



El futur de la sanitat vegetal a Europa

Marc legal

Santiago Planas de Martí

Servei de Sanitat Vegetal - Generalitat de Catalunya

GR Agricultura de Precisió – Agrotecnio - UdL

santiplanas@gencat.cat

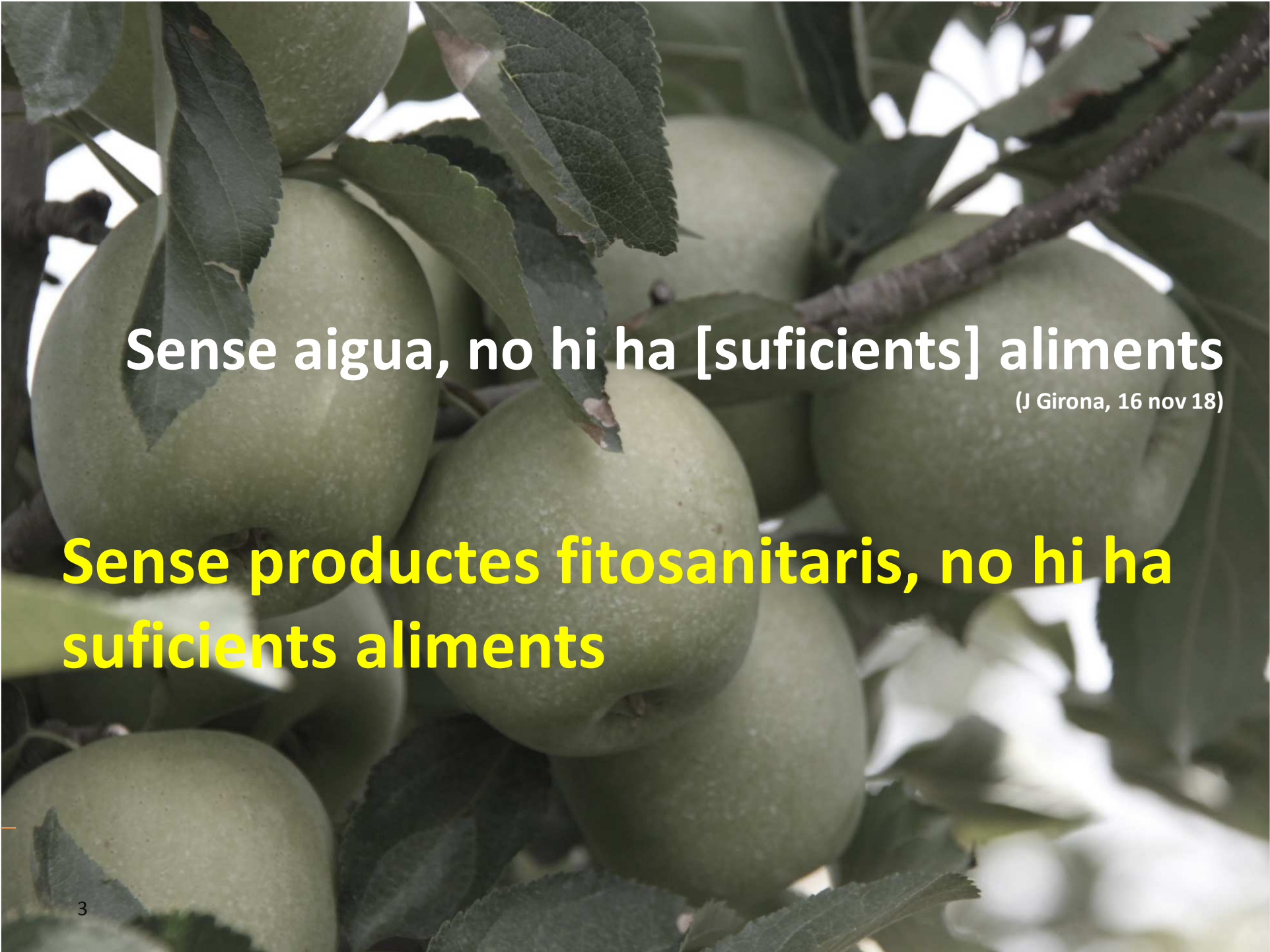


Lleida, 22 de novembre de 2018



Competències en matèria fitosanitària a la UE

- Protecció contra la introducció als EM d'organismes nocius per als vegetals
- Control de varietats vegetals (material multiplicació)
- Fixació dels LMR de PF
- **Homologació nacional i comercialització de productes fitosanitaris (PF)**



Sense aigua, no hi ha [suficients] aliments

(J Girona, 16 nov 18)

**Sense productes fitosanitaris, no hi ha
suficients aliments**

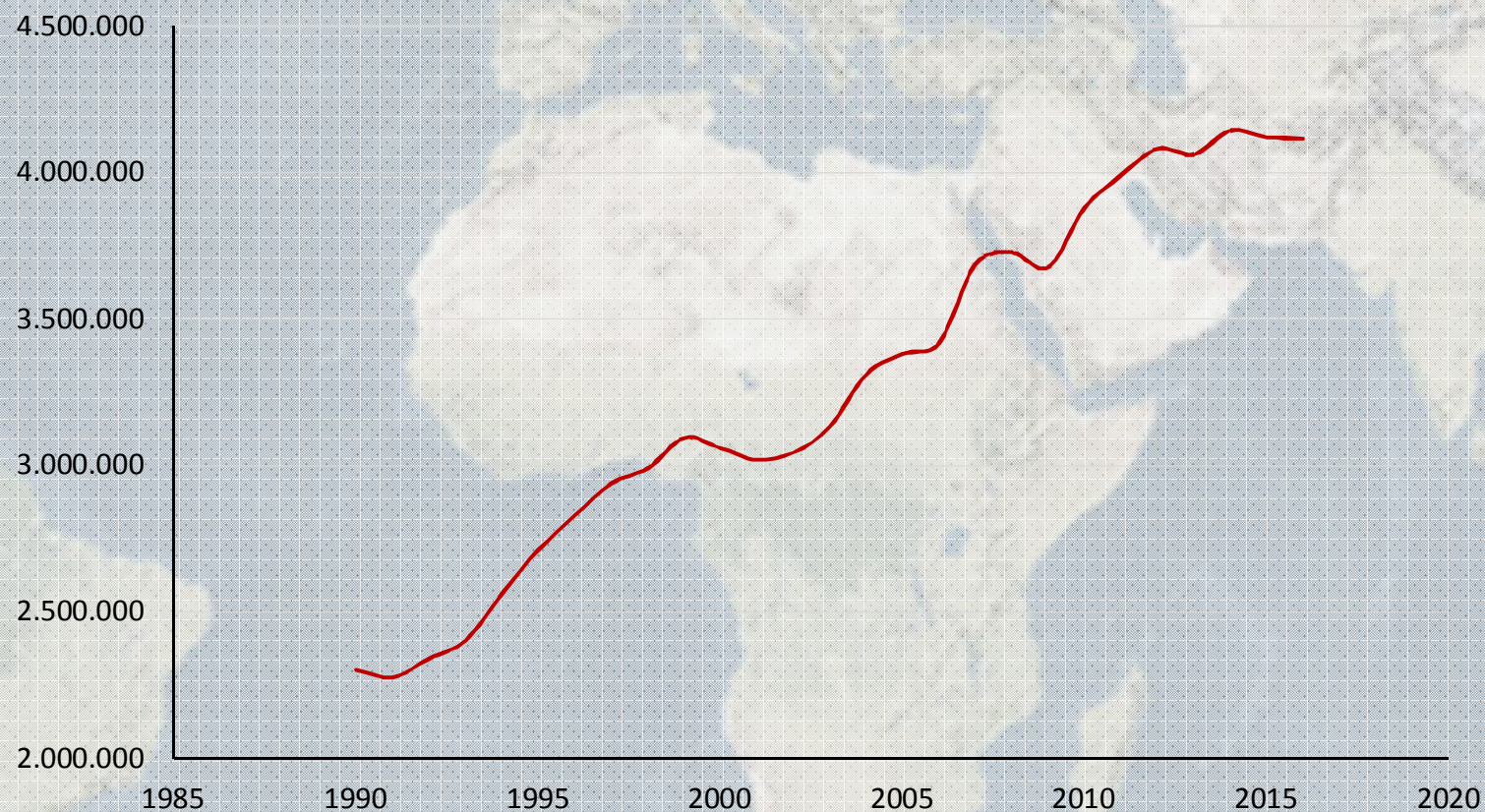


Food and Agriculture Organization
of the United Nations

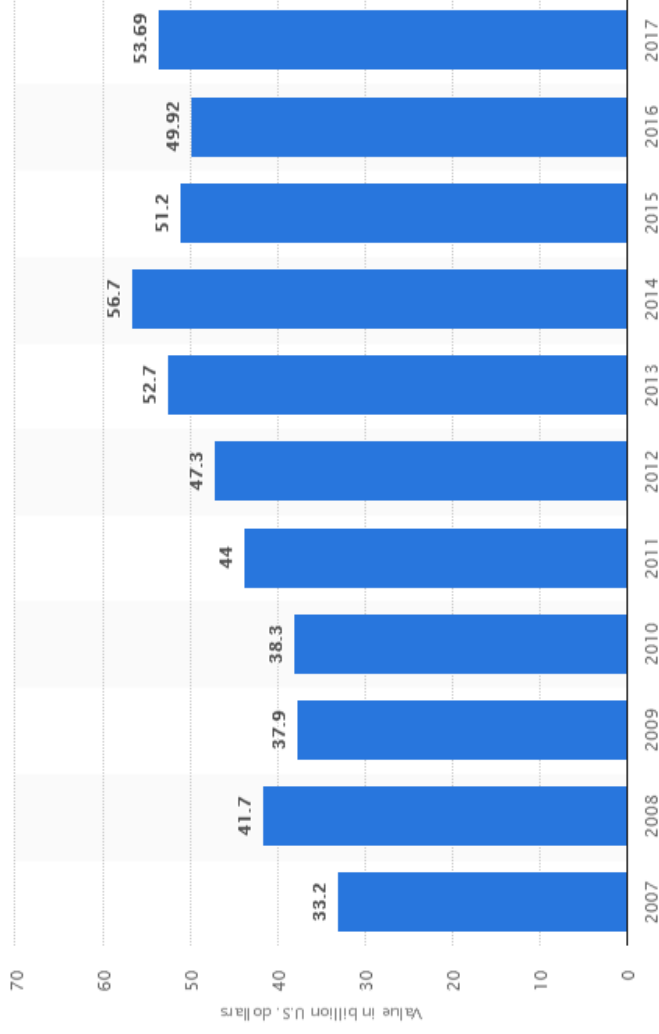
World pesticide Use

tonnes of active ingredients / year

Aggregate, may include official, semi-official, estimated or calculated data



Value of the global market for crop protection 2007 to 2017 (in billion U.S. dollars)



