European Commission

EU legislation concerning plant protection products

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

SANTE E4

Explanatory Meeting on the Acquis - Chapter 12

20 February 2019

Health and Consumers

EU legislative framework (PPPs)

Placing on the market of plant protection products

Reg.

Sustainable use of pesticides

Dir.

Collection of statistics

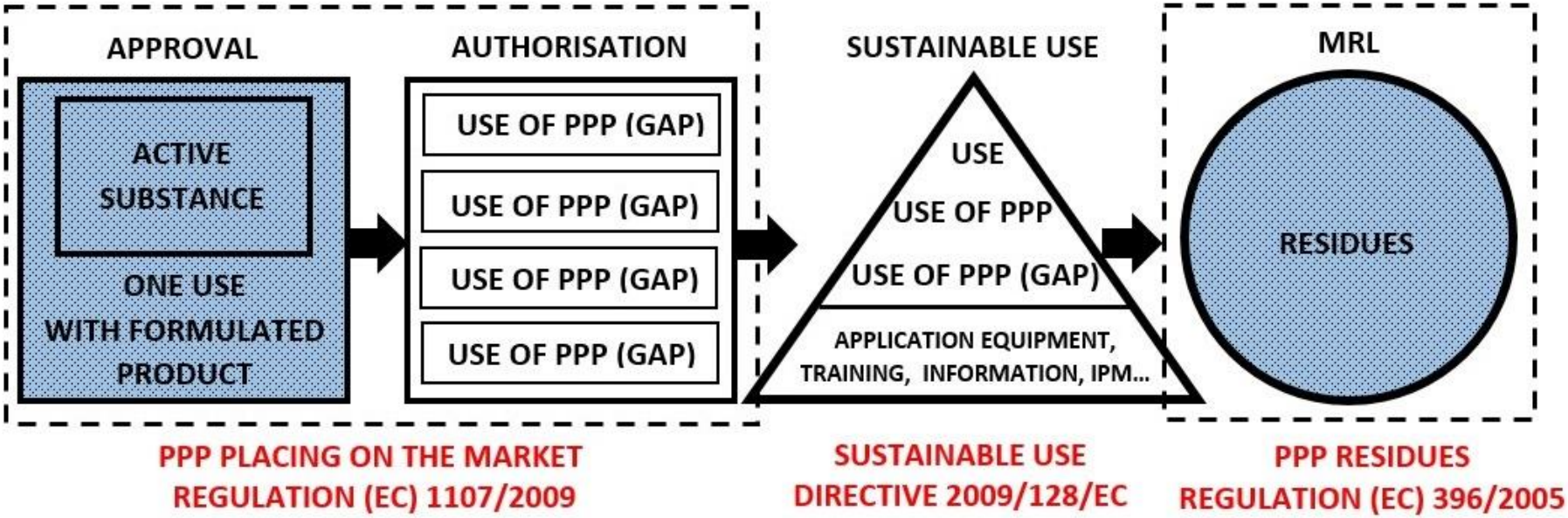
Reg.

Maximum residue levels of pesticides

Reg.

Technical requirements for machinery

EU Pesticide Legislation



Regulated at EU level

Regulated at Member State level

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Part 1 - Regulation 1107/2009 on placing on the market of plant protection products

Objectives

- ***High level of protection*** *of human and animal health and of the environment*
- *Safeguard* ***competitiveness of EU agriculture***
- *Increase* ***free movement*** *and* ***availability*** *of plant protection products*

High level of protection

- ***Strict criteria for approval*** *of active substances:*
  - **Human health, animal health** and **environment**
- *Only active substances which fulfil these criteria can be used in plant protection products*
  - **positive list** of substances approved for **limited time** → **periodic renewal**
- ***Prohibition*** *of unacceptable co-formulants (discussions on* ***negative list*** *close to finalisation: publication expected in 2019)*
- ***EU Approval*** *also for* ***safeners and synergists*** *(not yet implemented)*

