UNIVERSITY OF CHEMISTRY AND TECHNOLOGY, PRAGUE
Faculty of Food and Biochemical Technology
Department of Food Analysis and Nutrition

EUCHINASAFE
中欧食品安全

Overview of EU legislation related to pesticide residues, mycotoxins and plant toxins in food

Vladimír Kocourek

Prague, 2022

Food Law & food safety in EU

Mycotoxins

Alkaloids

Pesticide residues

Food Law & food safety in EU

'**FOOD LAW**' means:

the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at EU or national level; it covers any stage of production, processing and distribution of food.

Regulation 178/2002/EC establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

EU Food law: policy

(i) High level of protection of human life and health

(ii) Protection of consumers from fraud, adulteration, or other misleading practices

(iii) Protection of market/producers against unfair practices

(iv) Protection of animals, plants and sustainable environment

(v) Free movement of food and feed within (27) EU states

Obligations of Food and Feed Business Operators:

- **Safety**
- **Responsibility**
- **Traceability**
- **Transparency**
- **Prevention**
- **Emergency (re-call)**
- **Co-operation**

European Commission:

European Commission
Directorate-General for Health and Food Safety (DG SANTE)

DG SANTE:
Directorate-General for Health and Food Safety

Goals:

Protect and improve human health
Ensure food is safe and wholesome
Protect the health of animals and plants
Promote the humane treatment of animals

Prevention and Regulation

- ✓ **“prevention is better than cure”** to protect the consumer (humans and animals) from the toxic effect of contaminants → need for encouraging preventive actions such as good agricultural practice, good storage conditions, use of improved sorting procedures, good manufacturing practice …

- ✓ **Fixing maximum limits of harmful substances**

  Fixing maximum levels at a reasonably achievable level, stimulates preventive actions at all stages to avoid contamination of the feed/food chain.

„Food law shall be based on „Risk analysis“ !

RISK ANALYSIS - a scientific tool:

- ✓ **risk assessment** (hazard identification & description, exposure assessment, risk characterisation)

- ✓ **risk management** – prevention and control (state regulation, official control, producer’s control,….)

- ✓ **risk communication** (interpreted information for public, recommendation, education, media,…)

FOOD SAFETY - strategy

- ✓The **risk management shall take into account the results of risk assessment**, **other factors legitimate** to the matter under consideration and the precautionary principle where appropriate

- ✓The **precautionary principle:** where, following an assessment of available information, the **possibility of harmful effects** on health has been identified but **scientific uncertainty** persists, **provisional risk management measures** necessary to ensure the high level of health protection chosen in the EU may be adopted, **pending further scientific information for a more comprehensive risk assessment**

Principles of Food safety risk communication

Openneness

Transparency

Timeliness

Responsiveness

Impartiality

European Food Safety Administration (EFSA)

- **Regulation (EC) No 178/2002** of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (since 2003)

European Food Safety Authority (EFSA)

- ✓ as **the risk assessor**, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the EC, EP and EU Member States in taking effective risk management decisions.

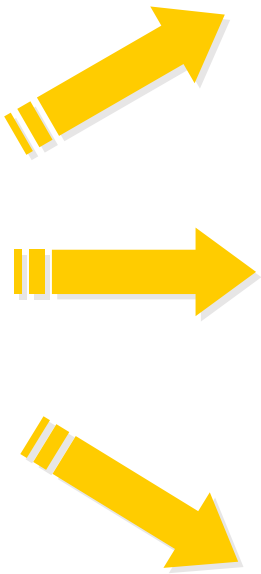
- ✓ provides objective **science-based advice and clear communication** grounded in the most up-to-date scientific information and data.

- ✓ provides **scientific and technical support on human nutrition** in relation to Community legislation and assistance concerning communication on nutritional issues.

- ✓ Scientific Panels of EFSA shall be composed of **independent scientific experts**.

What EFSA can do

WHY EFSA



To improve EU food safety

To re-build consumer confidence in EU food safety

To re-build confidence of trading partners in the EU food supply

What EFSA cannot do

- ✓ Be responsible for food safety legislation
- ✓ Take charge of food safety/quality controls, enforcements, administrative sanctions, labelling or other such issues
- ✓ Act as a substitute for national authorities
- ✓ No laboratories analysis

SCIENTIFIC REPORT

EFSA Journal

APPROVED: 13 July 2016

doi: 10.2903/j.efsa.2016.4572

Dietary exposure assessment to pyrrolizidine alkaloids in the European population

European Food Safety Authority (EFSA)

Abstract

Chronic and acute dietary exposure to pyrrolizidine alkaloids (PAs) was estimated in the European population via the consumption of plant-derived foods. This resulted in highest estimates of mean chronic dietary exposure of 34.5–48.4 ng/kg body weight (bw) per day in 'Toddlers' (LB–UB) and 154–214 ng/kg bw per day in the highly exposed population (LB–UB, also in 'Toddlers'). Following a rather conservative scenario, the highest estimates of acute mean exposure and 95th percentile exposure were calculated for 'Toddlers', with mean exposure up to 311 ng/kg bw per day and 95th percentile exposure up to 821 ng/kg bw per day. Tea and herbal infusions were by far the main average contributors to the total exposure to PAs. Among consumers only, in the adult population, the mean chronic exposure via the consumption of honey ranged between 0.1 and 7.4 ng/kg bw per day (minimum LB–maximum UB), while for high consumers, it was between 0.4 and 18 ng/kg bw per day (minimum LB–maximum UB). In the young population, for the average consumers of honey, estimates were between 0.3 and 27 ng/kg bw per day (minimum LB–maximum UB), and between 0.7 and 31 ng/kg bw per day (minimum LB–maximum UB) among the high consumers. Ad hoc exposure scenarios for food supplements via consumption of pollen-based supplements showed chronic exposure to PAs that ranged between 0.7 and 12 ng/kg bw per day (minimum LB–maximum UB),