DOWNLOAD SETTINGS SHARE



The Statistics Portal

Statistics and Studies from more than 22,500 Sources

DESCRIPTION

SOURCE

MORE INFORMATION

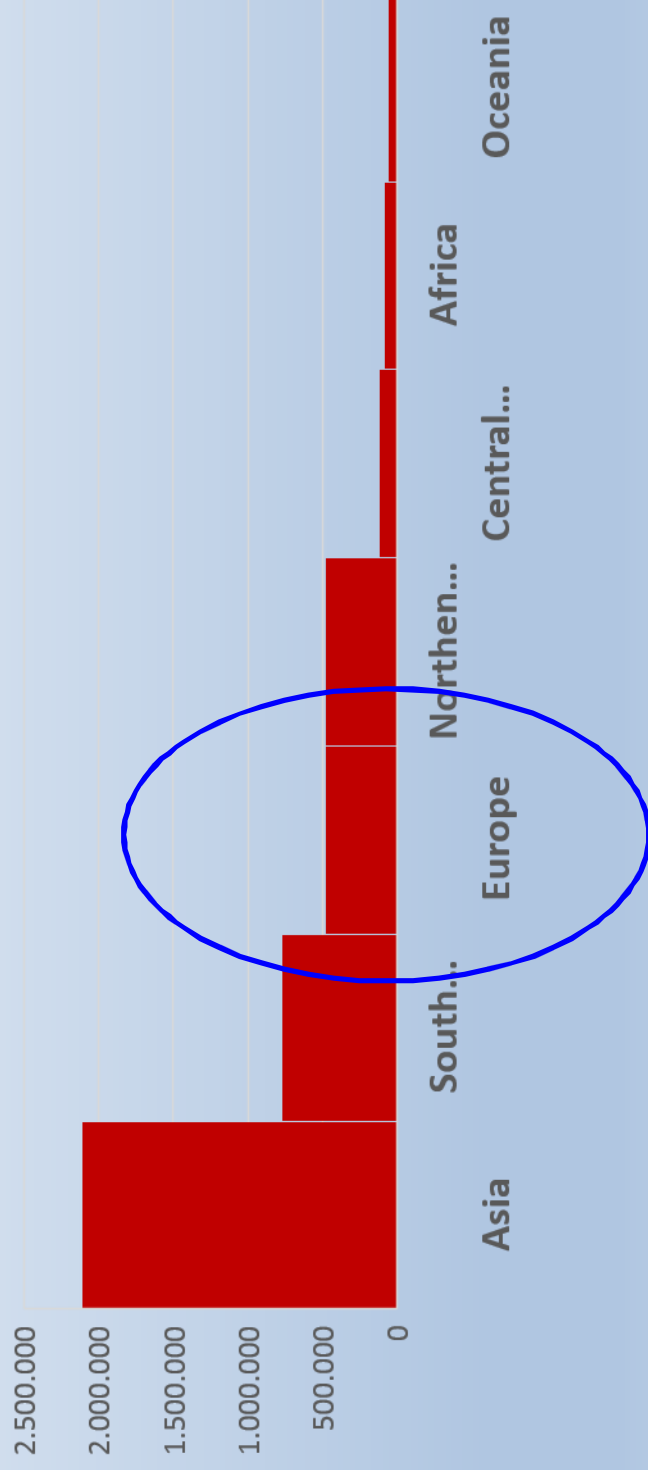
This statistic displays the total value of the crop protection market worldwide from 2007 to 2017. In 2017, the global crop protection market had a total value of some 53.69 billion U.S. dollars.



Pesticide Use in World regions

tonnes of active ingredients (2016)

Aggregate, may include official, semi-official, estimated or calculated data



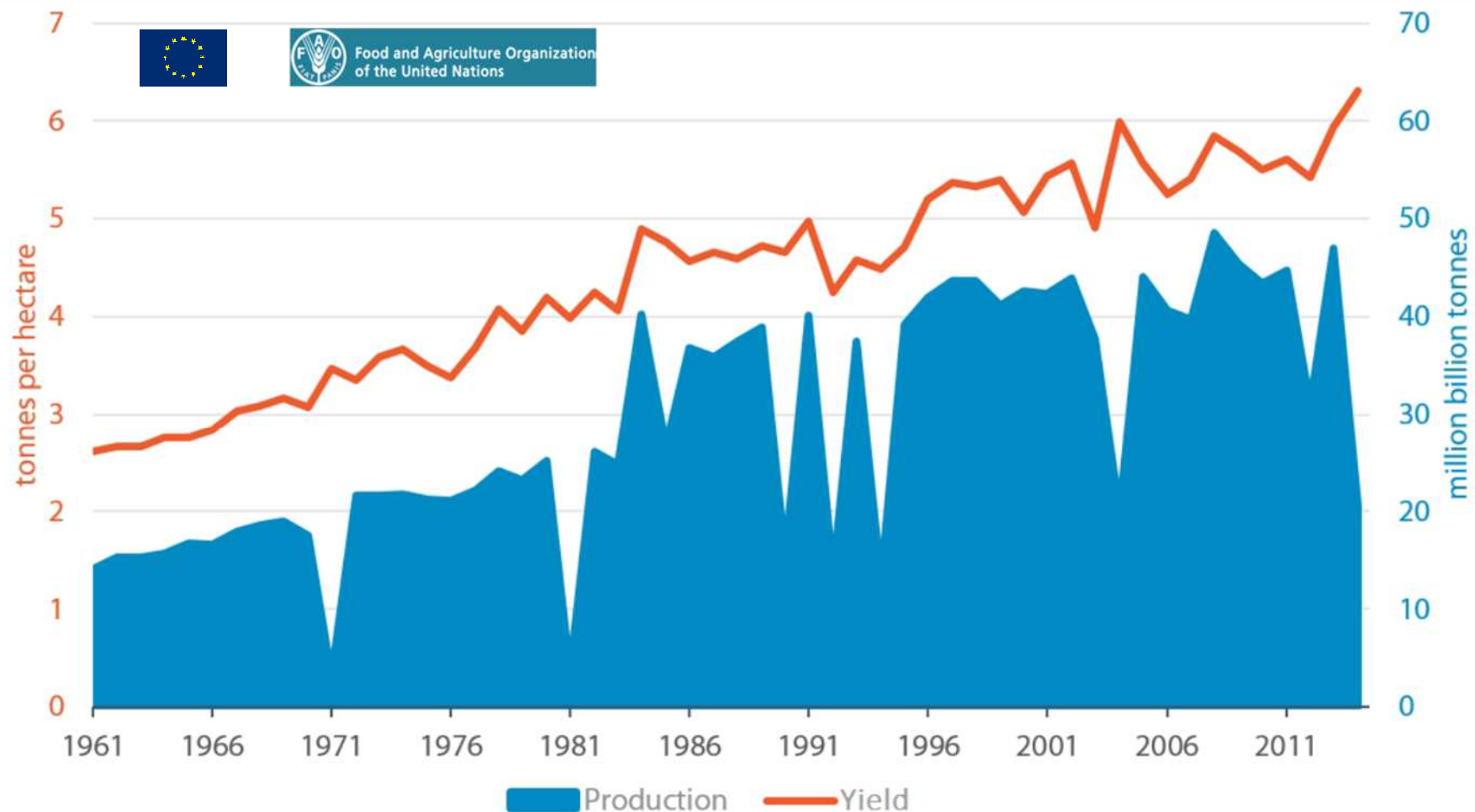
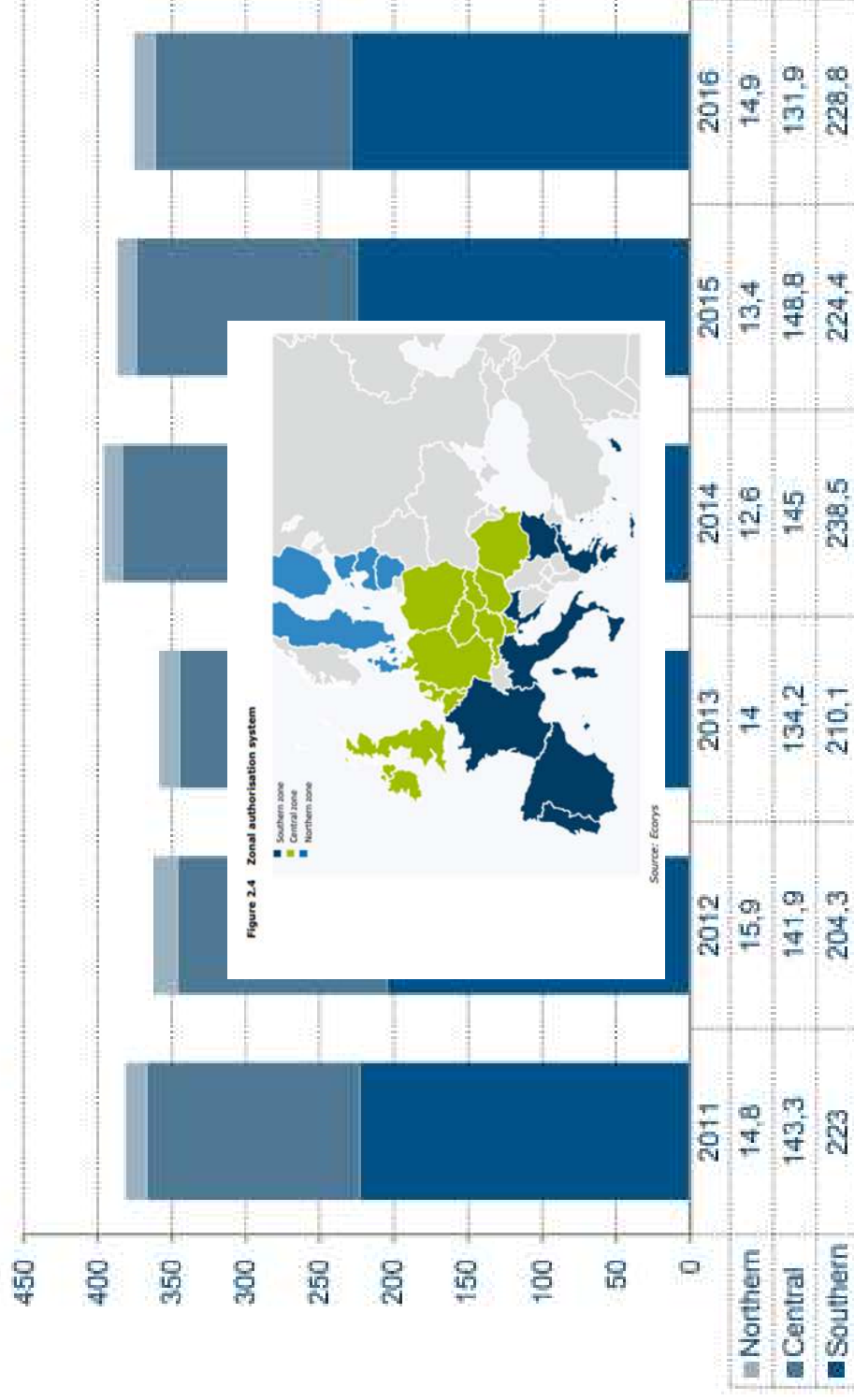