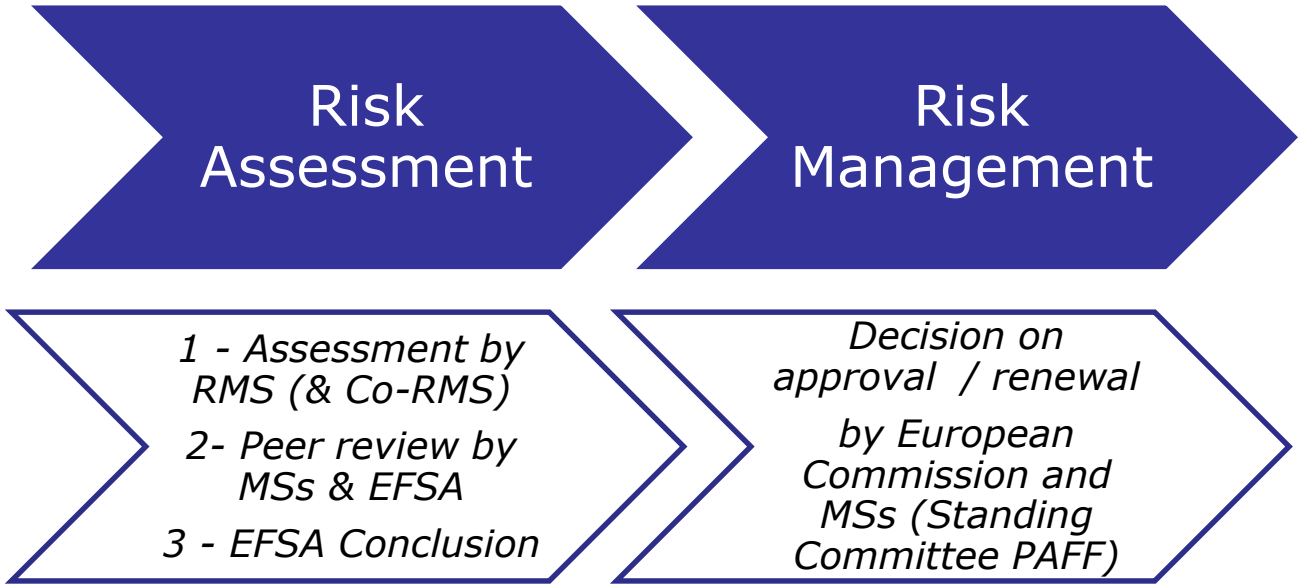
How does it work?
Dual pre-marketing authorisation

European Union assessment of **active substances** for possible approval

Member State authorisation of **plant protection products** containing these active substances

Substances = Approval at EU level

- Separation of ***risk assessment*** and ***risk management***
- Total length of the procedure = 2,5 to 3 years
- Approval for maximal 10 years (renewal for max. 15 years)



Substances = Approval at EU level (Risk Assessment)

- Application for approval (by applicant/industry)
  - In line with legally defined **Data requirements** *(Reg 283/2013 & Reg 284/2013)*
- Evaluation shared between 28 Member States
  - for each substance => 1 **Rapporteur MS** (and 1 Co-Rapporteur MS)
  - In line with legally defined **Uniform principles of evaluation** *(Reg 546/2011)*
- Peer review of the risk assessment by the European Food Safety Authority
  - ***EFSA Conclusion***

