



UNIVERSITÀ DEGLI STUDI DI TORINO

## FOOD SAFETY AND FOOD SECURITY

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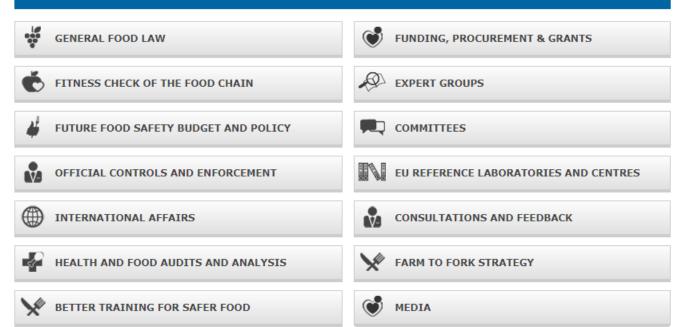
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https://ec.europa.eu/food/overview\_en



#### HORIZONTAL TOPICS RELATED TO FOOD SAFETY





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# For chemical substances in food, legislation is divided into the following areas:

• Food additives: based on the principle that only additives that are explicitly authorised may be used, often in limited quantities in specific foodstuffs. Prior to their authorisation by the Commission, food additives are evaluated for their safety

• Flavourings: sets limits on the presence of undesirable compounds, while for the chemically defined flavouring substances a vast safety evaluation programme is ongoing. Only substances for which the outcome of the evaluation is favourable will be authorised for use in foodstuffs by means of a future positive list

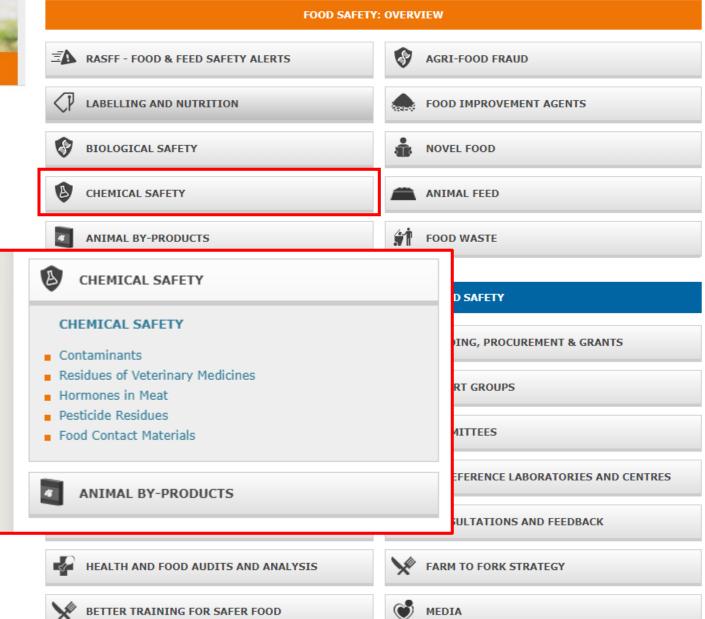
• Contaminants: based on scientific advice and the principle that contaminant levels shall be kept as low as can be reasonably achieved following good working practices. Maximum levels have been set for certain contaminants (e.g. mycotoxins, dioxins, heavy metals, nitrates, chloropropanols)

• Residues of veterinary medicinal products & Pesticides: used in food producing animals and on residues of plant protection products (pesticides). If necessary, maximum residue limits (MRLs) are established and in some cases the use of substances is prohibited

• Food contact materials: no migration of components into food in quantities that could endanger human health or change the composition, the taste or the texture of food 3