Figure 4 – Production and yield of cereal crops in the EU-28 (1961-2014)
Data source: Food and Agriculture Organisation of the United Nations, FAOSTAT, 2017.



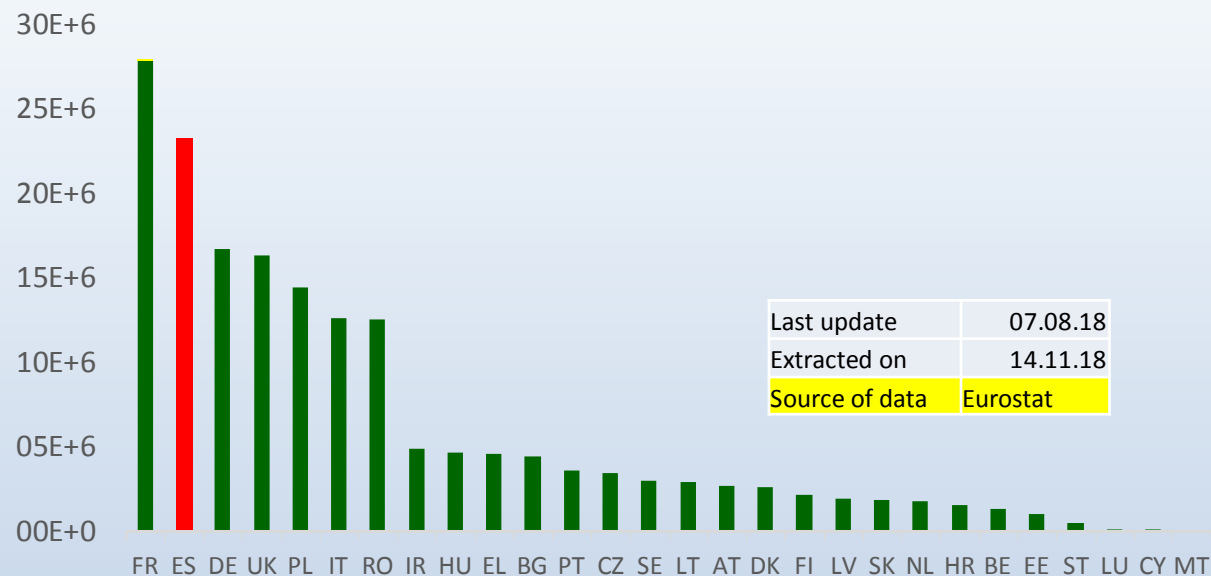
Figure 5.5 Total sales of PPPs in thousand tonnes of active substance (EU28)



Source: Eurostat [ael_fm_salpest09]



**EU 2017 – Utilized
agricultural area (ha)
Total 3D area: 168,3 Mha
(Spain 23,2 Mha)**



**EU 2014 – Sales on plant
protection products by
utilized agriculture area
(kg/ha)**

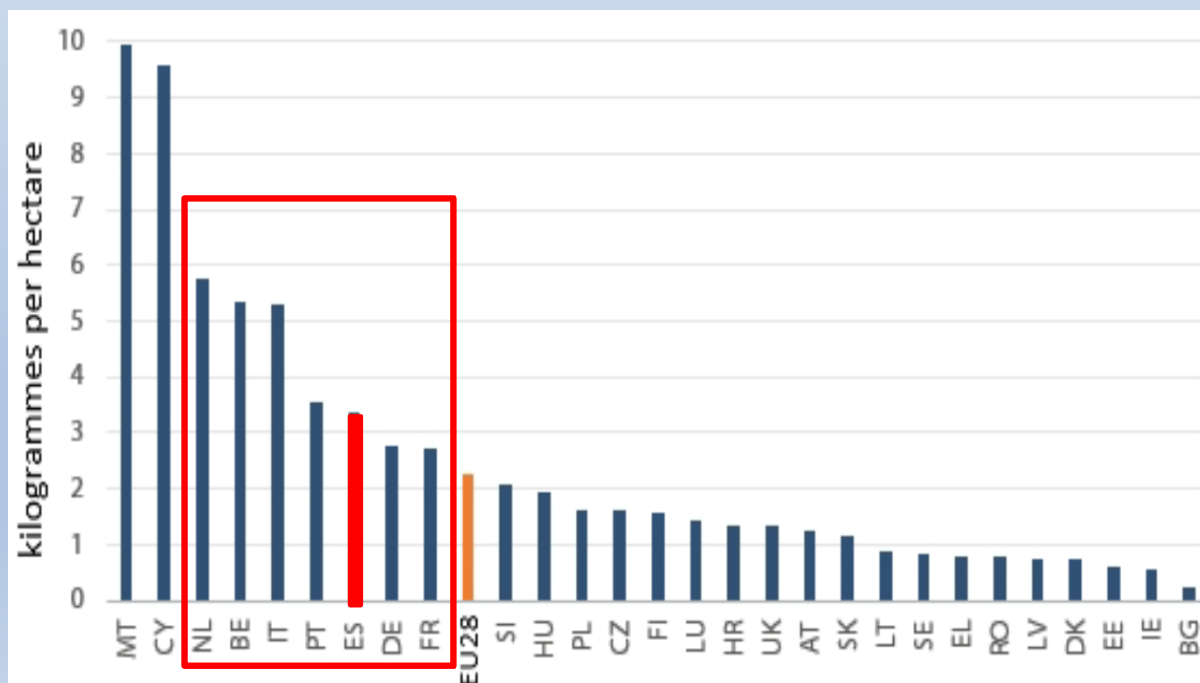
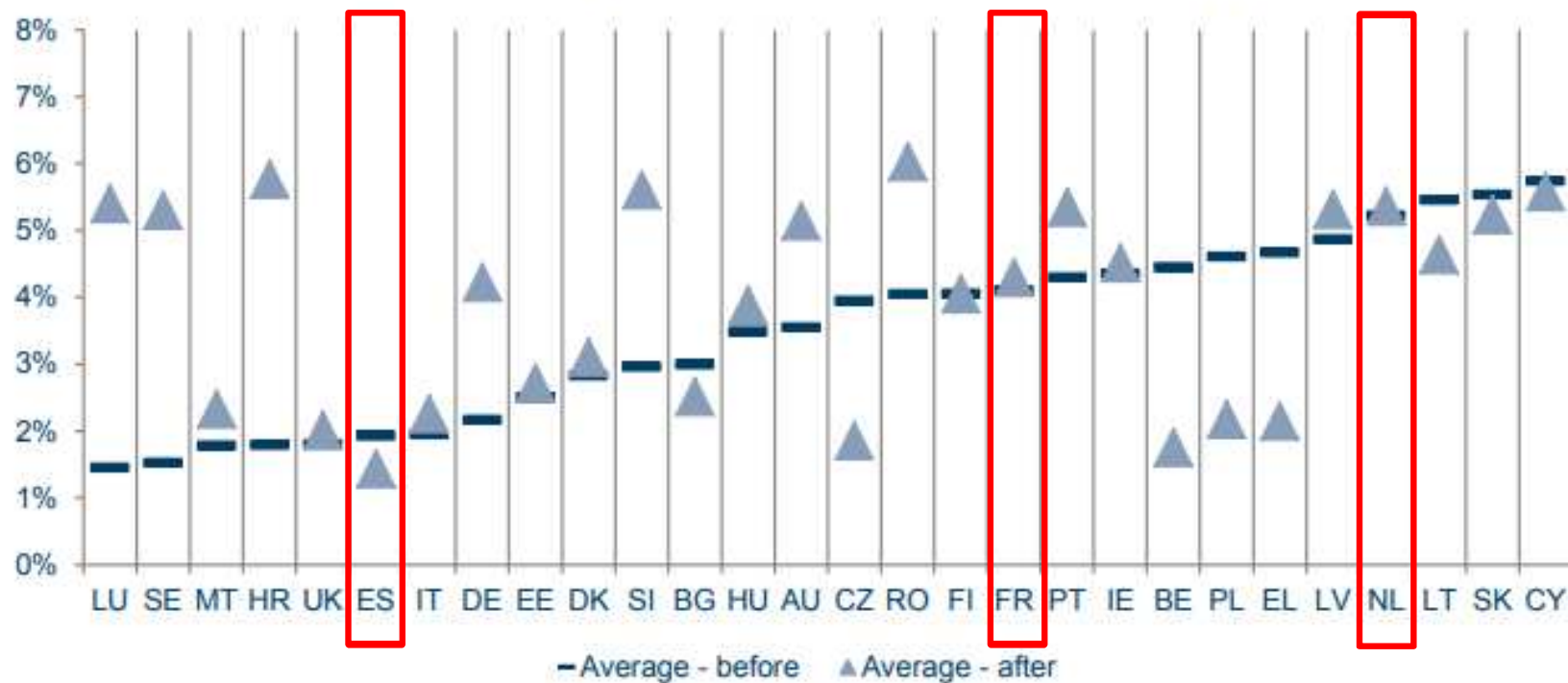