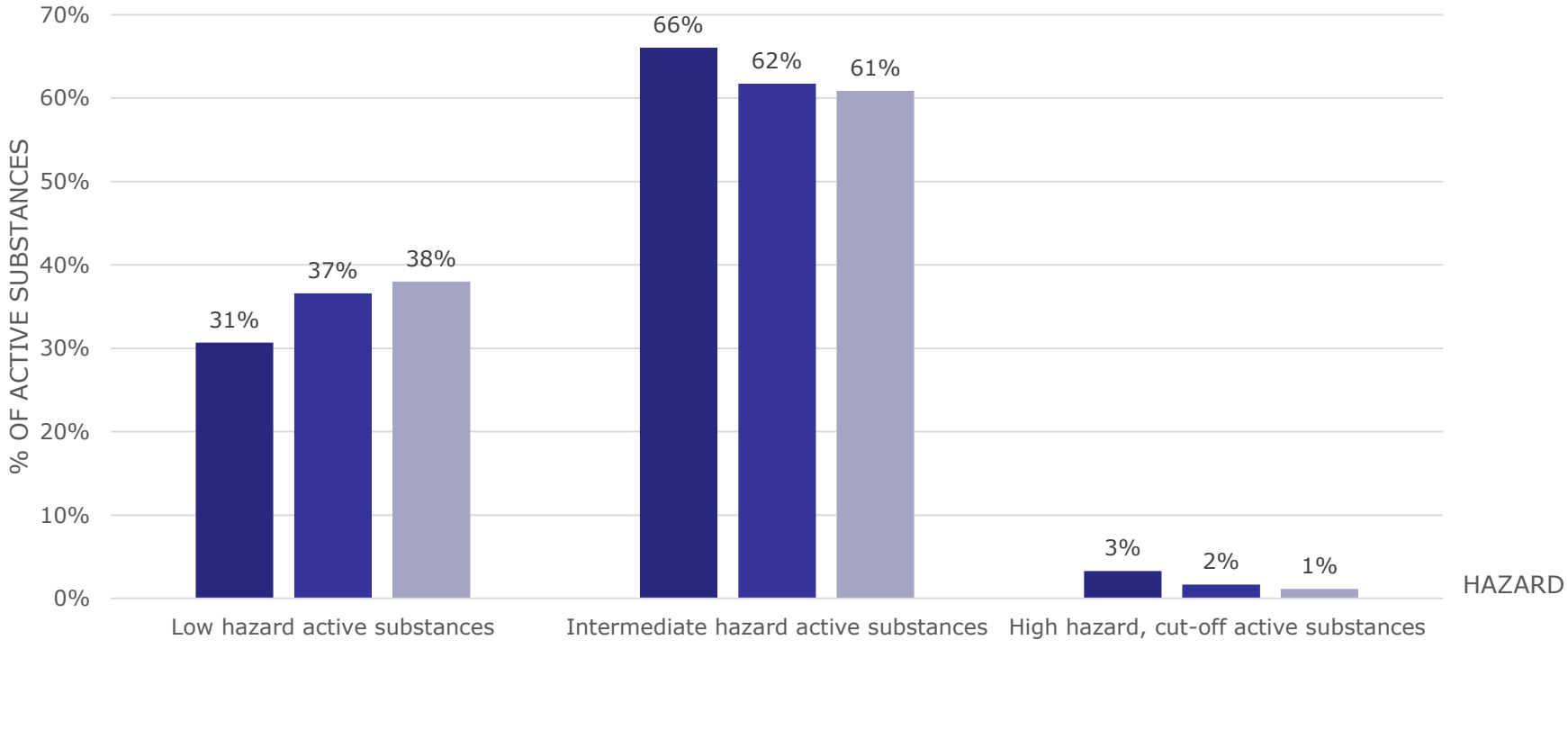
Substances = Approval at EU level (Risk Management)

- Decision making based on the EFSA Conclusion
  - Standing Commitee for Plants Animals Food and Feed (PAFF, 28 MS)
  - Approval or non-approval (renewal or non renewal)
  - Restrictions of use and/or risk mitigations could be set
- Approval =>List of approved substances
  - *Regulation 2015/2105*
  - Database for quick overview: **http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN**