EFSA Journal

REASONED OPINION

ADOPTED: 21 December 2021

doi: 10.2903/j.efsa.2022.7111

Review of the existing maximum residue levels for tetraconazole according to Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA),
Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, German Giner, Luna Greco, Samira Jarrah, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance tetraconazole. To assess the occurrence of tetraconazole residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, as well as the import tolerances and European authorisations reported by Member States and the UK (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and, with the exception of the MRL

Principal EU regulations

(regarding pesticide residues, mycotoxins and alkaloids):

Regulation 2002/178/EC

(It shall not apply to the domestic preparation, handling or storage of food for private domestic consumption)

…laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

EU countries implement harmonised legislation on Food safety and establish controls to enforce them.

...as a rule, food products legal / safe in one EU country are also legal in all the other EU countries

Mycotoxins, alkaloids, other toxins,...

Regulation 2006/1881/EC

setting maximum levels for certain contaminants in food

The foodstuffs shall not be placed on the market where they contain a contaminant listed in the Annex at a level exceeding the maximum level (ML).

When applying the maximum levels to foodstuffs which are dried, diluted, processed or composed of more than one ingredient, changes of the concentration caused by drying, dilution, or processing processes shall be taken into account, as well as the relative proportions of the ingredients in the product.

Where any food which is unsafe is part of a batch or consignment of food of the same class or description, it shall be presumed that all the food in that batch, or consignment is also unsafe (Reg. 2002/178/EC)

Article 3

Prohibitions on use, mixing and detoxification

1. Foodstuffs not complying with the maximum levels set out in the Annex shall not be used as food ingredients.

2. Foodstuffs complying with the maximum levels set out in the Annex shall not be mixed with foodstuffs which exceed these maximum levels.

3. Foodstuffs to be subjected to sorting or other physical treatment to reduce contamination levels shall not be mixed with foodstuffs intended for direct human consumption or with foodstuffs intended for use as a food ingredient.

4. Foodstuffs containing contaminants listed in section 2 of the Annex (Mycotoxins) shall not be deliberately detoxified by chemical treatments.

Food Law & food safety in EU

Mycotoxins

Alkaloids

Pesticide residues

Regulation 2006/1881/EC: mycotoxins, alkaloids,...

- Aflatoxins (ML for: B_1; sum of B_1, B_2, G_1, G_2; M_1)
- Ochratoxin A
- Patulin
- Deoxynivalenol (DON)
- Zearalenon
- Fumonisins (sum of B_1, B_2)
- T2 and HT2 (sum) - *still no ML values (indicative only)*
- Citrinine *(food supplements (Monascus purpureus)*
- Ergot alkaloids *(since 2021)*
- Tropane alkaloids *(since 2021)*
- Opium alkaloids (morphin + 0.2 x codein) *since July 2022*
- Pyrrolizidine alkaloids (sum of 21) *since July 2022*
- *Cannabinoids, Glycoalkaloids (proposals)*

Section 2: Mycotoxins

Foodstuffs (1)		Maximum levels (µg/kg)		
2.1.	**Aflatoxins** *(example)*	B_1	Sum of B_1, B_2, G_1 and G_2	M_1
2.1.1.	Groundnuts (peanuts) and other oilseeds (40), to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs, with the exception of: — groundnuts (peanuts) and other oilseeds for crushing for refined vegetable oil production	8,0 (5)	15,0 (5)	—
2.1.11.	All cereals and all products derived from cereals, including processed cereal products, with the exception of foodstuffs	2,0	4,0	—
2.1.15.	Processed cereal-based foods and baby foods for infants and young children (3) (7)	0,10	—	—
2.1.16.	Infant formulae and follow-on formulae, including infant milk and follow-on milk (4) ►**M20** (3) ◄	—	—	0,025
2.1.17.	Dietary foods for special medical purposes ►**M20** (3) ◄ (10) intended specifically for infants	0,10	—	0,025

etc, etc…

Mycotoxin	Product	Limits (µg/kg)
Total Aflatoxins	Groundnuts, nuts, dried fruit, cereals, spices,	4.0 – 15.0*
Aflatoxin B_1	Groundnuts, nuts, dried fruit, cereals, spices, baby food, dietary food	0.1 – 12.0*
Aflatoxin M_1	Dietary food, infant formula, milk	0.025 – 0.05*
Ochratoxin A	Cereals, dried vine fruit, coffee, wine, grape juice, baby food, dietary food, *beer, cocoa, meat products, liqueur, spices*	0.5 – 20*
Patulin	Fruit juice, spirit drinks and fermented drinks from apple, solid apple products, apple juice, baby food	10.0 – 50.0*
Deoxynivalenol (T-2 & HT-2 Toxins)	Cereals, flour, bread, pastries, snacks, breakfast cereals, pasta, baby food	200 – 1 750*
Zearalenone	Cereals, maize, maize flour, bread, maize oil, pastries, breakfast cereals, baby food	20 – 400*
Fumonisins (B1+B2)	Maize, unprocessed maize, maize flour, breakfast cereals,snacks, baby food	200 – 4000*
T-2 and HT-2 toxin	*Cereals, cereal products, flour, breakfast cereals, pastries, baby food*	*10 – 100***
Citrinin	Food supplements based on rice fermented with red yeast Monascus purpureus	100