Figure 4.5 Input costs stemming from crop protection in 2008/09 and 2015/16 per MS



Source: FADN Database

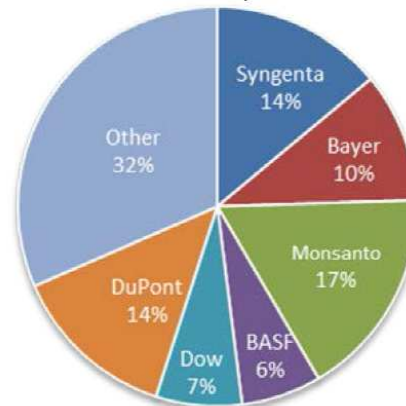
Table 1. Big 6 global market share of pesticides and seeds prior to the announced Dow-DuPont M&A in 2015.

Company	Pesticide	Seed
Syngenta	20%	8%
Bayer	18%	3%
Monsanto	8%	26%
BASF	13%	0%
Dow	10%	4%
DuPont	6%	21%
Total	75 %	62 %

Sources: Orbis, USDA, and the ETC Group

Note: Estimated sales for pesticides and seeds were \$51 billion and \$36 billion, respectively.

Figure 1. Big 6 global market share in the combined pesticides and seeds markets in 2015 (prior to announced Dow-DuPont M&A).



Sources: Orbis, USDA, and the ETC Group

Note: Figure is based off of \$88 billion in global sales.

April 2018

United States International Trade Commission

https://www.usitc.gov/publications/332/executive_briefings/ag_ma_ebot_final.pdf





ADAMA AGRICULTURE ESPAÑA, S.A.

ARYSTA LIFESCIENCE

BASF ESPAÑOLA, S.L.

BAYER CROPSCIENCE, S.L.

BELCHIM CROP PROTECTION ESPAÑA, S.L.

CERTIS EUROPE, B.V. Sucursal en España

FMC

COMERCIAL QUIMICA MASSO, S.A.

DOW AGROSCIENCES IBÉRICA, S.A.

DU PONT IBÉRICA, S.L.

GOWAN ESPAÑOLA FITOSANITARIOS, S.L.

INDUSTRIAS AFRASA, S. A.

IQV AGRO ESPAÑA, S.L.

ISAGRO ESPAÑA, S.L.

KENOGARD, S. A.

LAINCO, S. A.

MONSANTO AGRICULTURA ESPAÑA, S.L.

NUFARM ESPAÑA, S.A.

PROBELTE, S.A.

SAPEC AGRO

SIPCAM IBERIA, S.L.

SYNGENTA AGRO, S.A.U.

TECNIDEX, FRUIT PROTECTION, S.A.U.

TRADECORP

UPL IBERIA, S.A.

Pesticides

Substances used to suppress, eradicate and prevent organisms that are considered harmful are grouped under the term 'pesticide'.

The term includes

- **Plant protection products** (PPP), synthetic & biopesticides (biological control product), used on plants in agriculture, horticulture, parks and gardens
- **Biocidal products**, used in other applications, for example, as a disinfectant or to protect materials

A plant protection product usually contains more than one component. The active component against pests/plant diseases is called "active substance". Other substances are **coformulants**, **safeners**, **synergists** and **adjuvants**

Bases legals - Fitosanitaris i Biocides

1

Subjectes a doble procés d'aprovació:

- **substancies actives: nivell EU**
- **Productes fito: nivell EM (normalment)**

Risk prevention

Risk management

2

REGLAMENT CE 1107/2009 de comercialització de productes fitosanitaris



3

REGLAMENT UE 28/2012 sobre comercialització i ús de biocides



Determinats mitjans de defensa fitosanitària (DMDF)



RD 951/2014, regula la comercialització de determinats mitjans de defensa fitosanitària

Inclou exclusivament:

- els organismes de control biològic
- les trampes
- altres mitjans o dispositius de monitoratge

Bases legals

3

REGLAMENT CE 396/2005: de residus de productes fitosanitaris en aliments i pinsos

4

DIRECTIVA 2009/128/CE: marc d'actuació de la UE per assolir un ús sostenible dels plaguicides

Risk management



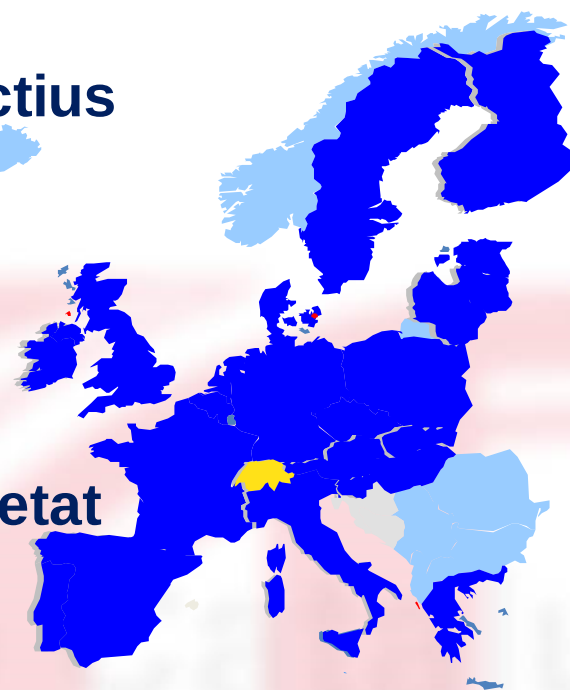
Real Decret 1702/2011, inspecció equips aplicació
Real Decret 1311/2012, ús sostenible fitosanitaris



Directiva 2009/128/CE (DUS)

Ús sostenible dels plaguicides

- ☐ Pla d'Acció Nacional: indicadors i objectius de reducció d'ús PF (5 anys)
- ☐ Formació, venda, informació
- ☐ Inspecció ETF
- ☐ Tractaments aeris
- ☐ Mitigació de la deriva: bandes de seguretat
- ☐ GIP



REGLAMENT CE 1107/2009 de comercialització de productes fitosanitaris

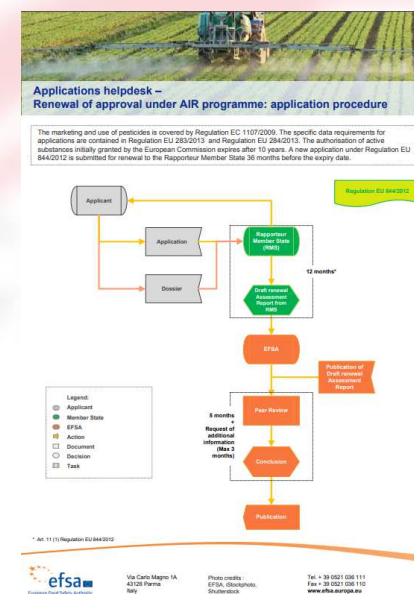
Aprovació de substàncies actives

The Commission evaluates every **active substance** for safety before it reaches the market in a product.

Substances must be proven safe for people's health, including their residues in food and effects on animal health and the environment.

Procedure

1. Application to an EU country Rapporteur Member State
2. RMS verifies if the application is admissible
3. RMS prepares a draft assessment report
4. EFSA issues its conclusions
5. Standing Committee for Food Chain and Animal Health votes on approval or non-approval
6. Adoption by the Commission
7. Publication of a Regulation in the EU Official Journal



List of Candidates for Substitution

“The European Commission is required by Regulation (EC) No 1107/2009 to establish a list of substances identified as “candidates for substitution”. The list identifies **active substances with certain properties**.

EU countries and stakeholders were consulted on the approach taken and on the input values taken to determine if an active substance qualifies to be a candidates for substitution.

The analysis has been conducted by comparing the agreed and peer reviewed endpoints, against the relevant seven conditions specified in Annex II, point 4 of the Regulation.

The current draft list contains **77 candidates for substitution**.

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_cfs_draft-list.pdf

First authorization of a PPP Art. 28-39 of [Regulation \(EU\) 1107/2009](#)

Applications are evaluated on a zonal basis

A single MS can evaluate a PPP on behalf of the entire EU for these uses:

- Greenhouse uses
- Post-harvest treatments
- Treatment of empty storage rooms or containers
- Seed treatments

Basic procedure

1. Application is made to the country/countries where the PPP is intended to be placed on the market
2. A zonal Rapporteur Member State (zRMS) is selected for each zone where the PPP shall be authorized and carries out an assessment of the application
3. Other Member States in the same zone comment on the zRMS's evaluation
4. Zonal RMS makes a decision on whether to grant or refuse an authorization
5. Other Member States make a decision to grant or refuse an authorization
6. To place the same product in another Member State(s), an application is made for 'mutual recognition' of the product in the concerned Member State.