Substances = Approval at EU level

Different categories of Active substances

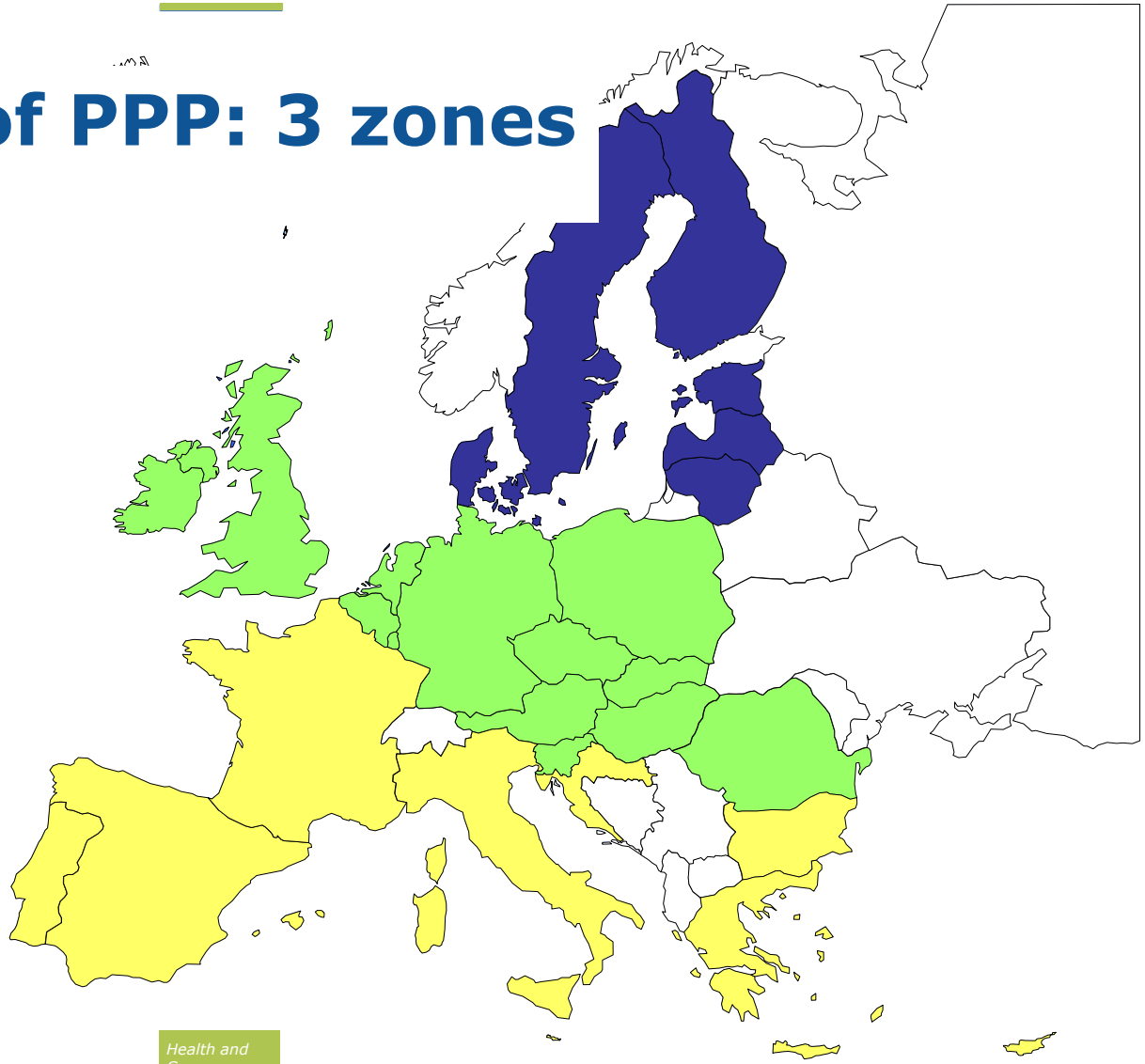
- Approved substances
- Low-risk substances
- Candidates for substitution
- Basic substances


70%
60%
50%
40%
30%
20%
10%
0%
% OF ACTIVE SUBSTANCES
31%
37%
38%
66%
62%
61%
3%
2%
1%
HAZARD
Low hazard active substances
Intermediate hazard active substances
High hazard, cut-off active substances
2011
2018
projection 2022

Reg. 1107/2009

Authorisation of PPP: 3 zones

- North
- Center
- South



ZONAL SYSTEM – Mutual recognition of authorisations

- ✓ *An authorisation **must** be taken over by all other MS of the same zone*
- ✓ *MS of a zone **co-operate** in the assessment of applications*
- ✓ *Less administrative burden, faster registration*
- ✓ *Harmonise **availability** of PPPs to farmers*

Plant protection products = Authorisation at national level

Zonal evaluation:

- **One evaluation per zone (even if several applications)**
- **Zonal peer review**
  - MS grant authorisations on the basis of the zonal evaluation
- **3 zones: North, South, Central**
- **For greenhouse, seed treatment and post-harvest:**
  - One evaluation for whole EU

Total length of the procedure = 16 to 22 months

Duration of the authorisation = Duration of approval of substance + one year

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PPP Application Management System (PPPAMS)

- *EU **harmonised** system for submission of applications for the authorisation of PPP*
  - Improved efficiency: submission of a single application to multiple MS at the same time
  - Easier zonal procedure or mutual recognition due to the electronic sharing of information.
  - Easier monitoring of applications – for Industry, MS and EC
  - Duplication of work is avoided.
- *An automatic notification system*
  - informs users
  - enables tracking of authorisation process
- *Implemented for **new authorization requests** and **emergency authorisations***
- *Published interface (planned): information on PPPs accessible; transparency*

https://ec.europa.eu/food/sites/food/files/plant/docs/plant_pesticides_auth_ppp_pppams_factsheet_en.pdf

PPPAMS: Links to other systems

- Usage of EPPO Global Database codes for species and pests
  - https://gd.eppo.int/
- EU Pesticides database with Active Substances and Pesticides EU-MRLs
  - http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

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Sustainable use of pesticides

Directive 2009/128/EC

Transposition by November 2011

Health and Food Safety

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SUD – Subject matter

"To establish a framework to achieve a **sustainable use** of pesticides by **reducing the risks and impacts** of pesticide use on **human health** and the **environment** and promoting the use of **integrated pest management** and of **alternative approaches or techniques** such as non-chemical alternatives to pesticides"