* depending on matrix and if unprocessed (intended for further processing) or for direct human consumption

The new limits for DON proposed in food products by DG SANTE (2021), compared to the maximum levels currently in force suggest for significant reductions for:

unprocessed cereals	1250 ► 1000 µg/kg
durum wheat and corn	1750 ► 1250 µg/kg
milling products and pasta	750 ► 500 µg/kg
bread, pastries, breakfast cereals	500 ► 400 µg/kg
foods for infants and children	200 ► 150 µg/kg

However:
study conducted by Italian Council for Agricultural Research (2011-2019)*:

- 6 % samples of soft wheat exceeded current DON maximum limit 1250 µg/kg
- 8 % samples of soft wheat exceeded new DON maximum limit 1000 µg/kg

Considering corn samples, 16 % of the batches presented DON values higher than 1750 µg/kg ► the limit lowered to 1250 µg/kg will exceed 20 % !

*https://affidiajournal.com/en/dg-sante-s-proposal-to-lower-the-limits-for-mycotoxins-in-cereals-and-pasta-is-it-feasible

Mycotoxins: sampling & analysis ?

EU general approach:

! …not to establish a specific method of analysis but to establish performance criteria with which the method of analysis used for official control has to comply.

***Regulation (EC) No 401/2006**
laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

„As the distribution of mycotoxins is generally non-homogeneous, samples shall be prepared, and especially homogenised, with extreme care“

**2022: updated version is under discussion / preparation*

Regulation (EC) No 401/2006: methods of sampling and analysis for the control of the levels of mycotoxins in food.

Sampling, sample preparation and methods of analysis used for the official control of the levels of mycotoxins in foodstuffs shall comply with the criteria set out in Annexes.

Number of incremental samples to be taken depending on the weight of the lot of spices

Lot weight (tonnes)	Number of incremental samples	Aggregate sample weight (kg)
≤ 0,01	5	0,5
> 0,01-≤ 0,1	10	1
> 0,1-≤ 0,2	15	1,5
> 0,2-≤ 0,5	20	2
> 0,5-≤ 1,0	30	3
> 1,0-≤ 2,0	40	4
> 2,0-≤ 5,0	60	6
> 5,0-≤ 10,0	80	8

Regulation (EC) No 401/2006: methods of sampling and analysis for the control of the levels of mycotoxins in food.

Performance criteria for aflatoxins

Criterion	Concentration Range	Recommended Value	Maximum permitted Value
Blanks	All	Negligible	—
Recovery — Aflatoxin M_1	0,01-0,05 µg/kg	60 to 120 %	
	> 0,05 µg/kg	70 to 110 %	
Recovery — Aflatoxins B_1, B_2, G_1, G_2	< 1,0 µg/kg	50 to 120 %	
	1-10 µg/kg	70 to 110 %	
	> 10 µg/kg	80 to 110 %	
Reproducibility RSD_R	All	As derived from Horwitz Equation (*)(**)	2 × value derived from Horwitz Equation (*)(**)

Repeatability RSD_r may be calculated as 0,66 times Reproducibility RSD_R at the concentration of interest.

New standards for mycotoxins (examples):

- ✓ **EN 17521** Determination of Alternaria toxins in tomato, wheat and sunflower seeds by SPE clean-up and HPLCMS/ MS
- ✓ **EN 17279** Multimethod for the screening of aflatoxin B1, deoxynivalenol, fumonisin B1 and B2, ochratoxin A, T-2 toxin, HT-2 toxin and zearalenone in foodstuffs by LC-MS/MS
- ✓ **EN 17280** Determination of zearalenone and trichothecenes including deoxynivalenol and its acetylated derivatives (3-acetyl-deoxynivalenol and 15-acetyldeoxynivalenol), nivalenol T-2 toxin and HT-2 toxin in cereals and cereal products by LC-MS/MS
- ✓ **EN 17424** Determination of aflatoxins in spices by IAC clean-up and HPLC-FLD with postcolumn derivatization
- ✓ **EN ISO 14501** Milk and milk powder - Determination of aflatoxin M1 content - Clean-up by immunoaffinity chromatography and determination by high-performance liquid chromatography
- ✓ **EN 17203** Determination of citrinin in food by HPLCMS/ MS

Food Law & food safety in EU

Mycotoxins

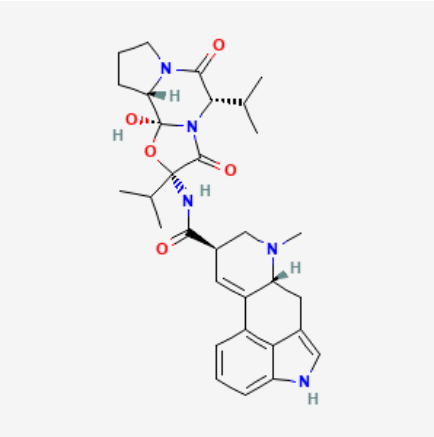
Alkaloids

Pesticide residues

Regulation 2006/1881/EC: ergot alkaloids

Ergot:

The most prominent member of this group is *Claviceps purpurea* ("rye ergot fungus").
This fungus grows on rye and related plants, and produces alkaloids that can cause ergotism in humans who consume grains contaminated with its fruiting structure called ergot *sclerotium*.



ergocornine

Abb. 5: Pieter Brueghel d.Ä. Die Krüppel (1568), Paris.