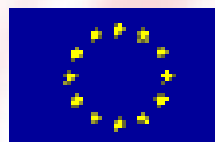
Procés d'avaluació de productes fitosanitaris

S

DOSSIER

Identitat
Propietats fisicoquímiques
Dades d'aplicació
Classificació i etiquetat
Eficàcia i selectivitat
Mètodes d'anàlisi
Toxicologia i metabolisme
Residus
Comportament i destí en el medi
Ecotoxicologia

Principis Uniformes
AVALUACIÓ
PROPOSTA DE DECISIÓ



DECISIÓ

Procedure to apply for authorization of a PPP

Plants

PESTICIDES

EU Pesticides database

Sustainable use of pesticides

Approval of active substances

Authorisation of Plant Protection Products

Procedure to apply for authorisation of a PPP

Plant Protection Products Application Management System (PPPAMS)

Maximum Residue Levels

REFIT Evaluation

ALL TOPICS

Procedure to apply for authorisation of a PPP

A zonal system of authorisation operates in the EU to enable a harmonised and efficient system to operate.

The EU is divided into 3 zones; North, Central and South. EU countries assess applications on behalf of other countries in their zone and sometimes on behalf of all zones.

Regulation (EU) 1107/2009 sets out the requirements, procedure and timeframes for authorisation of Plant Protection Products (PPPs).

Applicants, EU countries, the European Commission and the European Food Safety Authority (EFSA) can be involved in the process of authorisation.

There are different types of application that can be submitted depending on the intended use of the PPP, the Member State(s) for which the PPP is required and the regulatory status of any existing authorisations. These are explained in further detail here:

[Expand All]

First authorisation of a PPP (PPPAMS ready to use)

Mutual Recognition (PPPAMS ready to use)

Amendment or withdrawal of an existing authorisation

Renewal of authorisation

Emergency authorisation (PPPAMS ready to use)

Application for Minor Uses

Parallel trade permits

Assessment of technical equivalence

Share

QUICK LINKS

GMO register

EU Pesticides database

Procedure to apply for authorisation of a PPP

Plant variety database

Community Plant Variety Office (CPVO)

Health and food audits and analysis

Access to documents project

European Food Safety Authority (EFSA)

E-news

Press Releases

Infographics and factsheets

Plants

PESTICIDES

EU Pesticides database

Sustainable use of pesticides

Approval of active substances

Authorisation of Plant Protection Products

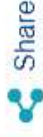
Maximum Residue Levels

REFIT Evaluation



ALL TOPICS

Pesticides



RELATED LINKS

- [Pesticides authorisation and use in the EU](#)

RELATED DOCUMENTS

Brexit

- [Brexit/ Notice to stakeholders on plant protection products](#)
- [Q&A related to UK's withdrawal from the EU](#)

QUICK LINKS

- [GMO register](#)
- [EU Pesticides database](#)
- [Procedure to apply for authorisation of a PPP](#)
- [Plant variety database](#)
- [Community Plant Variety Office](#)

Brexit

- Notice to stakeholders withdrawal of the United Kingdom and EU rules on plant protection products
- Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to Plant Protection Products and Pesticide Residues

What is a Pesticide?

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, nematocides, molluscicides, rodenticides, growth regulators, repellents, rodenticides and biocides.

What is a Plant Protection Product?

Plant protection products are 'pesticides' that protect crops or desirable or useful plants.

They are primarily used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens.

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 (such as substances influencing their growth,



PLANTS

EU Pesticides database

[European Commission](#) > [Food Safety](#) > [Plants](#) > [Pesticides](#) > [Pesticides Database](#)

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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

- Non-renewal of approval of the active substance diquat Regulation (EU) 2018/1532 of 12 October 2018 17/10/2018
- Non-renewal of approval of the active substance thiram Regulation (EU) 2018/1500 of 9 October 2018 12/10/2018
- Non-renewal of approval of the active substance pymetrozine Regulation (EU) 2018/1501 of 9 October 2018 12/10/2018
- Conditions of approval of the active substance malathion Regulation (EU) 2018/1495 of 8 October 2018 11/10/2018
- Renewal of approval of the active substance pethoxamid Regulation (EU) 2018/1264 of 20 September 2018 (shall apply from 1 December 2018) 20/09/2018

PESTICIDES EU-MRLs

Regulation (EC) No 396/2005

Latest MRL updates

- Publication of Commission Regulation (EU) 2018/1516 of 10 October 2018 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 penoxsulam, triflumizole and triflumuron in or on certain products 09/11/2018
- Publication of Commission Regulation (EU) 2018/832 of 5 June 2018 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 cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products 26/06/2018
- Publication of Commission Regulation (EU) 2018/687 of 4 May 2018 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 acibenzolar-S-methyl, benzovindiflupyr, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluazifop-P, isofetamid, metrafenone, pendimethalin and teflubenzuron in or on certain products 24/05/2018
- Publication of Commission Regulation (EU) 2018/686 of 4 May 2018 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 chlorpyrifos, chlorpyrifos-methyl and triclopyr in or on certain products 24/05/2018



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Estadísticas

Sede electrónica

Sala de prensa

Inicio > Agricultura > Sanidad vegetal > Medios de defensa fitosanitaria

Medios de defensa fitosanitaria

Registro de productos fitosanitarios

Notas informativas del registro de productos fitosanitarios

Registro de determinados medios de defensa fitosanitaria (MDF)

Uso sostenible de productos fitosanitarios

Guías de Gestión Integrada de Plagas

Registro oficial de productores y operadores de medios de defensa fitosanitaria (ROPO)

Registro electrónico de transacciones y operaciones (RETO)

Registro de Productos Fitosanitarios



Para realizar consultas al Registro, pulse sobre el icono:



Última actualización de la base de datos: 4 de Octubre de 2018

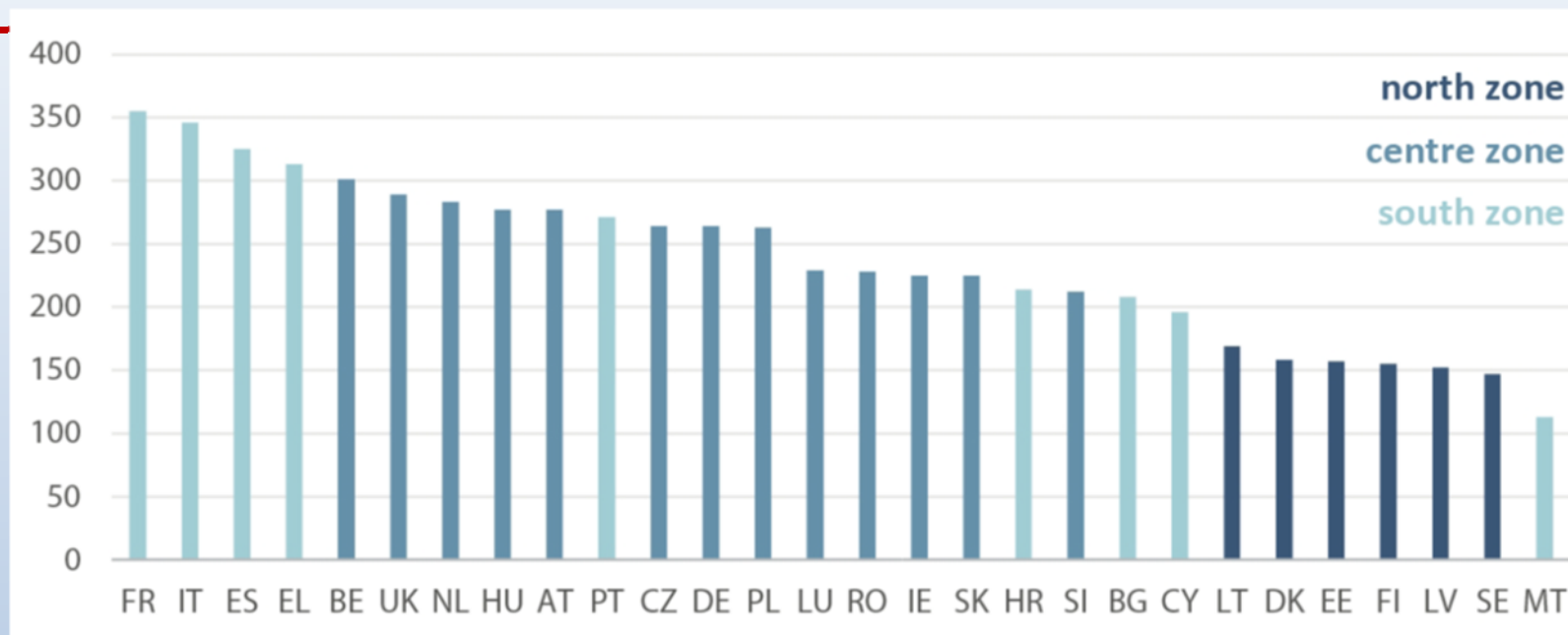
ESTA BASE DE DATOS SE ACTUALIZA PERIODICAMENTE, POR LO QUE LOS DATOS CONTENIDOS EN ELLA PUEDEN HABER EXPERIMENTADO VARIACIONES QUE NO APARECERÁN RECOGIDAS HASTA LA SIGUIENTE ACTUALIZACIÓN.

Los productos fitosanitarios son medios imprescindibles para la producción agrícola, tanto bajo los sistemas convencionales de agricultura, como bajo otros sistemas de agricultura, como la integrada o la ecológica, pues los estragos potenciales de las diferentes clases de plagas, determinarían la inviabilidad de muchos cultivos en las zonas de producción de mayor interés económico y social e incluso la posibilidad de mantener almacenadas las cosechas.

Sin embargo, la utilización de productos fitosanitarios puede tener otros efectos no deseables y es imprescindible que estos efectos no sean en ningún modo peligrosos para la salud humana, ni tampoco que lleguen a presentar niveles de riesgo inaceptables para el medio ambiente, incluidas la flora y la fauna silvestres.