Sustainable Use

Reduce risks and impacts on human health and the environment

Tools

1. Training
2. Sales
3. Awareness raising
4. Equipment
5. Aerial applications
6. Aquatic environment
7. Protected areas
8. Handling, storage, disposal
9. Integrated pest management
10. Harmonised indicators

NATIONAL ACTION PLANS

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National Action Plans

Member States shall adopt National Action Plans:

- to set up their **quantitative objectives, targets, measures and timetables to reduce risks and impacts** of pesticide use on human health and the environment, and

- to encourage the development and introduction of **integrated pest management** and of **alternative approaches** or techniques in order to **reduce dependency** on the use of pesticides.

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Deadlines for implementation by MSs

- *Submission of NAPs:* ***26 November 2012***
- *Review of NAPs: at least* ***every 5 years***
- *Establish a certification system for pesticide operators:* ***26 November 2013***
- *Pesticides sales restricted to persons holding certificate + certified sales persons available at pesticide distributors:* ***26 November 2015***
- *Pesticide Application Equipment in use tested:* ***26 November 2016****;*
- *Implementation of IPM general principles by all professional users:* ***01 January 2014***

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RISK INDICATORS

HARMONISED RISK INDICATORS (HRI):

- *Commission Directive awaited (voted in January 2019, Scrutiny of EP and Council on-going, eventual adoption & publication in 2019)*

MEMBER STATES:

- *Shall calculate HRI using statistical data available at EU level;*
- *Shall identify trends in the use of some active substances;*
- *Shall identify priority items (active substances, crops, practices) to be used as examples for achieving SUD objectives*
- *May continue using any existing national indicators, in addition to HRIs.*

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SUD WEB PORTAL

- Established upon request by MSs;
- A tool for exchange of information and practices between MSs;
- Search function: by MS, OR by topic;
- Useful external links

https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides_en

Sustainable use of pesticides

Directive 2009/128/EC aims to achieve a sustainable use of pesticides in the EU by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of Integrated Pest Management (IPM) and of alternative approaches or techniques, such as non-chemical alternatives to pesticides. EU countries have drawn up National Action Plans to implement the range of actions set out in the Directive.

The main actions relate to training of users, advisors and distributors of pesticides, inspection of pesticide application equipment, the prohibition of aerial spraying, limitation of pesticide use in sensitive areas, and information and awareness raising about pesticide risks.

EU countries must also promote Integrated Pest Management, for which, general principles are laid down in Annex III to the Directive.

The main purpose of this web-portal is to provide:

- key information on the sustainable use of pesticides and
- links to relevant information contained on official websites in the Member States.

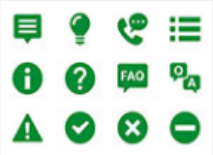
There is a search function to help find the links you are looking for.

Harmonised Risk Indicators

The Commission is currently establishing Harmonised Risk Indicators to estimate trends in the risks from pesticide use under Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides.

Click here for more information on Harmonised Risk Indicators.

Main Actions



More information on main actions.

Integrated Pest Management (IPM)

Click here for an overview of IPM, definitions and key principles.