Regulation 2006/1881/EC: ergot alkaloids

	Foodstuffs (1)	Maximum levels (µg/kg)
2.9.2.	**Ergot alkaloids** (63)	
2.9.2.1.	Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)	100 µg/kg 50 µg/kg as from 1.7.2024
2.9.2.2.	Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g) Barley, wheat, spelt and oats grains placed on the market for the final consumer	150 µg/kg
2.9.2.3.	Rye milling products Rye placed on the market for the final consumer	500 µg/kg until 30.6.2024 250 µg/kg as from 1.7.2024
2.9.2.4.	Wheat gluten	400 µg/kg
2.9.2.5.	Processed cereal based food for infants and young children (3) (29)	20 µg/kg
2.9.1.	**Ergot sclerotia**	
2.9.1.1.	Unprocessed cereals (18) with the exception of — maize, rye and rice	0,2 g/kg
2.9.1.2.	Unprocessed rye (18)	0,5 g/kg until 30.6.2024 0,2 g/kg as from 1.7.2024

Regulation 2006/1881/EC: ergot alkaloids

The Maximum Level (ML) for ergot alkaloids refers to the lowerbound sum of the following 12 ergot alkaloids:

- Ergocornine / ergocorninine
- Ergocristine / ergocristinine
- Ergocryptine / ergocryptinine (*α- and β-form*)
- Ergometrine / ergometrinine
- Ergosine / ergosinine
- Ergotamine / ergotaminine

The „lowerbound sum“ means that
the contribution of each non-quantified epimer is set at zero.

SCIENTIFIC REPORT

EFSA Journal

Arcella D, Altieri A, Horváth Z. Scientific report on human acute exposure assessment to tropane alkaloids. EFSA Journal 2018;16(2):5160, 29 pp. EFSA

High occurrence values were found for **atropine** in '**Hempseed**' (77.2 µg/kg), '**Spices**' (i.e. coriander seed, 35.0 µg/kg), '**Tea and herbs for infusions**' (unspecified tea 6.71 µg/kg, green tea 10.0 µg/kg), '**Cereal bars**' (6.3 µg/kg). For **scopolamine** in '**Hempseed**' (64.9 µg/kg), '**Tea and herbs for infusions**' (Chamomile flowers 11 µg/kg, green tea 10 µg/kg), and '**Spices**' (i.e. coriander seed, 22 µg/kg)

The acute dietary exposure to the sum of atropine and scopolamine were highest in infants and other children. **ARfD was exceeded for atropine and scopolamine in infants, and other children** (and for atropine in adolescents as well). The main contributors to the exposure of atropine and scopolamine were **bread and other grain milling products** for all age classes.

The analytical techniques used to analyse the TAs were based on LC-MS/MS (> 97%)

Regulation 2006/1881/EC: tropane alkaloids

Foodstuffs (1)		Maximum level (µg/kg)	
8.2	**Tropane alkaloids** (62)		
		Atropine	Scopolamine
8.2.1.	Processed cereal-based foods and baby foods for infants and young children, containing millet, sorghum, buckwheat, maize or their derived products (3) (29)	1,0	1,0
		Sum of atropine and scopolamine	
8.2.2.	Unprocessed millet and sorghum (18)	5,0 as from 1 September 2022	
8.2.3.	Unprocessed maize (18) with the exception of — unprocessed maize intended to be processed by wet milling (37) and — unprocessed maize for popping	15 as from 1 September 2022	
8.2.6.	Buckwheat placed on the market for the final consumer Milling products of buckwheat	10 as from 1 September 2022	
8.2.7.	Herbal infusions (dried product) with the exception of the herbal infusions referred to in 8.2.8.	25 as from 1 September 2022	
8.2.8.	Herbal infusions (dried product) of anise seeds	50 as from 1 September 2022	
8.2.9.	Herbal infusions (liquid)	0,20 as from 1 September 2022	

Regulation 2006/1881/EC: pyrrolizidine alkaloids

Pyrrolizidine alkaloids are produced by plants as a defense mechanism against insect herbivores.

More than 660 PAs and PA N-oxides have been identified in over 6,000 plants, and about half of them exhibit hepatotoxicity.

They are found frequently in plants in the *Boraginaceae, Asteraceae, Orchidaceae* and *Fabaceae* families.

It has been estimated that 3 % of the world's flowering plants contain pyrrolizidine alkaloids. Thus honey can contain pyrrolizidine alkaloids, as can grains, milk, eggs, etc.