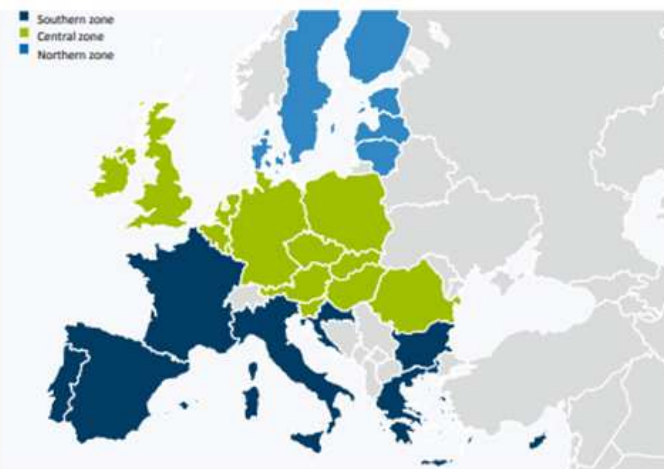
En consecuencia el Estado aplica los mecanismos necesarios para que sólo puedan comercializarse aquellos productos fitosanitarios que sean útiles y eficaces para combatir las plagas, pero que no comporten otros riesgos colaterales. Para que un producto pueda comercializarse debe estar autorizado previamente e inscrito necesariamente en el Registro Oficial de Productos Fitosanitarios

Number of PPP authorized in the Member States



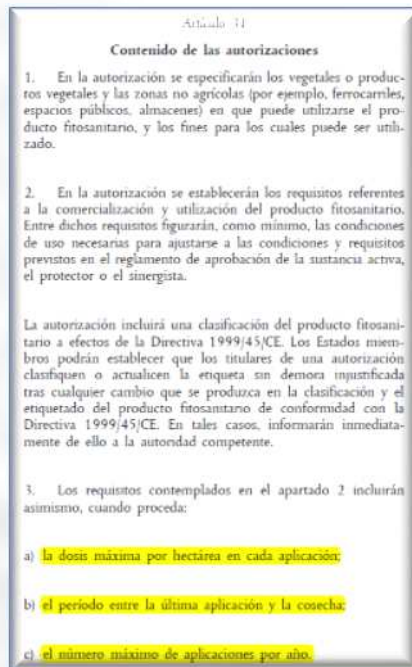
Administrative zones for plant protection product authorisation

Figure 2.4 Zonal authorisation system



Source: Ecorys

REGLAMENT CE 1107/2009: de comercialització de productes fitosanitaris



Article 31

Requisits referents a l'ús dels productes fitosanitaris autoritzats

- Dosi màxima per hectàrea per tractament (kg o L/ha)
- Màxim de tractaments anuals
- Període entre la darrera aplicació i la collita (termini de seguretat)

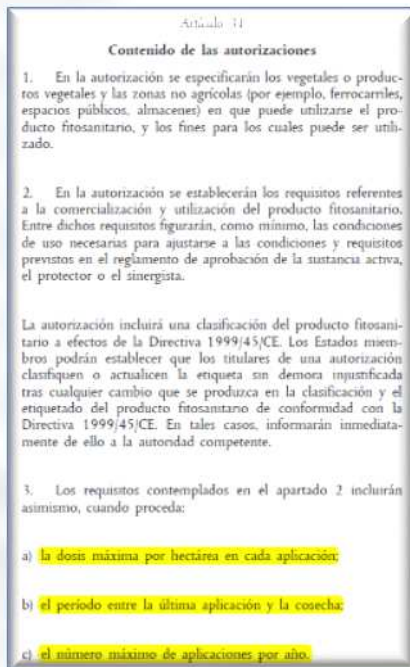
https://ec.europa.eu/food/plant_en

REGLAMENTO CE 1107/2009 de comercialización de productos fitosanitarios

Artículo 3.18

Buenas prácticas fitosanitarias

- ☐ los tratamientos con productos fitosanitarios, con arreglo a las condiciones de sus usos autorizados, **se seleccionan, se dosifican y se programan en el tiempo para garantizar una eficacia aceptable con la cantidad mínima necesaria.**
- ☐ teniendo debidamente en cuenta las condiciones locales y las posibilidades de control cultural y biológico.



Main derogation applicable to substance approved

Max. duration	Plant protection substances	Biocidal substances
5 years	substance does not meet approval criteria but is 'necessary to control a serious danger to plant health which cannot be contained by other available means'	substance does not meet approval criteria unless: • the risk is negligible; or • the substance is required to prevent or overcome a serious hazard; or • non-approval would have disproportionate negative consequences for society
7 years	substitution of substance planned owing to high risk to human health or the environment ⁵³ glyphosate	
15 years	low-risk substance ⁵⁴	
unlimited	basic substance ⁵⁵	Substance with no grounds for concern ⁵⁶

Source: European Parliamentary Research Service (EPRS).

Approval can be renewed for a maximum duration of 15 years upon application by the manufacturer, subject to a similar procedure to that for initial approval. The Commission may review the approval of a substance at any time.

- ☐ Caiguda de substàncies actives
- ☐ Caiguda de productes
- ☐ Caiguda d'usos (cultius, àmbits d'utilització, ..)
- ☐ 400 productes revisats a Espanya (2018)
- ☐ Període de gràcia de 6 mesos

Avaluació comparativa Art. 50 [Regulation \(EU\) 1107/2009](#)

- Per a sol·licituds d'autorització de PF que continguin una substància activa candidata a la substitució.
- Es disposa de mètodes de control no químics o de mètodes preventius.
- La diversitat química de substàncies químiques és suficient per evitar l'aparició de resistències.
- Un candidat a la substitució es aprova per un termini màxim de 7 anys.
- Avaluació risc / benefici

Experience from Spain

Spain has performed between 43 to 60 comparative assessments since 2015. The MS does not maintain a database to keep track of the number of comparative assessment procedures that have been performed. Within the MS, three persons work on a fulltime basis on the evaluation of the efficacy of PPPs, including comparative assessments. For the evaluation, the Competent Authority frequently works together with the National Institute for Agriculture (INIA).

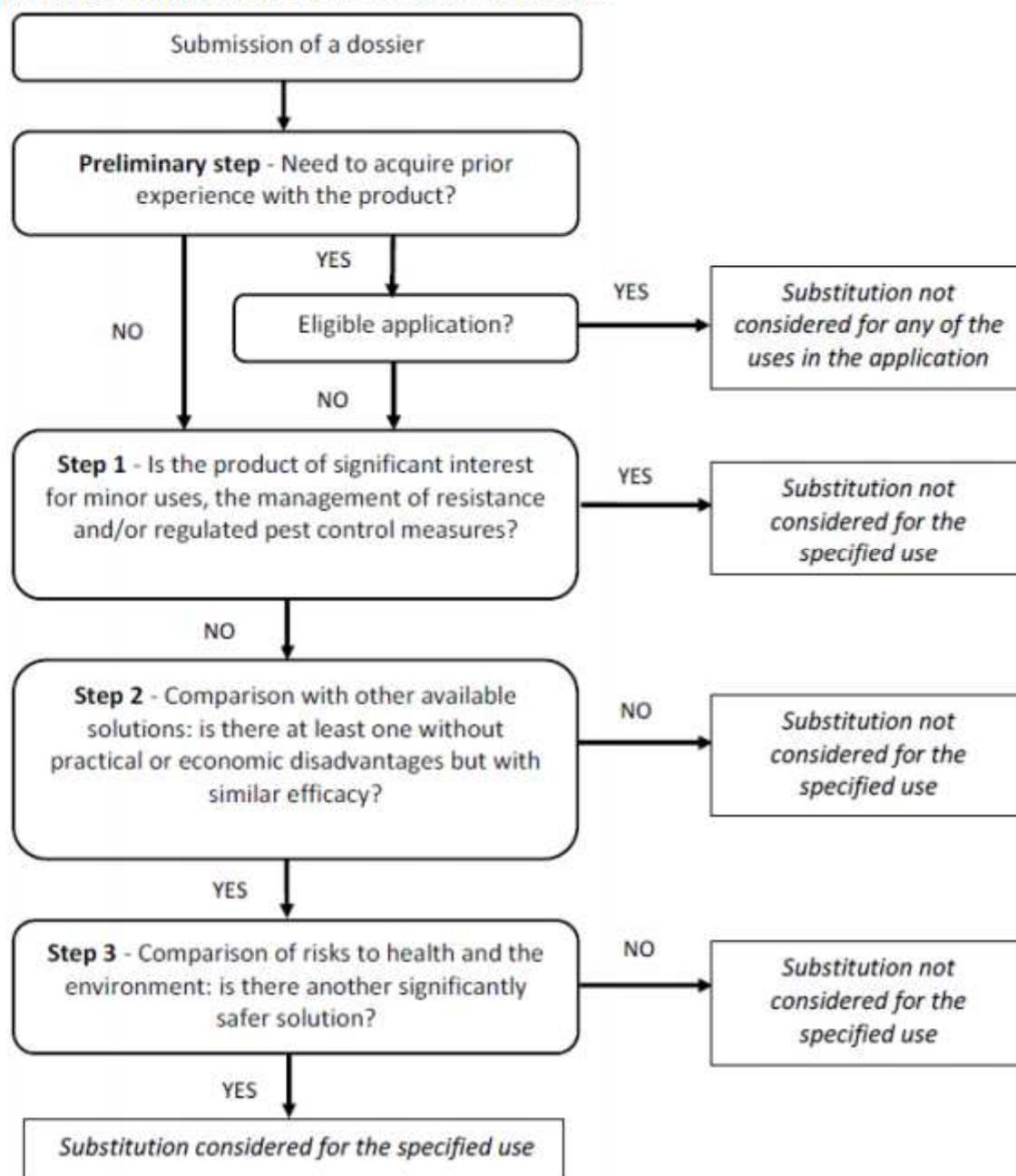
None of the reviews of PPPs containing CfS have made it to the last step in the guidance document, and no substitutions have been made to date (June 2018). In its national guidance document for the comparative assessment and substitution of PPPs⁴²⁰ 11 steps have been identified that must be followed in the assessment.