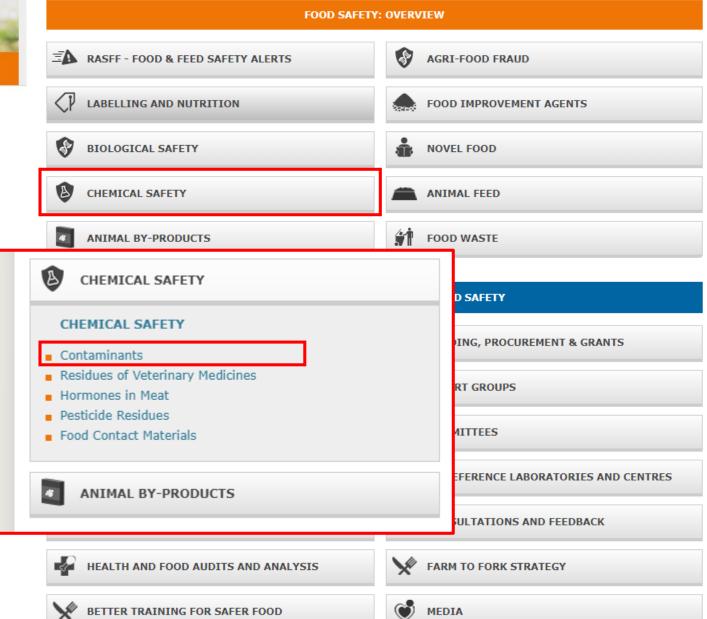


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### **EU Food Safety Contaminants**

**<u>Contaminants</u>**: substances **not intentionally added to food**.

These substances may be present in food as a result of the various stages of its **production**, **packaging**, **transport** or **holding**. They also might result from **environmental contamination**.

Contamination generally has a negative impact on the quality of food and may imply a risk to human health.

European Union measures (establishment of maximum levels) have been taken for the following contaminants:

- mycotoxins (aflatoxins, ochratoxin A, fusarium-toxins, patulin, citrinin)
- **metals** (cadmium, lead, mercury, inorganic tin, arsenic)
- dioxins and Polychlorinated Biphenyls (PCBs)
- Polycyclic Aromatic Hydrocarbons (PAH)
- **3-MCPD**
- melamine
- erucic acid
- nitrates

### **EU Food Safety Residue of Veterinary Medicine Product**

Food-producing animals may be treated with veterinary medicines to prevent or cure disease. These substances **may leave residues in the food from treated animals**. Food may also contain residues of pesticides and contaminants to which animals have been exposed to. In all cases, the levels of residues in food should not harm the consumer.

#### **Obligations**

- EU countries must implement <u>residue monitoring plans</u> to detect the illegal use or misuse of authorised veterinary medicines in food producing animals and investigate the reasons for residue violations
- Non-EU countries exporting to the EU must implement a residue monitoring plan which guarantees an equivalent level of food safety

#### The European Medicines Agency (EMA) is responsible for assessing Maximum

<u>Residue Limits</u> for veterinary medicinal products marketed in the EU.

### **EU Food Safety Hormones in Meat**

**Hormones:** substances having a hormonal action for growth promotion in farm animals. *E.g. oestradiol 17β, testosterone, progesterone, zeranol, trenbolone acetate and melengestrol acetate (MGA).* 

- 1981 the EU prohibited the use of hormones and the imports from third countries
- **1991** The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) concluded that no acceptable daily intake (ADI) could be established for any of these hormones. For oestradiol 17β it concluded that has to be considered as a complete carcinogen.
- **1996** Directive 96/22 confirms the prohibition of substances having a hormonal action.
- **1997** a panel of the WTO ruled that the EU measure was not in line with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS).
- **1998** the WTO Appellate Body reversed most of the findings of the panel claiming that the risk assessment was not performed properly.
- **2000** The SCVPH performed a new risk assessment complying with WTO requirements. It confirmed its opinion.
- 2003 Directive 2003/74 confirms the prohibition of substances having a hormonal action, but implemented its international obligations in the context of the WTO.

### **EU Food Safety Pesticide Residue**

A 'pesticide' is something that:

- prevents, destroys, or controls a harmful organism ('pest') or disease, or
- protects plants or plant products during production, storage and transport.

The term includes, amongst others: herbicides, fungicides, insecticides, acaricides, nematicides, molluscicides, rodenticides, growth regulators, repellents, rodenticides and biocides.

The term *'pesticide'* is often used interchangeably with *'plant protection product'*, however, pesticide is a broader term that also covers non plant/crop uses, for example biocides.

#### **EU Food Safety Pesticide Residue**

They contain at least one **active substance** and have one of the following functions:

- protect plants or plant products against pests/diseases, before or after harvest
- influence the life processes of plants
- preserve plant products
- destroy or prevent growth of undesired plants or parts of plants

They may also contain other components including safeners and synergists.

The traces pesticides leave in treated products are called "residues".