EFSA (2016). Dietary exposure assessment to pyrrolizidine alkaloids in the European population. EFSA Journal 2016;14(8):4572.
Roger A. Coulombe J. (2003). „ Pyrrolizidine alkaloids in food". Advances in Food and Nutrition Research. ***45****: pp. 61–99.*

Reg (EU) 2020/2040/EU amending Reg 1881/2006/EC as regards MLs of pyrrolizidine alkaloids in certain foodstuffs

	"Foodstuffs (1)	Maximum level (*) (µg/kg)
8.4.	**Pyrrolizidine alkaloids**	
8.4.1.	Herbal infusions (dried product) (**) (***) with the exception of the herbal infusions referred to in 8.4.2. and 8.4.4.	200
8.4.2.	Herbal infusions of rooibos, anise (*Pimpinella anisum*), lemon balm, chamomile, thyme, peppermint, lemon verbena (dried product) and mixtures exclusively composed of these dried herbs (**) (***) with the exception of the herbal infusions referred to in 8.4.4.	400
8.4.3.	Tea (*Camellia sinensis*) and flavoured tea (****)(*Camellia sinensis*) (dried product) (***) with the exception of the tea and flavoured tea referred to in 8.4.4.	150
8.4.4.	Tea (*Camellia sinensis*), flavoured tea (****)(*Camellia sinensis*) and herbal infusions for infants and young children (dried product)	75
8.4.5.	Tea (*Camellia sinensis*), flavoured tea (****)(*Camellia sinensis*) and herbal infusions for infants and young children (liquid)	1,0
8.4.6.	Food supplements containing herbal ingredients including extracts (**) with the exception of the food supplements referred to in 8.4.7.	400
8.4.7.	Pollen based food supplements (39) Pollen and pollen products	500
8.4.8.	Borage leaves (fresh, frozen) placed on the market for the final consumer (**)	750
8.4.9.	Dried herbs with the exception of the dried herbs referred to in 8.4.10. (**)	400
8.4.10.	Borage, lovage, marjoram and oregano (dried) and mixtures exclusively composed of these dried herbs (**)	1 000
8.4.11.	Cumin seeds (seed spice)	400

ML refers to the lowerbound sum of the 21 pyrrolizidine alkaloids:

- intermedine/lycopsamine, intermedine-N-oxide/lycopsamine-N-oxide,
- senecionine/senecivernine, senecionine-N-oxide/senecivernine-N-oxide,
- seneciphylline, seneciphylline-N-oxide,
- retrorsine, retrorsine-N-oxide,
- echimidine, echimidine-N-oxide,
- lasiocarpine, lasiocarpine-N-oxide,
- senkirkine,
- europine, europine-N-oxide,
- heliotrine and heliotrine-N-oxide

+ the additional 14 PAs known to co-elute with above identified 21 PAs:

- indicine, echinatine, rinderine *(co-elution with lycopsamine/intermedine)*
- indicine-N-oxide, echinatine-N-oxide, rinderine-N-oxide *(co-elution with lycopsamine-N-oxide/intermedine-N-oxide)*
- integerrimine *(co-elution with senecivernine/senecionine)*
- integerrimine-N-oxide *(co-elution with senecivernine-N-oxide/senecionine-N-oxide)*
- heliosupine *(co-elution with echimidine)*
- heliosupine-N-oxide *(co-elution with echimidine-N-oxide)*
- spartioidine *(co-elution with seneciphylline)*
- spartioidine-N-oxide *(co-elution with seneciphylline-N-oxide)*
- usaramine *(co-elution with retrorsine)*
- usaramine N-oxide *(co-elution with retrorsine N-oxide)*

Reg (EU) 2021/2142/EU amending Reg 1881/2006/EC as regards MLs of opium alkaloids in certain foodstuffs

Poppy seeds are obtained from the opium poppy (*Papaver somniferum L.*). The opium poppy plant contains opium alkaloids (morphine, codeine, etc.)

Poppy seeds do not contain the opium alkaloids (or contain only very low levels), but can become contaminated with alkaloids as a result of damage, or through external contamination of seeds during harvesting, when particles of dust from the straw (including the capsule wall) adhere to the seeds.

Maximum levels for morphine and codeine, expressed in morphine equivalents, are therefore set for poppy seeds placed on the market for the final consumer and for bakery products containing poppy seeds or derived products thereof. *Those levels are set taking into account that food processing may reduce the alkaloid content in the raw poppy seeds by 25-100 % in the final product*.

Reg (EU) 2021/2142/EU amending Reg 1881/2006/EC as regards MLs of opium alkaloids in certain foodstuffs

In Section 8 of the Annex to Regulation (EC) No 1881/2006, the following entry 8.5 is added:

	'Foodstuffs (1)	Maximum level (mg/kg)
8.5.	**Opium alkaloids** (*)	
8.5.1.	Whole, ground or milled poppy seeds placed on the market for the final consumer	20
8.5.2.	Bakery products (**) containing poppy seeds and/or derived products thereof (***)	1,50

(*) The maximum level refers to the sum of morphine and codeine, for which a factor of 0,2 is applied to the level of codeine. Therefore, the maximum level refers to the sum of morphine + 0,2 codeine.

(**) Bakery products include also flour-based ready-to-eat savouries and snacks.

(***) The food business operator supplying the poppy seeds to the food business operator manufacturing the bakery products shall provide the necessary information to enable the manufacturer of the bakery products to place products on the market that comply with the maximum level. This information shall include analytical data, where appropriate.'

It shall apply from 1 July 2022.

Food Law & food safety in EU

Mycotoxins

Alkaloids

Pesticide residues

Regulation 2005/396/EC

on **maximum residue levels of pesticides** in or on food and feed of plant and animal origin

2005 - 2022:

3.538 pages, data in very unfriendly format, often incomprehensible !

174 other regulations have changed this document since 2005 !