Procedure for Comparative Assessments in Spain

- **Step 1:** Application details to be considered in the comparative assessment
- **Step 2:** Product details of label extension requested
- **Step 3:** Major uses of the product to be considered in the comparative assessment
- **Step 4:** Alternatives to be considered in the comparative assessment
- **Step 5:** Diversity of alternative chemical substitutes to support resistance management practices
- **Step 6:** Consequences for minor uses if the product in question is substituted for the major uses, subject to the comparative assessment
- **Step 7:** Assessment of comparability regarding effectiveness
- **Step 8:** Assessment of necessity in IPM Systems
- **Step 9:** Economic and practical disadvantages of alternatives for the user
- **Step 10:** Comparability for health and the environment, and the identification of the alternatives likely to provide a safer option for pest control
- **Step 11:** Specialist comparative assessment

As mentioned above, no database exists showing the step at which the different

Figure 12 Steps in the comparative assessment in France



Conclusion

France, Spain and the Netherlands have set up procedures for comparative assessments on a national level. Each MS has published national guidance documents based on the EU guidance document. The comparative assessment procedure, however, creates an additional administrative burden on the MSs, but so far, is not considered to have added to delays with regard to the procedure for product authorisation. However, the comparative assessments carried out by France, Spain and the Netherlands have not led to the substitution of any product in these three MSs. Most of the applications for substitution have been stopped after the agronomic assessment for alternative uses due to a lack of agricultural alternatives.



EU policy and legislation on pesticides

Plant protection products
and biocides



IN-DEPTH ANALYSIS

EPRS | European Parliamentary Research Service
Author: Didier Bourguignon
Members' Research Service
April 2017 — PE 599.428

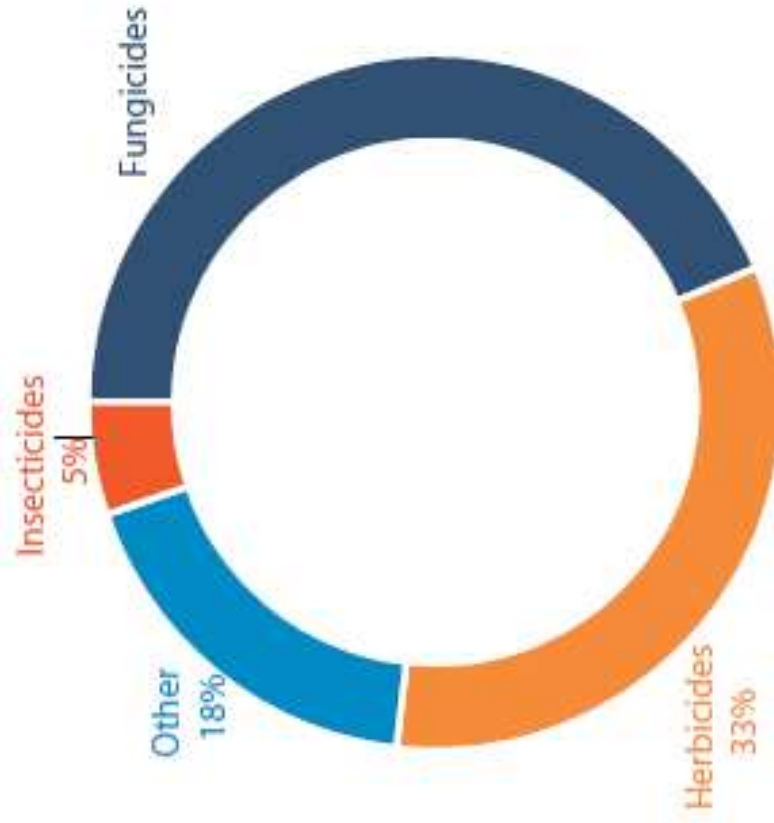
EN
(or. FR)

Substances used to suppress, eradicate and prevent organisms that are considered harmful are grouped under the term '**pesticide**'.

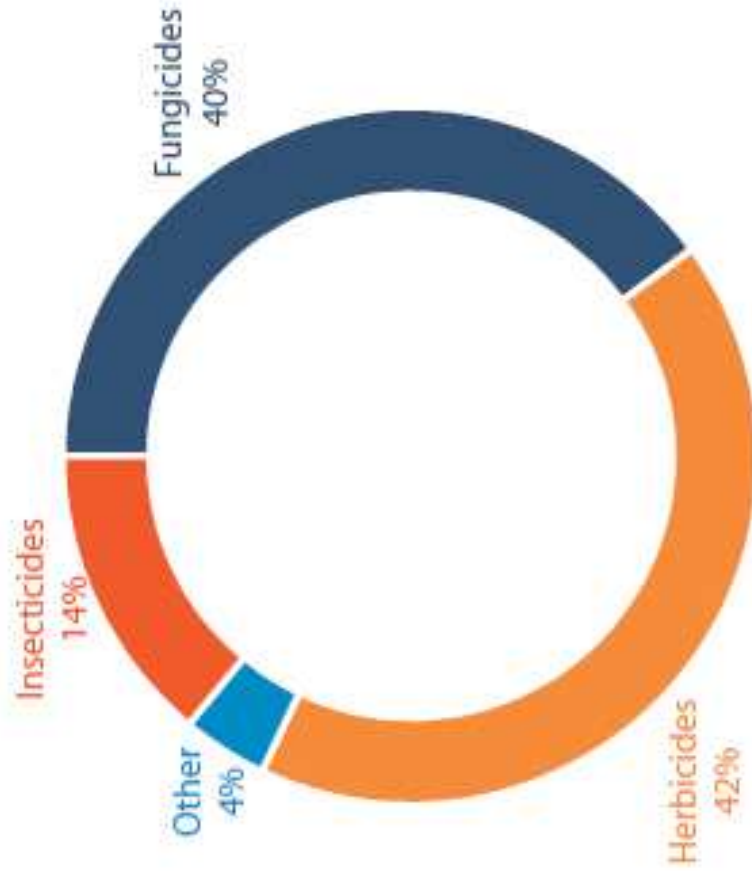
The term includes both **plant protection products**, synthetic & bio-pesticides, (used on plants in agriculture, horticulture, parks and gardens) and **biocidal** products (used in other applications, for example, as a disinfectant or to protect materials).

Figure 3 – Plant protection products by target in 2014¹⁰

Breakdown according to volume (kg)



Breakdown according to market share (€)



Data source: Eurostat, [Pesticide sales](#) (aei_fm_salpest09) and European Crop Protection Association, [Annual Review 2015](#), 2016, p.15. The figures show the breakdown of the market, including the 28 Member States, Iceland, Lichtenstein, Norway and Switzerland.

Ús dels PF

Avantatges

- Increment dels rendiments des de la II GM (40's)

Desavantatges

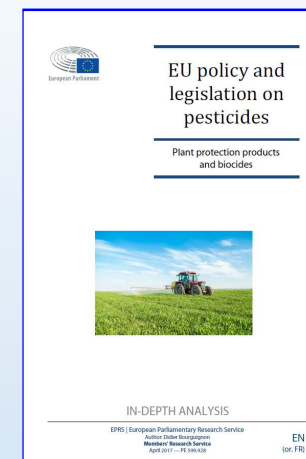
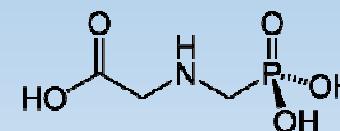
- Impacte ambiental (aire, aigua, sòl)
- Riscos per la salut humana (exposició a residus, llarg termini...)
- Efectes sobre la protecció de cultius (fauna auxiliar, resistències...)

Debat social intens (pro/con)

- Disruptors endocrins
- Neonicotinoids: [clothianidin](https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids/), [imidacloprid](https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids/), [thiamethoxam](https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids/) 

Es prohibeixen tots els usos excepte en hivernacles permanents

- Glifosat https://ec.europa.eu/food/plant/pesticides/glyphosate_en
- Coures



Els neonicotinoids

Reglamento de Ejecución (UE) 2018/783 de la Comisión, de 29 de mayo de 2018, por el que se modifica el Reglamento de Ejecución (UE) n.º 540/2011 en lo que respecta a las condiciones de aprobación de la sustancia activa imidacloprid ⁽¹⁾

Reglamento de Ejecución (UE) 2018/784 de la Comisión, de 29 de mayo de 2018, por el que se modifica el Reglamento de Ejecución (UE) n.º 540/2011 en lo que respecta a las condiciones de aprobación de la sustancia activa clotianidina ⁽¹⁾

Reglamento de Ejecución (UE) 2018/785 de la Comisión, de 29 de mayo de 2018, por el que se modifica el Reglamento de Ejecución (UE) n.º 540/2011 en lo que respecta a las condiciones de aprobación de la sustancia activa tiametoxam ⁽¹⁾

- Els 3 reglaments no foren votats per unanimitat.
- D'acord amb aquests reglaments, els terminis no poden superar:
 - 19 setembre per vendes (màxim)
 - 19 desembre per a ús (màxim)

Els fungicides cúprics

- Les autoritzacions substàncies actives de compostos de coure a la UE acaba el 31/1/2019. En fase de renovació.
- A ES s'acaben de revisar per principis uniformes d'acord amb la anterior directiva 91/414/CE:
 - Dels més de 200 formulats autoritzats en vinya s'ha passat a uns 40
 - El núm. d'aplicacions permeses per campanya es redueix molt (de 1 a 4 aplicacions/any).
 - En diversos productes cúprics, no en tots, figura en el nou full de registre la restricció de no superar la dosi de 4 kg/ha de Cu (coure inorgànic) per campanya.
 - Formulats de coure similars, uns continuen autoritzats en vinya i altres han estat cancel·lats

