regulations (EU) 2020/17 and 2020/18 of the Commission dated 10 January 2020, the non-renewal of the approval of the active agents chlorpyrifos-methyl and chlorpyrifos is ruled. The regulations came into force on 16 January and the Member States had to revoke the corresponding approvals until 16 February 2020. Any grace periods will end at the latest on 16 April 2020 (Official Journal L 7 dated 13 January 2020, page 11 and 14).

According to the Implementing Regulation (EU) 2020/23 from 13 January 2020, the approval for the active agent thiacloprid was not renewed. The regulation came into force on 3 February 2020. At the latest until 3 August 2020, the Member States shall revoke the approvals for pesticides that contain thiacloprid as an active agent. Any grace periods end at the latest on 3 February 2021 (Official Journal L 8 dated 14 January 2020, page 8).

- Maximum residue levels (MRL) – prochloraz: with Regulation (EU) 2020/192, the MRL for the active agent prochloraz in or on certain products were modified. Furthermore, a new residue definition for prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) was also stipulated. The regulation came into force on 4 March 2020 and will apply from 4 September 2020 (Official Journal L 40 dated 13 February 2020, page 4).

- Indoxacarb – harmful to bees: the Federal Office of Consumer Protection and Food Safety (BVL) communicated on 7 February 2020 that the pesticide SINDOXA with the active agent indoxacarb is classified as harmful to bees and that, therefore, it must not be applied to flourishing plants or plants that are able to be reached by bees (in German: https://www.bvl.bund.de/SharedDocs/Fachmeldung/en/04_pflanzenschutzmittel/2020/2020_02_07_Fa_Sindoxa_B1.html).

Note:

Extensive information on approved pesticides, revoked and suspended approvals and also on emergency approvals, for example, can be retrieved

on the homepage of the Federal Office of Consumer Protection and Food Safety (BVL) at www.bvl.bund.de (https://www.bvl.bund.de/EN/Tasks/04_Plant_protection_products/01_ppp_tasks/ppp_tasks_node.html).

Modifications Regarding Veterinary Drugs

■ Bambermycin and ciclesonide: in Table 1 of the annex of Regulation (EU) No. 37/2010 ("Allowed substances"), the substances bambermycin and ciclesonide were newly included (Implementing Regulations (EU) 2020/42 and 2020/43 dated 17 January 2020, Official Journal L 15 dated 20 January 2020; pages 2 and 5).

■ BVL – approval of veterinary drugs: the Federal Office of Consumer Protection and Food Safety (BVL) published the announcement regarding the approval of veterinary drugs dated 27 January 2020 (in German: https://www.bvl.bund.de/SharedDocs/Fachmeldungen/05_tierarzneimittel/2020/2020_03_02_Fa_Bekanntmachung_Zulassung_TA.html).

Sentences

■ Fruit gums – "without artificial colourants": in its sentence dated 10 December 2019, the Administrative Court of Freiburg argued that fruit gums that are coloured with plant and fruit extracts may be promoted with the reference "without artificial colourants" (Ref. No. 8 K 6149/18; in German: https://verwaltungsgesicht-freiburg.justiz-bw.de/pb/.Lde/Startseite/Presse/Fruchtgummi_+Suesswarenhersteller+darf+mit+dem+Hinweis+ ohne+kuenstliche+Farbstoffe +werben/?LISTPAGE=1215828).

■ Indication of origin for fruit and vegetables in the online trade: the District Court of Munich decided on 14 January 2020 that the origin of fruit and vegetables must also explicitly be indicated in the online trade. Several possible countries of origin must not be indicated, nor must products from countries of origin other than the ones specified in the order be delivered subsequent to ordering (Ref. No. 1 HK O 6852/18).

■ Chia seeds – permissible in fried snacks: according to the Union list of allowed novel food (Regulation (EU) 2017/2470), chia seeds may be used, amongst others, in "baked products". The Administrative Court Hanover decided on 15 January 2020 that the term "baked products" also includes a fried product that contains chia seeds and which is marketed as a snack, provided that this product consists mainly of cereals or cereal products (Ref. No. 15 A 819/18; in German: <http://www.dbovg.niedersachsen.de/jportal/?quelle=link&docid=MWRE200000745&psml=bsndprod.psm1&max=true>).