A maximum residue level (MRL) is the highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly GAP. Key points

- The amounts of residues in food must be safe for consumers and must be as low as possible. •
- The European Commission fixes MRLs for all food and animal feed ٠
- The MRLs for all crops and all pesticides can be found in the MRL database on the • Commission website. 10



fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and

spinetoram in or on certain products



lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and

spinetoram in or on certain products

Search active substances						
Show	Image: Search       Image: Search<					
	Name	Status under Reg. (EC) No 1107/2009 ¢	Date of approval 🔅	Expiration of approval \$	Legislation 🔶	
•	(4Z-9Z)-7,9-Dodecadien-1-ol	Not Approved			2004/129/EC	
•	(E)-10-Dodecen-1-yl acetate	Not Approved			2004/129/EC	
0	(E)-11-Tetradecen-1-yl acetate	Approved	01/09/2009	31/08/2021	Reg. (EU) No 540/2011Reg. (EU) No 918/2014Reg. (EU)2020/1160 (2008/127,Reg. (EU) 2017/195)	
0	(E)-2-Methyl-6-methylene-2,7-octadien-1-ol (myrcenol)	Not Approved			2007/442	
0	(E)-2-Methyl-6-methylene-3,7-octadien-2-ol (isomyrcenol)	Not Approved			Reg 647/2007	
0	(E)-5-Decen-1-ol	Approved	01/09/2009	31/08/2021	Reg. (EU) No 540/2011Reg. (EU) No 918/2014Reg. (EU)2020/1160 (2008/127,Reg. (EU) 2017/195)	
0	(E)-5-Decen-1-yl acetate	Approved	01/09/2009	31/08/2021	Reg. (EU) No 540/2011Reg. (EU) No 918/2014Reg. (EU)2020/1160 (2008/127,Reg. (EU) 2017/195)	
0	(E)-8-Dodecen-1-yl acetate	Approved	01/09/2009	31/08/2021	Reg. (EU) No 540/2011Reg. (EU) No 918/2014Reg. (EU)2020/1160 (2008/127,Reg. (EU)	



 Publication of Commission Regulation (EU) 2020/856 of 9 June 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fengyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products

#### Search products

Table legend							
Open details	ils 🗏 Category 📕 Group 📕 Subgroup 📕 Main product 📕 Others 📕 Footnote						
50 v re	records per page	Search:					
Showing 1 to 5	o 50 of 381 entries		< 1	2 3	4 5	8	8 >
Code number	Products listed in Annex I to Regulation (EC) No 396/2005 (Part A: Main product of the group or subgroup and Part B: Other products to which the same MRLs apply) <sup>(1)</sup>						
• 0100000	10 I FRUITS, FRESH or FROZEN; TREE NUTS						
• 0110000	0 Citrus fruits						
• 0110010	0 Grapefruits						
• 0110020	0 Cranges						
• 0110030	10 Etemons						
0110040	10 Limes						
• 0110050	io Mandarins						
• 0110990	00 Others (2)						
0120000	10 Tree nuts						
• 0120010	.0 Almonds						
0120020	20 Brazil nuts						
• 0120030	10 Cashew nuts						
• 0120040	10 Chestnuts						
• 0120050	i0 Coconuts						
• 0120060	i0 Hazelnuts/cobnuts						
0120070	70 Macadamias						^

Search products

50 v records per page		0110030 : Lemons 🗘			
		E   Export to Excel	rch:		
		Showing 1 to 50 of 495 entries 50 v records per page	( 1 2 3 4 5 10		
Code number	Products listed in Annex I to Regulation (Part A: Main product of the group or sub				
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	Pesticide Residue	Maximum residue level (mg/kg)		
-	Citrus fruits	<ul> <li>1,1-dichloro-2,2-bis(4-ethylphenyl)ethane (F)</li> </ul>	0.01*		
0110000		1,2-dibromoethane (ethylene dibromide) (F)	0.01*		
0110010	Grapefruits	1,2-dichloroethane (ethylene dichloride) (F)	0.01*		
0110020	Oranges	• 1,3-Dichloropropene	0.01*		
0110030	Lemons	1-methylcyclopropene	0.01*		
-	Lines	1-Naphthylacetamide and 1-naphthylacetic acid (sum of 1-naphthylacetamide and 1-naphthylacetic acid and its salts, expressed as 1-naphythlacetic acid)	0.06*		
0110040	Limes	2			
0110050	Mandarins	2,4,5-T (sum of 2,4,5-T, its salts and esters, expressed as 2,4,5-T) (F)	0.01*		
0110990	Others (2)	2,4-DB (sum of 2,4-DB, its salts, its esters and its conjugates, expressed as 2,4-DB) (R)	0.01*		
0120000	Tree nuts	0 2,4-D (sum of 2,4-D, its salts, its esters and its conjugates, expressed as 2,4-D)	1		
0120000		2,5-Dichlorobenzoic acid methylester	0.01*		
0120010	Almonds	2-amino-4-methoxy-6-(trifluormethyl)-1,3,5-triazine (AMTT), resulting from the use of tritosulfuron (F)	0.01*		
0120020	Brazil nuts	0 2-naphthyloxyacetic acid	0.01*		
0120030	Cashew nuts	2-phenylphenol (sum of 2-phenylphenol and its conjugates, expressed as 2-phenylphenol) (R)			
-			0.1*		
0120040	Chestnuts	3-decen-2-one	0.1*		
0120050	Coconuts	<ul> <li>8</li> <li>8-hydroxyquinoline (sum of 8-hydroxyquinoline and its salts, expressed as 8-hydroxyquinoline)</li> </ul>	0.01**		
0120060	Hazelnuts/cobnuts				