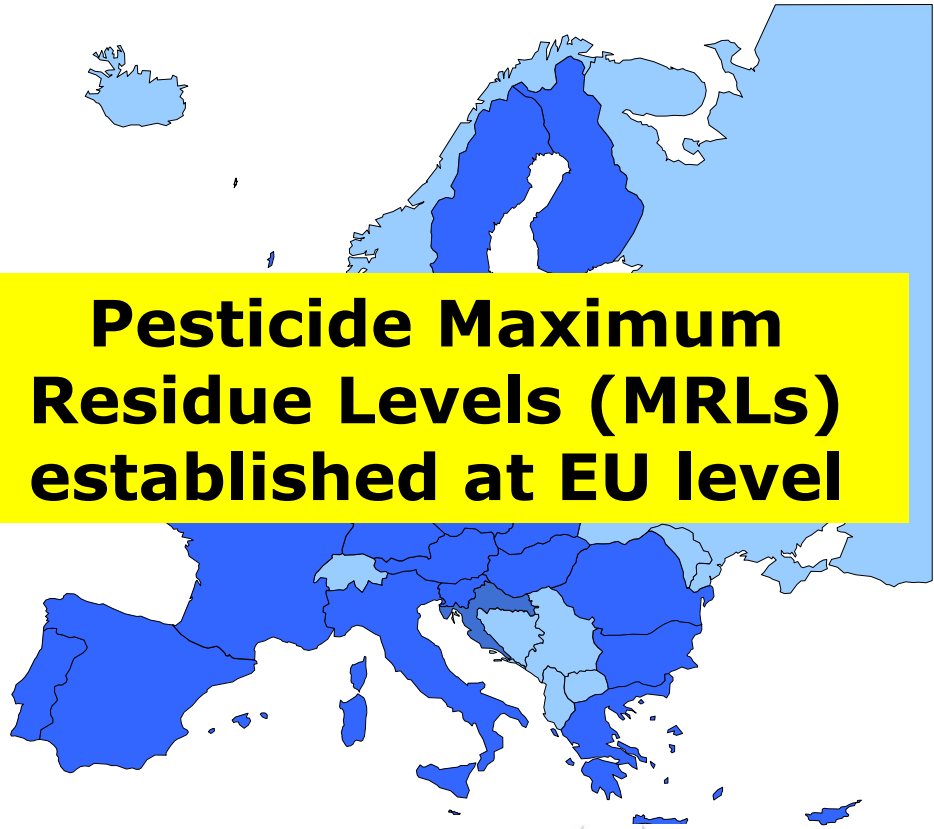
PART 2 – Regulation (EC) No 396/2005 on Maximum Residue Levels (MRLs)

Pesticide residues

Food can circulate freely on the EU market
(domestic and imported)

Guarantee a high level of protection for all EU consumers

Pesticide Maximum Residue Levels (MRLs) established at EU level



Pesticide residues

- *Ensure a harmonised high level of consumer protection:*
  - **No unacceptable risk to humans**
  - **MRL set at lowest achievable level consistent with most critical Good Agricultural Practices (GAPs)**
  - **Protecting vulnerable groups (children, unborn)**

    Directive 2006/141/EC, Directive 2006/125/EC: Baby Food Directives
  - **Cumulative and synergistic effects**
- *Public health > interest of crop protection*
- *Free circulation of food and feed in EU*
- *Transparency and predictability*
- *Provisions for third countries (imports into EU)*

Regulation (EC) No 396/2005

Annex 1: Commodities to which MRLs apply :	If Residues limits are not set (or Pesticides not covered by any of the Annexes)
• 315 commodities • 10 main groups • Fish and plants used for animal feed: for the time being no MRL setting	• Default MRL of 0.01 mg/kg

How are MRLs set?

- *3 parameters to be considered*

Residues expected in food + **Food consumption** + **Toxicological limits**

- *Evaluation by European Food Safety Authority*
- *Decision making at the Standing Committee PAFF-Section Residues*

National and Community control programmes of pesticide residues (article 30)

MSs shall:

- ✓ *Establish National **risk based** Control Programmes*
- ✓ *Participate in the **EU Multi-annual Control Programme***
- ✓ *Submit **results and updated national program** by end of September each year to COM and EFSA*

  After 14 Dec 2022: by end of August, Reg(EU)625/2017 (art155)
- ✓ ***Publish results** of national programmes on Internet*

Information by MS and annual reports (article 31)

To COM, EFSA and MS by 31 August each year:

- ✓ ***Results*** *of national and EU-coordinated controls*
- ✓ ***LODs*** *applied*
- ✓ *Details of the participating* ***analytical laboratories***
- ✓ ***Accreditation*** *is a must*
- ✓ *Details of* ***enforcement measures*** *taken*

Currently under article 30, MSs have to update on the changes of their NCPs at least 3 months before the end of each calendar year(i.e end of September). Based on the below article 155 and article 113 of the OCR, MSs will have to update the Commission on their NCP by 31 August. But this is applicable on 14/12 The rest of the MSs obligations under article 31 of Reg396/2005 with a deadline 31/01/08 are not changed (included in the slides already).

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Amendments by Official Control Regulation *(Reg(EU) 2017/625)*

changes to articles 26, 27, 28(1)(2) and 30 of Reg.396/2005, applicable by 13/12/2022.

Article 155

Amendments to Regulation (EC) No 396/2005 and related transitional measures

1. Articles 26 and 27, Article 28(1) and (2) and Article 30 of Regulation (EC) No 396/2005 are deleted.

2. Article 26, Article 27(1) and Article 30 of Regulation (EC) No 396/2005 shall continue to apply instead of the corresponding provisions of this Regulation until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article.