■ ECJ – "accompanied" according to HCR: According to Article 10 (3) of the Health Claims Regulation (Regulation (EC) No. 1924/2006, HCR),

references to general, non-specific advantages for the health or health-related well-being are only permissible if accompanied by a special health-related claim that is included in one of the lists according to Articles 13 or 14 of the regulation. With its sentence dated 30 January 2020, the European Court of Justice (ECJ) decided that the requirements are not met when the general, non-specific indication is placed on the front side of the packaging but the special health-related indication only on the back side of the packaging, and when there is no hint regarding the reference between both indications (for example by means of an asterisk hint). However, it is for the national courts (here: the Federal High Court of Justice (BGH), I ZR 162/16), "to verify and determine, in the light of all the circumstances of the case...", as to whether or not the requirements of visual proximity resulting from Article 10(3) are met.

Furthermore, according to the ECJ's view, the requirement to support and ensure "general" health-related indications by generally accepted scientific evidence are already met when a checked and approved special indication according to the lists of Articles 13 and 14 is added (Case C-524/1

<http://curia.europa.eu/juris/document/document.jsf?ext=&docid=222888&pageIndex=0&doclang=EN&ode=req&dir=&occ=first&part=1>).

Miscellaneous

■ Food labelling – since 1 April 2020 indication of origin for primary ingredients: Implementing Regulation (EU) 2018/775, in which details are specified for the application of Article 26(3) of the Food Information Regulation (Regulation (EU) No. 1169/2011, LMIV) regarding the provisions for the indications of the country of origin or the place of provenance of the primary ingredient are stipulated, will apply from 1 April 2020. On 31 January 2020, a catalogue of questions and answers concerning primary ingredients was published by the Commission. However, the announcement only serves as a non-binding interpretation aid, since, according to the introductory text, the presented positions "cannot prejudice the position that the European Commission might take before the Union and national courts".

(Official Journal C 32 dated 31 January 2020, page 1; <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583761718051&uri=CELEX%3A52020XC0131%2801%29>).

■ Acrylamide: the European Commission updated its web page regarding acrylamide (https://ec.europa.eu/food/safety/chemical_safety/contaminants/catalogue/acrylamide_en). The interpretation guideline for Regulation (EU) 2017/2158 "establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food" is now available in all 23 official languages, for example.

■ Novel Food – extension of the Union List: Implementing Regulation (EU) 2017/2470 of the Commission for the creation of the Union List of novel food was modified by further EU implementing regulations, inter alia as follows:

- Nicotinamide-riboside chloride was approved (Implementing Regulation 2020/16 dated 10 January 2020, Official Journal L 7 dated 13 January 2020, page 6),
- Chia seeds (*Salvia hispanica*), extension of the purposes of use, modification of the conditions of use and of the labelling provisions (Implementing Regulation 2020/24 dated 13 January 2020, Official Journal L 8 dated 14 January 2020, page 12),
- Fruit pulp, juice and concentrated juice from fruit pulp from *Theobroma cacao* L. approved as traditional foods from a third country (Implementing Regulation 2020/206 dated 14 February 2020, Official Journal L 43 dated 17 February 2020, page 66).

■ Additives – modifications regarding sorbic acid (E 200) and soya bean polyose (E 426):

- Sorbic acid in liquid egg dyes: with Regulation (EU) 2020/268 of the Commission dated 26 February 2020, sorbic acid was approved for liquid dye preparations that are offered for sale to the end user in order to obtain colour effects on the shells of eggs (Official Journal L 56 dated 27 February 2020, page 4). The regulation came into force on 18 March 2020.
- Soya bean polyose: the allowed range of use of soya bean polyose was extended with Regulation (EU) 2020/279 dated 27 February 2020 (Official Journal L 59 dated 28 February 2020, page 6). The regulation came into force on 19 March 2020.

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EC Alert Notifications

Following are notifications chosen from the European Rapid Alert System for Food. Considered were alerts, information and border rejections which arrived **between 17 January 2020 and 27 February 2020**.