PESTICIDES	EU - Pesticides database				
EU Pesticides database Search active substances Search products		ACTIVE SUBSTANCES Regulation (EC) No 1107/2009	PESTICIDES EU-MRLs Regulation (EC) No 396/2005		
Search pesticide residues Search emergency authorisations	Latest active subs	Maximum Residue Levels	Jpdates		
Download MRLs data Sustainable use of pesticides	Non-renewal     2020/1246 of     Extension of     sulphate, alum	EU legislation on MRLs	tion of Commission Regulation (EU) 2020/1085 of 23 July 2020 amending 23/07/2020 is II and V to Regulation (EC) No 396/2005 of the European Parliament and of the las regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl in or ain products (shall apply from 13 November 2020)		
Approval of active substances Authorisation of Plant Protection Products	<ul> <li>tea tree, fat c gibberellins, h oils/rape seed smell of anim tebuconazole a</li> <li>Approval of 2020/1018 of</li> <li>Approval of the vRainwel of the VRA 1984 and</li> </ul>	How are EU MRLs set?	tion of Commission Regulation (EU)2020/749 of 4 June 2020 amending Annex III ulation (EC) No 396/2005 of the European Parliament and of the Council as a maximum residue levels for chlorate in or on certain products tion of Commission Regulation (EU) 2020/785 of 9 June 2020 amending Annexes		
Maximum Residue levels		Who does what?	III to Regulation (EC) No 396/2005 of the European Parliament and of the Council ards maximum residue levels for chromafenozide, fluometuron, pencycuron, ne, tau-fluvalinate and triazoxide in or on certain products (shall apply from 06 / 2021)		
« ALL TOPICS		Enforcement	<ul> <li>tion of Commission Regulation (EU) 2020/703 of 26 May 2020 amending Annex II ulation (EC) No 396/2005 of the European Parliament and of the Council as s maximum residue levels for dimethoate and omethoate in or on cherries (shall rom 16 December 2020)</li> </ul>		
		Guidelines	tion of Commission Regulation (EU) 2020/856 of 9 June 2020 amending Annexes III to Regulation (EC) No 396/2005 of the European Parliament and of the Council Jards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, ximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, on, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and ram in or on certain products		
		Cumulative Risk Assessment			
		Chlorate			
		REFIT Evaluation			

#### **EU Food Safety Maximum Residue Level: How are they set?**

Applicants must submit the following for the setting of MRLs for pesticides:

- The <u>use</u> of a pesticide on the crop e.g. quantity, frequency, growth stage of the plant, etc;
- Experimental data on the expected residues when the pesticide is applied according to GAP;
- <u>Toxicological reference</u> values for the pesticide.

Based on the available information, the intake of residues through all food that may be treated with that pesticide is compared with the:

- Acceptable Daily Intake (ADI)
- Acute Reference Dose (ARfD) for long and short-term intake

### **EU Food Safety Maximum Residue Level: How are they set?**

**Risk assessment:** The European Food Safety Authority (EFSA) verifies that this residue is safe for all European consumer groups, including vulnerable groups such as babies, children and vegetarians.

When a risk is established for any consumer group, the MRL application is rejected and the pesticide may not be used on that crop.

**Setting MRLs:** The Commission sets a new MRL and amends or removes an existing one after EFSA's opinion. The Commission adopts Regulations for the purpose.

**Enforcement & control:** The national authorities define how and when the pesticide may be used. That information is on the label of the pesticide.

Authorisations are granted on a national basis because local and environmental conditions and the occurrence of pests (therefore, use of pesticides) may differ.