3. The Commission is empowered to adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the date referred to in paragraph 2 of this Article. That date shall be the date of application of the corresponding rules to be established pursuant to the delegated or implementing acts provided for in Article 19.

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EU Data base on Pesticides

http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

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EU Pesticides database

European Commission > Food Safety > Plants > Pesticides > Pesticides Database

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- EU Pesticides database
  - Search active substances
  - Search products
  - Search pesticide residues
  - Download MRLs data
- Sustainable use of pesticides
- Approval of active substances
- Authorisation of Plant Protection Products
- Maximum Residue levels

ALL TOPICS

EU - Pesticides database

ACTIVE SUBSTANCES
Regulation (EC) No 1107/2009

Latest active substance updates

- Renewal of approval of the active substance methoxyfenozide Regulation (EU) 2019/158 of 31 January 2019 — 31/01/2019
- Renewal of approval of the active substance Clonostachys rosea strain J1446 as a low-risk active substance Regulation (EU) 2019/151 of 30 January 2019 — 30/01/2019
- Non-approval of the active substance propanil Regulation (EU) 2019/148 of 30 January 2019 — 30/01/2019
- Approval of the active substance Beauveria bassiana strain PPRI 5339 Regulation (EU) No 2019/147 of 30 January 2019 — 30/01/2019
- Approval of the active substance Beauveria bassiana strain IMI389521 Regulation (EC) No 2019/139 of 29 January 2019 — 29/01/2019

PESTICIDES EU-MRLs
Regulation (EC) No 396/2005

Latest MRL updates

- Publication of Commission Regulation (EU) 2019/89 of 18 January 2019 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bromadiolone, etofenprox, paclobutrazol and penconazole in or on certain products — 24/01/2019
- Publication of Commission Regulation (EU) 2019/88 of 18 January 2019 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid in certain products — 24/01/2019
- Publication of Commission Regulation (EU) 2019/90 of 18 January 2019 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben in or on certain products — 24/01/2019
- Publication of Commission Regulation (EU) 2019/91 of 18 January 2019 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim in or on certain products — 24/01/2019
- Publication of Commission Regulation (EU) 2019/58 of 14 January 2019 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament — 15/01/2019

EU database on active substances

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EU Pesticides database

European Commission > Food Safety > Plants > Pesticides > Pesticides Database

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Search active substances

Pesticides home | Advanced Search | Export to Excel

Search:

Showing 1 to 50 of 1,383 entries 50 records per page

‹ 1 2 3 4 5 ... 28 ›

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
(E)-11-Tetradecen-1-yl acetate	Approved	01/09/2009	31/08/2020	2008/127Reg. (EU) 2017/195Reg. (EU) No 540/2011Reg. (EU) No 918/2014
(E)-2-Methyl-6-methylene-2,7-octadien-1-ol (myrcenol)	Not Approved			2007/442
(E)-2-Methyl-6-methylene-3,7-octadien-2-ol (isomyrcenol)	Not Approved			Reg 647/2007
(E)-5-Decen-1-ol	Approved	01/09/2009	31/08/2020	2008/127Reg. (EU) 2017/195Reg. (EU) No 540/2011Reg. (EU) No 918/2014
(E)-5-Decen-1-yl acetate	Approved	01/09/2009	31/08/2020	2008/127Reg. (EU) 2017/195Reg. (EU) No 540/2011Reg. (EU) No 918/2014
(E)-8-Dodecen-1-yl acetate	Approved	01/09/2009	31/08/2020	2008/127Reg. (EU) 2017/195Reg. (EU) No 540/2011Reg. (EU) No

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EU Database on Maximum Residue Levels

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  - Search active substances
  - Search products
  - Search pesticide residues
  - Download MRLs data
- Sustainable use of pesticides
- Approval of active substances
- Authorisation of Plant Protection Products
- Maximum Residue levels

« ALL TOPICS

Search pesticide residues

1 Select pesticide residues (5 max)

Search:

	Pesticide residues
1	
☐	1,1-dichloro-2,2-bis(4-ethylphenyl)ethane (F)
☐	1,2-dibromoethane (ethylene dibromide) (F)
☐	1,2-dichloroethane (ethylene dichloride) (F)
☐	1,3-Dichloropropene
☐	1,4-Diaminobutane (aka Putrescine) (++)
☐	1,4-Dimethylnaphthalene
☐	1-Decanol (++)
☐	1-methylcyclopropene
☐	1-Naphthylacetamide and 1-naphthylacetic acid (sum of 1-naphthylacetamide and 1-naphthylacetic acid and its salts, expressed as 1-naphythlacetic acid)
2	
☐	2,4,5-T (sum of 2,4,5-T, its salts and esters, expressed as 2,4,5-T) (F)
☐	2,4-DB (sum of 2,4-DB, its salts, its esters and its conjugates, expressed as 2,4-DB) (R)
☐	2,4-D (sum of 2,4-D, its salts, its esters and its conjugates, expressed as