Source:

https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/01_Aufgaben/04_Schnellwarnsystem/01_aktuelle_rasff_meldungen/aktuelle_meldungen_node.html (extracts of the RASFF, anonymized and shortened by editorial preparation at the BVL, only in German)

Reason for Notifying	Product	Country of Origin	Notes	Number
Mycotoxins				
Aflatoxins total: 84	nuts, figs, pistachios, peanuts, almonds (including products)			76
	organic chili powder, chili powder	India	B1: 8.8 µg/kg; total: 9.8 µg/kg	2
	nutmeg	Indonesia		1
	rice	Sri Lanka	B1: 3.4 µg/kg	1
	ogbono	UK	B1: 15 µg/kg; total: 32 µg/kg	4
Ochratoxin A	organic figs, figs	Turkey, Netherlands, Germany	up 154 µg/kg	17
	raisins	Bosnia and Herzegovina, Uzbekistan	up 21.78 µg/kg	2
	plums	China	21 µg/kg	3
	nutmeg	Indonesia	36 µg/kg	1
	fig bread	Spain	114 µg/kg	8
	organic rice, instant rye flakes	Italy (raw mat. Greece, India), Poland		2
Deoxynivalenol (DON)	breadcrumbs	China	771 µg/kg	1
Patulin	apple puree	Spain	81 µg/kg	10
	apple juice	Spain	up 130 µg/kg	2

Reason for Notifying	Product	Country of Origin	Notes	Number
Heavy Metals / Other Metals				
Lead	vernison	Spain		3
	food supplement	Morocco, Spain	up 15.46 mg/kg	5
	passion fruit puree	France		1
Cadmium	black scabbardfish	Portugal	0.068 mg/kg	3
	fish product, cuttlefish, swordfish fillets	China, India, Spain		7
	prawns	Bangladesh		1
	mussels	Chile	1.575 mg/kg	2
	chocolate product	Belgium (raw mat. Netherlands)		4
Mercury	fish / fish products	Indonesia, Netherlands Portugal, Spain		18
	infant formula	Czech Rep.		1
Arsenic	infant formula	Czech Rep.		1
	rice	Italy		1
Other Contaminants / Residues				
Benzo(a)pyrene, PAH	organic hempseed oil	Estonia	Benzo(a)pyrene: 2.24 µg/kg; PAH: 19 µg/kg	23
	palm oil, sesame oil, black cumin oil	Guinea, Singapore, Egypt	Benzo(a)pyrene: up 6.1 µg/kg; PAH: up 32 µg/kg	34
	cocoa powder	Hungary (raw mat. Netherlands)		3
	cereal product	Turkey	PAH: up 81.1 µg/kg	2
	food supplement	Finland, China, USA		5
Mineral oil components	infant formula, follow-on formula	(not specified)		1
	basmati rice	Lithuania	MOAH: 1.5 mg/kg	1
Chlorate	food supplement	(not specified)		1
	pangasius fillet	Vietnam	19 mg/kg	10
Acrylamide	chips	Netherlands	up 2,690.7 µg/kg	8
3-Monochlorpropandiol (3-MCPD)	soy sauce	China, Philippines	up 193 µg/kg	3
Glycidyl esters	ghee (clarified butter)	Syria, United Arab Emirates	1,346 µg/kg	2
	sunflower oil, rice oil, vegetable fat	Belgium, India, Turkey, United Arab Emirates		10
	biscuits	Russ. Federation	5,384 µg/kg	13
Semicarbazide (SEM)	sausage	Spain (raw mat. Belgium)		1
Tropan alkaloids (Atropine, scopolamine)	organic soy flakes	Austria (partly raw mat. Czech Rep.)	Atropin: 19 µg/kg; Scopolamin: 6.4 µg/kg	13
Morphine	poppy seed	Slovakia		1
Shellfish poisoning toxins (DSP)	wedge shell clams	Portugal	444 µg/kg	3
Ergot alkaloids (<i>Claviceps purpurea</i>)	rye flour	France		1