Frequent changes in:

- Maximum Residue Levels
- Residue definitions (sum of a.i. + metabolites)
- Expression of results
- Conditions for MRLs interpretation

Regulation 2005/396/EC: pesticide residues

'**Maximum Residue Level**' (MRL) means the upper legal concentration for a pesticide residue in or on food set in this Regulation - *based on Good Agricultural Practice and the lowest consumer exposure necessary to protect vulnerable consumers*

Article 18

Compliance with MRLs

1. The products covered by Annex I shall not contain, from the time they are placed on the market as food or feed, or fed to animals, any pesticide residue exceeding:

(a) the MRLs for those products set out in Annexes II and III;

(b) 0,01 mg/kg for those products for which no specific MRL is set out in Annexes II or III, or for active substances not listed in Annex IV unless different default values are fixed for an active substance while taking into account the routine analytical methods available.

Regulation 2005/396/EC: pesticide residues

…too much active substances….

English EN

Search

European Commission > Food, farming, fisheries > Food Safety > Plants > Pesticides > EU Pesticides database

Search Pesticide Residues

Search options

Product

Select any product

Legislation

Nothing selected

Footnote

Pesticide Residues (651 matching records)

Display selected items >

Filter results ...

1,1-dichloro-2,2-bis(4-ethylphenyl)ethane (F)

Regulation 2005/396/EC: pesticide residues

…a lot of commodities (x 651)

European Commission > Food, farming, fisheries > Food Safety > Plants > Pesticides > EU Pesticides database

Search products

Table legend: Category Group Subgroup Main product Others

Please click a main product or « others » label in the products tree

Hover on product name to see scientific and other product names or synonyms

Search in tree...

Product Code	Products to which MRLs apply
0100000	FRUITS, FRESH or FROZEN; TREE NUTS
0110000	Citrus fruits
0110010	Grapefruits
0110020	Oranges
0110030	Lemons
0110040	Limes
0110050	Mandarins
0110990	Others (2)

Reg 2005/396/EC: example of changes in 2021 (20 regs.)

— Legislation on MRLs – 2021

- EU 2021/155 EN
MRLs for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products
- EU 2021/590 EN
MRLs for aclonifen, boscalid, cow milk, etofenprox, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr in or on certain products
- EU 2021/616 EN
MRLs for benalaxyl, benalaxyl-M, dichlobenil, fluopicolide, proquinazid and pyridalyl in or on certain products
- EU 2021/618 EN
MRLs for diclofop, fluopyram, ipconazole and terbuthylazine in or on certain products
- EU 2021/644 EN
MRLs for fluxapyroxad, hymexazol, metamitron, penflufen and spirotetramat in or on certain products
- EU 2021/663 EN
MRLs for chlordecone in or on certain products
- EU 2021/976 EN
MRLs for cycloxydim, mepiquat, Metschnikowia fructicola strain NRRL Y-27328 and prohexadione in or on certain products
- EU 2021/1098 EN
MRLs for 24-epibrassinolide, Allium cepa L. bulb extract, cyflumetofen, fludioxonil, fluroxypyr, sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in or on certain products
- EU 2021/1110 EN
MRLs for ametoctradin, bixafen, fenazaquin, spinetoram, tefluthrin and thiencarbazone-methyl
- EU 2021/1531 EN
MRLs for aclonifen, acrinathrin, bacillus pumilus QST, ethirimol, penthiopyrad, picloram, pseudomonas sp. strain DSMZ 13134 in or on certain products.
- EU 2021/1795
MRLs for Terbuthylazine (R) (F) in or on certain products
- EU 2021/1804
MRLs for Bentazone (Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated), expressed as bentazone) (R) in or on certain products
- EU 2021/1807
MRLs for Acibenzolar-S-methyl (sum of acibenzolar-S-methyl and acibenzolar acid (free and conjugated), expressed as acibenzolar-S-methyl), Aqueous extract from the germinated seeds of sweet Lupinus, Azoxystrobin, Clopyralid, Cyflufenamid (sum of cyflufenamid (Z-isomer) and its E-isomer, expressed as cyflufenamid) (R) (A), Fludioxonil (R) (F), Fluopyram (R), Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl), Metazachlor (Sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor) (R), Oxathiapiprolin, Tebufenozide (F) and Thiabendazole (R) in or on certain products
- EU 2021/1810
MRLs for Cyprodinil (R) (F) in or on certain products
- EU 2021/1841
MRLs for 6-Benzyladenine, Aminopyralid (sum of aminopyralid, its salts and its conjugates, expressed as aminopyralid) (R) in or on certain products
- EU 2021/1842
MRLs for Difluoroacetic acid (DFA) and Flupyradifurone in or on certain products
- EU 2021/1864
MRLs for Amisulbrom, Flubendiamide (F), Meptyldinocap (sum of 2,4 DNOPC and 2,4 DNOP expressed as meptyldinocap), Metaflumizone (sum of E- and Z- isomers) and Propineb (expressed as propilendiamine) in or on certain products
- EU 2021/1881
MRLs for Imidacloprid in or on certain products
- EU 2021/1884
MRLs for Chlorantraniliprole (DPX E-2Y45) (F) in or on certain products

Table legend: Category Group Subgroup Main product Others

Please click a main product or « others » label in the products tree

Hover on product name to see scientific and other product names or synonyms

Search in tree...