2 Select products

Search:

Code	Groups and examples of individual products to which the MRLs apply (a)
☑	All
☐ 0100000	FRUITS, FRESH or FROZEN; TREE NUTS
☐ 0110000	Citrus fruits
☐ 0110010	Grapefruits
☐ 0110020	Oranges
☐ 0110030	Lemons
☐ 0110040	Limes
☐ 0110050	Mandarins
☐ 0110990	Others (2)
☐ 0120000	Tree nuts
☐ 0120010	Almonds
☐ 0120020	Brazil nuts
☐ 0120030	Cashew nuts
☐ 0120040	Chestnuts
☐ 0120050	Coconuts
☐ 0120060	Hazelnuts/cobnuts

3 Select

◉ Current MRLs

○ MRLs evolution (max 1 pesticide)

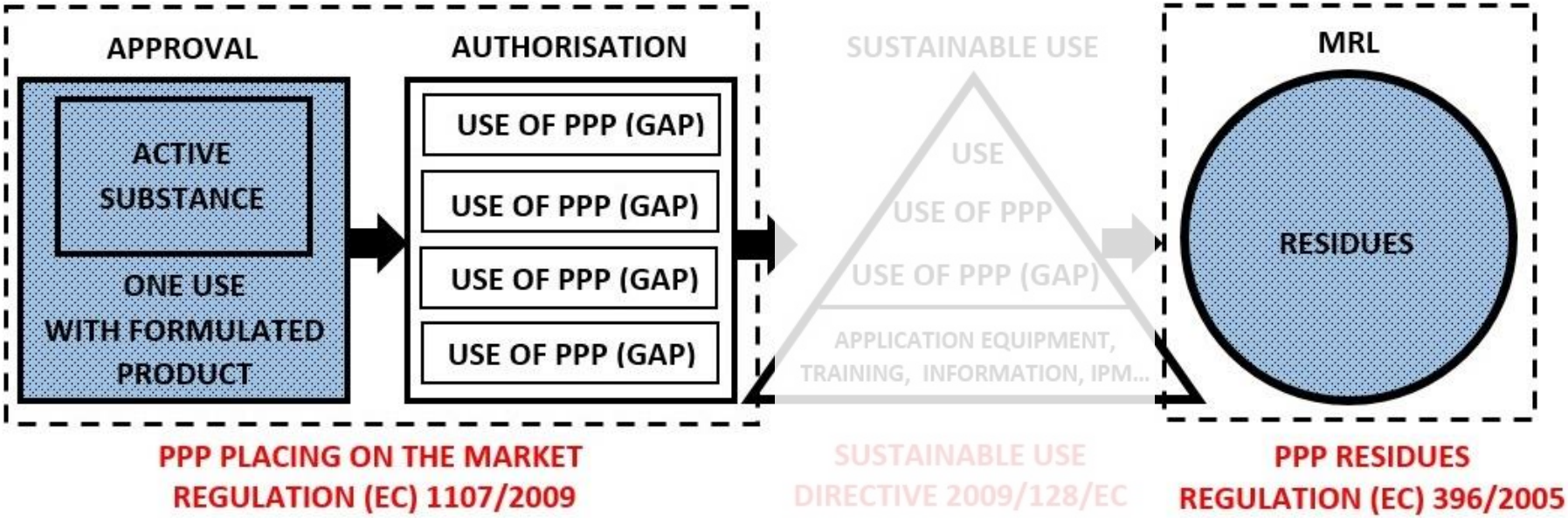
4 Display

Pesticides selected

Products selected

All ×

EU Pesticide Legislation – REFIT evaluation



Evaluation is on-going, expected to be finalised June 2019

Regulated at EU level

Regulated at Member State level

European Commission

Other useful links

SANTE website

https://ec.europa.eu/food/plant/pesticides_en

Infographics link:

https://ec.europa.eu/food/see-the/infographics-factsheets_en

http://ec.europa.eu/assets/sante/food/plants/pesticides/lop/index.html

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