Reason for Notifying	Product	Country of Origin	Notes	Number
Histamine	fish / fish products			4
Hydrocyanic acid	linseed	India		1
Pharmacological Active Substances				
1,3-Dimethylamylamin (DMAA), 1,5-Dimethylhexylamin (DMHA)	food supplement	USA, UK		8
2,4-Dinitrophenol (DNP)	food supplement	Turkey, unknown		8
4,4'-Diaminodiphenyl sulfone (Dapsone)	mixed honey	Poland (raw mat. Latvia, Argentina)		2
Amoxicillin	pig carcasses	Belgium		1
Anthraquinone	tea, mate tea	Syria, Paraguay		5
Chloramphenicol	enzymes	Germany, France	up 86 µg/kg	7
	shrimps	Vietnam	0.48 µg/kg	2
Cannabidiol (CBD)	food supplement	Netherlands (partly produced Poland), Austria, Poland, UK, unknown		33
	hempseed oil	unknown		1
	CBD water	Spain		2
	products	Belgium, Netherlands, Italy		10
	chewing gum, chocolate and tea	Spain		3
Tetrahydrocannabinol (THC)	food supplement	Ireland, Austria, UK, Netherlands (produced Poland)	up 308 mg/kg	36
	CBD oil, CBD drops	Netherlands, Slovenia, USA, UK	up > 750 mg/kg	11
	chewing gum	Austria	339.4 mg/kg	1
	chewing gum, chocolate and tea	Spain		3
Ivermectin	beef	Brazil		1
Sibutramine	herbal tea	Turkey		2
Sildenafil	food supplement	Bulgaria, Hong Kong, Morocco, Sweden, Turkey		12
Sulfonamides	honey	Turkey	(Sulfadimidin)	1
	pork	Italy	(Sulfadimethoxin)	3
Yohimbine	food supplement	UK, USA, not specified		13
Zopiclone	food supplement	Canada		3
Unauthorised Colours				
Rhodamine B	beets	Lebanon		1
Miscellaneous				
Datura fruit (<i>Datura stamonium L.</i>)	tomatoes	Spain		2

Reason for Notifying	Product	Country of Origin	Notes	Number
Parasite infestation with anisakis	cod fillets, fish, John Dory, red gurnard (<i>Chelidonichthys lucerna</i>), mackerel, European hake	China, France, Morocco, Netherlands, Spain		8
Pyrrolizidine alkaloids (PA)	camomile tea	unknown via Netherlands		2
	food supplement	Czech Rep.		2
	flower pollen	Spain		1
	oregano	Germany, Turkey		16
GMO, not authorised	rice	China		1
	maize	China		1
Irradiation, not authorised	herbs	USA		1
Food dependent disease outbreak	algae salad	China		1
	oysters, pacific crupped oysters, mussels	France, Ireland, UK, Spain		39
	yellowfin tuna	Vietnam		2
	sausages, chicken breast fillets	Germany, Netherlands		4
	organic eggs, eggs	Italy, Spain		10
	raw milk cheese, cheese	France, Sweden, Spain, Netherlands		8
	pesto	Italy		1
	other food products / mixtures	UK		3
Pathogenic Germs				
<i>Pseudomonas aeruginosa</i>	ice	Spain (processed Italy)		1
Salmonella total: 214	meat / meat products (including poultry)			152
	oysters	France		2
	sweets	Syria		6
	coriander	raw mat. Bulgaria, packed Germany		15
	basil, cumin, paprika powder, chili powder, long pepper, pepper, turmeric, onion powder	Egypt, Syria, China, India, Vietnam, Brazil		17
	mushrooms	China		1
	organic green salad	Spain		2
	sesame seeds	India, Nigeria, Sudan		11
	hazelnuts, almonds, walnuts, melon kernels	Georgia, Spain, USA, Hungary, Ghana		8
<i>Listeria monocytogenes</i>	meat / meat products (including poultry)	France, Belgium, Germany, Italy, Poland, Spain		20
	fish / fish products	France, Netherlands, Poland, Slovakia, Turkey		14
	shrimps	Netherlands		3
	pancake	France		1

Reason for Notifying	Product	Country of Origin	Notes	Number
	camembert, raw goat milk cheese	France		12
	cream cheese and tomato sticks, potato slices, gherkin cubes, dessert	Poland, Belgium, Spain, UK		7
	rocket, cabbage	Netherlands		5
Enteropathogenic E.coli	organic leek seeds	China		4
Shiga toxin-producing E.coli (STEC)	beef	Argentina, Brazil, Poland		7
	bovine carcasses	Belgium		3
<i>Bacillus cytotoxicus</i>	products with insect flour	Germany (raw mat. Thailand)		1
Norovirus	blueberries	Peru, South America		12
	oysters, mussels, pacific crupped oysters	France, Korea		100

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