Product Code	Products to which MRLs apply
0130990	Others (2)
0140000	Stone fruits
0140010	Apricots
0140020	Cherries (sweet)
0140030	Peaches
0140040	Plums
0140990	Others (2)
0150000	Berries and small fruits
0151000	(a) grapes
0151010	Table grapes
0151020	Wine grapes
0152000	(b) strawberries

Selected product: Table grapes

Main product of the group or subgroup | Other products to which the same MRLs apply

Code Number	Name	Scientific Name
0151010	Table grapes	Vitis vinifera

Main product of the group or subgroup | **Other products to which the same MRLs apply**

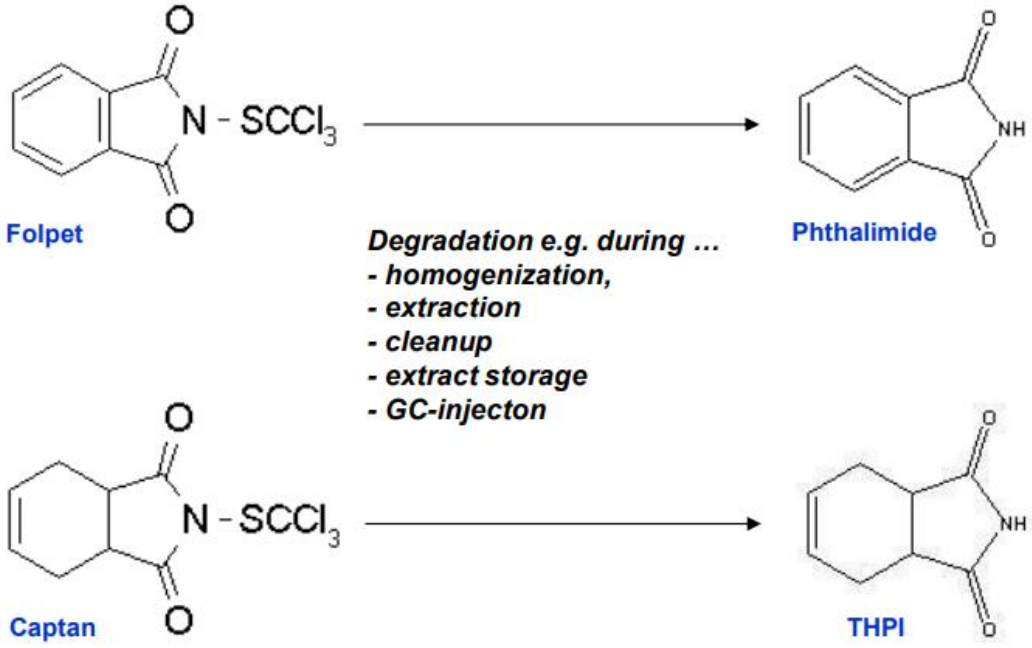
Code Number	Name	Scientific Name
0151010-001	Kiwiberries/dwarf kiwi	Actinidia arguta
0151010-002	Schisandra berries	Schisandra chinensis

Current MRL values for the product

Pesticide residue	Maximum residue level (mg/kg)
1,1-dichloro-2,2-bis(4-ethylphenyl)ethane (F)	0.01*
1,2-dibromoethane (ethylene dibromide) (F)	0.01*
1,2-dichloroethane (ethylene dichloride) (F)	0.01*
1,3-Dichloropropene	0.01*
1,4-Dimethylnaphthalene	
1-Naphthylacetamide and 1-naphthylacetic acid (sum of 1-naphthylacetamide and 1-naphthylacetic acid and its salts, expressed as 1-naphythlacetic acid)	0.06*
1-methylcyclopropene	0.01*
2,4,5-T (sum of 2,4,5-T, its salts and esters, expressed as 2,4,5-T) (F)	0.01*

showing all 506 entries

Main product of the group or subgroup	Other products to which the same MRLs apply	
Code Number	**Name**	**Scientific Name**
0151020	Wine grapes	Vitis vinifera



300.58 g/mol

151.17 g/mol

conversion factor THPI back to Captan: 1,998

„Residue definition“ (reg. 396/2005/2005):

Captan = Sum of captan and THPI, expressed as captan

Selected product: Table grapes

Main product of the group or subgroup | Other products to which the same MRLs apply

Code Number	Name	Scientific Name
0151010	Table grapes	Vitis vinifera

Pesticide residue	Maximum residue level (mg/kg)
Captan (Sum of captan and THPI, expressed as captan) (R)	0.03*

Main product of the group or subgroup | Other products to which the same MRLs apply

Code Number	Name	Scientific Name
0151020	Wine grapes	Vitis vinifera

Pesticide residue	Maximum residue level (mg/kg)
Captan (Sum of captan and THPI, expressed as captan) (R)	0.02*

(R) =The residue definition differs for the following combinations pesticide-code number: code 1000000 except 1040000: Sum of THPI, 3-OH THPI and 5-OH THPI, expressed as captan; code 0151020: captan

(1040000 = honey...)

Food intended for infants and young children*

Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/2013 as regards the specific compositional requirements for infant formula and as regards requirements on information relating to infant and young child feeding

Infant formula and follow-on formula shall not contain residues at levels > **0.01 mg/kg**.

For pesticides listed in Annex IV, the individual MRLs shall apply:

Chemical name of the parent compound of the substance (1)	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl Demeton-S-methyl sulfone Oxydemeton-methyl	0,006
Ethoprophos	0,008
Fipronil	0,004
Propineb	0,006

** 'young child' means a child aged between one and three years*

Food intended for infants and young children*

Regulation (EU) 2016/127

Infant formula and follow-on formula shall only be produced from agricultural products for the production of which plant protection products containing the active substances listed in Annex V („black list“) have not been used.