#### Non-EU imported crops

For crops grown outside the EU, MRLs are set on the request of the exporting country.

### **EU Food Safety Maximum Residue Level: How are they set?**

#### What if the requested MRL is not safe?

It is set at the **lowest limit of analytical determination** (LOD). That is the MRL also for crops on which the pesticide has not been used or when its use has not left detectable residues.

The default lowest limit (LOD) in EU law is **0,01 mg/kg**.

### **EU Food Safety Food Contact Materials**

Food comes into contact with many materials and articles during its production, processing, storage, preparation and serving, before its eventual consumption. Such materials and articles are called **Food Contact Materials (FCMs)**.

#### This includes direct or indirect contact. Examples include:

- containers for transporting food
- machinery to process food
- packaging materials
- kitchenware and tableware

The term does not cover fixed public or private water supply equipment.

FCMs should be <u>sufficiently inert</u> so that their constituents neither adversely affect <u>consumer health</u> nor influence the <u>quality of the food</u>.

To ensure the safety of FCMs, and to facilitate the free movement of goods, EU law provides for binding rules that business operators must comply with.

### **EU Food Safety Food Contact Materials**

The safety of FCM is evaluated by the **European Food Safety Authority** (EFSA). At EFSA's website you can search for opinions on substances to be used in food contact materials.





### **EU Food Safety Food Contact Materials**

The safety of FCMs is tested by the business operators placing them on the market, and by the competent authorities of the Member States during official controls. Scientific knowledge and technical competence on testing methods is being maintained by the <u>European Reference Laboratory for Food Contact Materials (EURL-FCM</u>). Its website provides guidelines and other resources concerning the testing of food contact materials.

#### The framework Regulation

<u>Commission Regulation (EC) No 1935/2004</u> provides a harmonised legal EU framework. It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs). The principles set out in Reg. No 1935/2004 require that materials do not:

- Release their constituents into food at levels harmful to human health
- Change food composition, taste and odour in an unacceptable way

Moreover, the framework provides:

- for special rules on active and intelligent materials (they are by their design not inert)
- powers to enact additional EU measures for specific materials (e.g. for plastics)
- the procedure to perform safety assessments of substances used to manufacture FCMs involving the EFSA
- rules on labelling including an indication for use (e.g. as a coffee machine, a wine bottle) or by reproducing the appropriate symbol.
- for compliance documentation and traceability

<u>Commission Regulation (EC) No 2023/2006</u> ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation:

- premises fit for purpose and staff awareness of critical production stages
- documented quality assurance and quality control systems maintained at the premises, and
- selection of suitable starting materials for the manufacturing process with a view to the safety and inertness of the final articles

Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

Certain FCMs are covered by specific EU measures. There are also specific rules on some starting substances used to produce FCMs.

- $\checkmark$  Ceramic materials,
- ✓ Regenerated cellulose film,
- ✓ Plastics
- ✓ Recycled plastic)
- ✓ Active and intelligent materials

#### **III. Other Legislation**

#### Legislation on Specific Substances

- Commission Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials (Questions & Answers on BPA)
- *Commission Regulation 1895/2005/EC* restricting use of certain epoxy derivatives in materials and articles intended to come into contact with food
- *Commission Directive 93/11/EEC* release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers

#### EU Food Safety Food Contact Materials Authorized substances

Certain legislation on Food Contact Materials (FCM), such as the Regulation on plastic materials and articles, provides for <u>listing of substances</u>. Once these are listed they are permitted for use taking account of restrictions and specifications. Through this listing, these substances hence become 'authorised'.

For recycled plastics a very similar procedure is in place, although this authorises recycling processes via individual decisions.

#### EU Food Safety Food Contact Materials Authorized substances

The authorisation process consists of the following key steps:

- A business operator provide a <u>dossier</u> following the guidance provided by EFSA and send it to a competent authorities of the Member States.
- Via the Member State, EFSA receives the dossier. If the dossier is valid, <u>EFSA will evaluate it</u>, and provide an opinion on the safety of that substance taking account of its intended use
- The Commission will use the EFSA opinion as basis for deciding on its authorisation.
- The substance is authorised through an **amendment of the list of substances** under the applicable legislation. Once authorised, the substance can be used by everyone, subject to the restrictions set out in its authorisation. For recycling processes individual decisions are foreseen, addressed only to the applicant.
- The Commission must be immediately inform of any **new scientific or technical information**, which might affect the safety assessment of the authorised substance in relation to human.