Substance is considered not to have been used if its residue ***> 0,003 mg/kg****.*

Substances on the **black-list**:

Aldrin, Dieldrin, Disulfoton, Endrin, Fensulfothion, Fentin, Haloxyfop, Heptachlor, Hexachlorobenzene, Nitrofen, Omethoate, Terbufos

The levels referred to shall apply to the product ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

? Tea leaves (reg. 396/2005) vs. Tea infusion (reg. 127/2016) ?

** 'young child' means a child aged between one and three years*

Organic farming and pesticide residues

Since January 2022, **Regulation (EU) 2018/848** is the applicable legislative act

The Commission may authorise products and substances for use in organic production for the following purposes as:

- **active substances to be used in plant protection products**
- fertilisers, soil conditioners and nutrients
- products for the cleaning and disinfection
- food additives and processing aids

Where the competent authority receives information about the presence of substance that are not authorised or detects such substance in an organic product, it shall:

- immediately carry out an official investigation,
- (provisionally) prohibit the placing on the market of the product as organic

In order to avoid risk of contamination with unauthorised substances, operators shall take the precautionary measures at every stage of production, preparation and distribution !

Organic farming is a system that limits the use of pesticides to a very small number of substances.

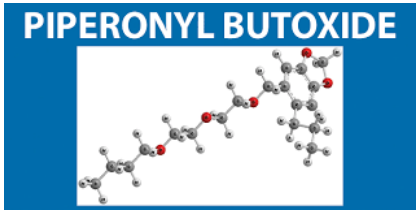
Organic food are produced in a world where pesticides are commonly used. Hence the risk of contamination with pesticides is always there: field, processing, transport,…

For practical reasons the baby food level (0,01 mg/kg) was generally taken as action level for organic products.

Regulation 2021/1165/EU authorising substances for use in organic production

The following substances shall be also allowed for use in organic production (provided that PPPs are authorised):

- safeners, synergists and co-formulants as components of PPPs;
- adjuvants that are to be mixed with PPPs



Regulation 2021/1165/EU authorising substances for use in organic production - examples

Number and part of Annex (1)	CAS	Name	Specific conditions and limits
139A	131929-60-7 131929-63-0	Spinosad	
228A	68647-73-4	Tea tree oil	all uses authorised, except herbicide
246A	8003-34-7	Pyrethrins extracted from plants	
292A	7704-34-9	Sulphur	
343A	11141-17-6 84696-25-3	Azadirachtin (Margosa extract)	extracted from Neem tree seeds (*Azadirachta indica*)
10E	20427-59-2	Copper hydroxide	in accordance with Implementing Regulation (EU) No 540/2011 only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years may be authorised
10E	1332-65-6 1332-40-7	Copper oxychloride	
10E	1317-39-1	Copper oxide	
10E	8011-63-0	Bordeaux mixture	
40A	52918-63-5	Deltamethrin,	only in traps with specific attractants against *Bactrocera oleae* and *Ceratitis capitata*
5E	91465-08-6	Lambda-cyhalothrin	only in traps with specific attractants against *Bactrocera oleae* and *Ceratitis capitata*

Pesticide residues: sampling & analysis ?

Directive 2002/63/EC: methods of sampling for the official control of pesticide residues in and on products of plant and animal origin

	Commodity classification (1)	Examples	Nature of primary sample to be taken	Minimum size of each laboratory sample
Primary food commodities of plant origin				
1.	All fresh fruits All fresh vegetables including potatoes and sugar beets and excluding herbs			
1.1.	Small sized fresh products units generally < 25 g	Berries, peas, olives	Whole units, or packages, or units taken with a sampling device	1 kg
1.2.	Medium sized fresh products, units generally 25 to 250 g	Apples, oranges	Whole units	1 kg (at least 10 units)
1.3.	Large sized fresh products, units generally > 250 g	Cabbages, cucumbers, grapes (bunches)	Whole unit(s)	2 kg (at least 5 units)

Directive 2002/63/EC: methods of sampling for the official control of pesticide residues in and on products of plant and animal origin

Commodity classification ([1])	Examples	Nature of primary sample to be taken	Minimum size of each laboratory sample
Pulses	Beans, dried; peas, dried		1 kg
Cereal grains	Rice, wheat		1 kg
Tree nuts	Except coconuts		1 kg
	Coconuts		5 units
Oilseeds	Peanuts		0,5 kg
Seeds for beverages and sweets	Coffee beans		0,5 kg
Solid products of low bulk	Hops, tea, herb tea	Packaged units or units taken with a sampling device	0,2 kg
Other solid products	Bread, flour, dried fruit	Packages or other whole units, or units taken with a	0,5 kg

Pesticide residues: analysis ?

ANALYTICAL QUALITY CONTROL AND METHOD VALIDATION PROCEDURES FOR PESTICIDE RESIDUES ANALYSIS IN FOOD AND FEED

Document Nº SANTE/12682 /2019 Implemented by 01/01/2020

Please follow the next lecture…

www.euchinasafe.eu

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 727864 and from the Chinese Ministry of Science and Technology (MOST).

Disclaimer: The content of this presentation does not reflect the official opinion of the European Commission and/or the Chinese government. Responsibility for the information and views expressed therein lies entirely with the author(s).