Els fungicides cúprics

- Terminis:
 - 3 mesos per vendre (o reetiquetar)
 - 6 mesos per al seu ús pels agricultors d'acord amb les anteriors autoritzacions

Mitigació dels efectes negatius dels PF

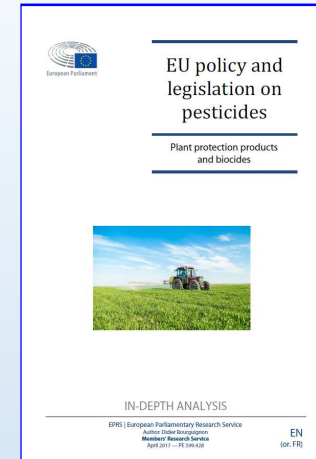
IPM

- Priorització de mètodes no químics

Control biològic

- Costos elevats, eficàcia inferior, no adopció universal

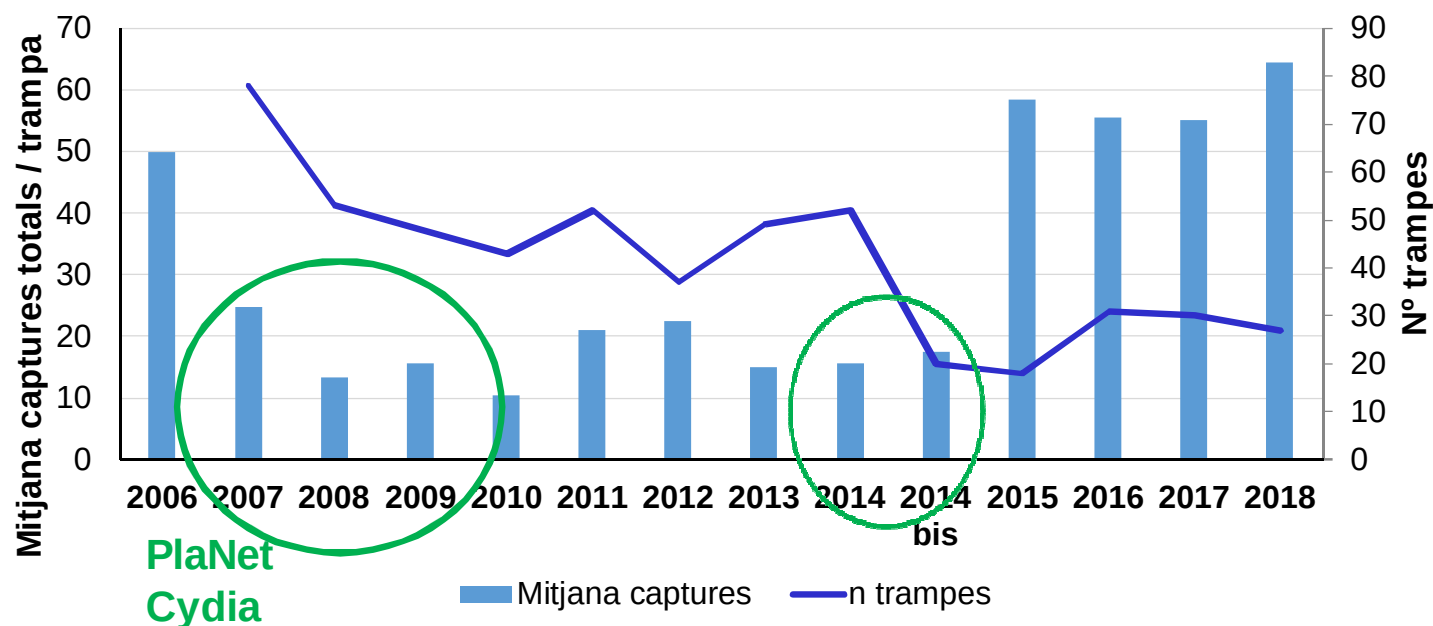
Agricultura de precisió



<https://youtu.be/XH-EFtTa6IU>

Evolució de la població de carpocapsa (*Cydia pomonella*)

Mitjana suma captures per finca
El Poal: poma -pera - noguer
Confusió sexual
Combo



L'any 2015 hi va haver un increment important de captures respecte als anys 2007-14

Opportunities and Challenges

Cost

- Regulatory costs for the pesticide industry
- Research and development costs for new pesticides

Approval procedure

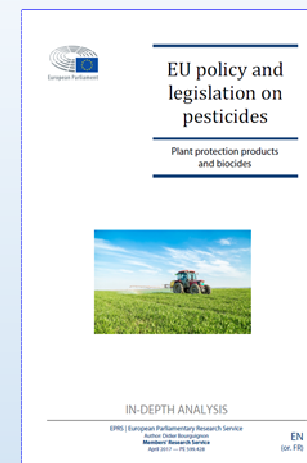
- Assessment of active substance
- Potential conflicts of interest
- Emergency authorization
- Substitution of active substances
- Assessment of cumulative risks posed by residues of plant protection products

Sustainability

- Integrated pest management
- Use of biopesticides (plant protection products of biological origin)

Other legislation

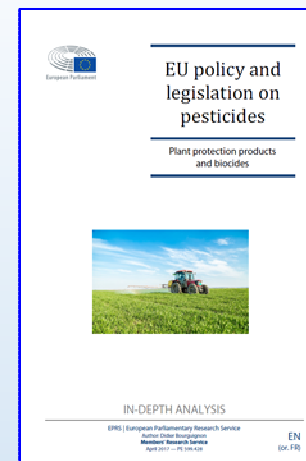
- Counterfeit plant protection products
- Minor uses of plant protection products



EU Parliament position



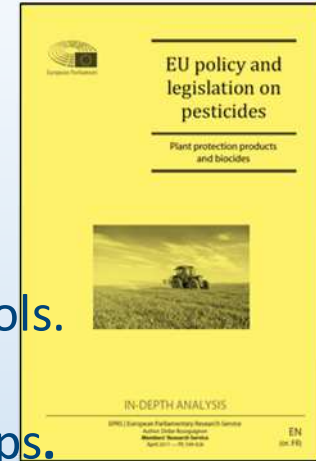
1. **Approval procedure** the implementation of the regulatory framework for plant protection products urgently **needs to be reviewed** and a coherent assessment system.
2. The need **for farmers** to have **more instruments** to protect their crops
3. The need to improve the availability of **low-risk pesticides**, without further delay, as the current authorization procedure is not ideal for low-risk pesticides of biological origin.



Stakeholders' views

European Crop Protection Association (ECPA)

It complains of a politicized process that ignores science and innovation, does not recognize the merits of risk management and does not consider the need for farmers to have appropriate tools. The risk that the substitution process may cause a 10 % to 14 % reduction in yield for main crops and up to 85 % for specialised crops.



International Biocontrol Manufacturers Association (IBMA)

New approach to the approval and authorisation of low-risk plant protection substances and products by speeding up and prioritising their assessment.

The European Farmers' Association and their Copa & Cogeca cooperatives

Are opposed to the ban on using plant protection products on protein crops in ecological focus areas, as proposed by the Commission.

The environmental NGO Pesticide Action Network Europe (PAN Europe)

Criticises the conflict of interest and approach taken by EFSA with regard to cumulative risk assessment.

REFIT - Evaluation of the EU legislation on PPP and residues

To be finalized in the first half of 2019.



English 

Search

[Home](#) > [Law](#) > [Law-making process](#) > [Evaluating and improving existing laws](#) > [REFIT – making EU law simpler and less costly](#)

REFIT – making EU law simpler and less costly

The European Commission's regulatory fitness and performance (REFIT) programme aims to ensure that EU legislation delivers results for citizens and businesses effectively, efficiently and at minimum cost. REFIT aims to keep EU law simple, remove unnecessary burdens and adapt existing legislation without compromising on policy objectives.

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



Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)

Final report
10 October 2018

Written by Ecorys
October – 2018

Number of responses received by country

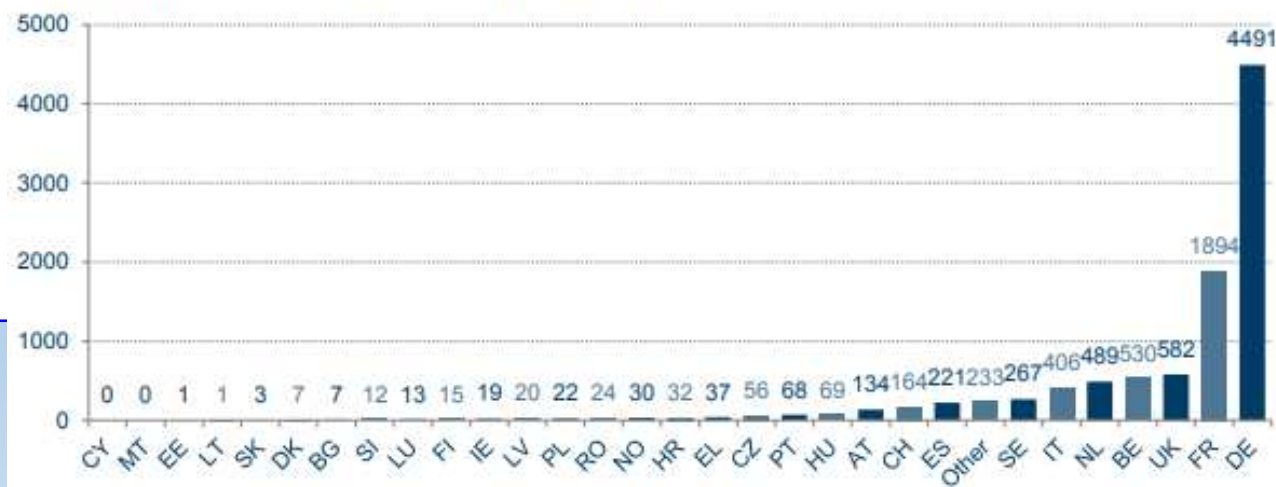
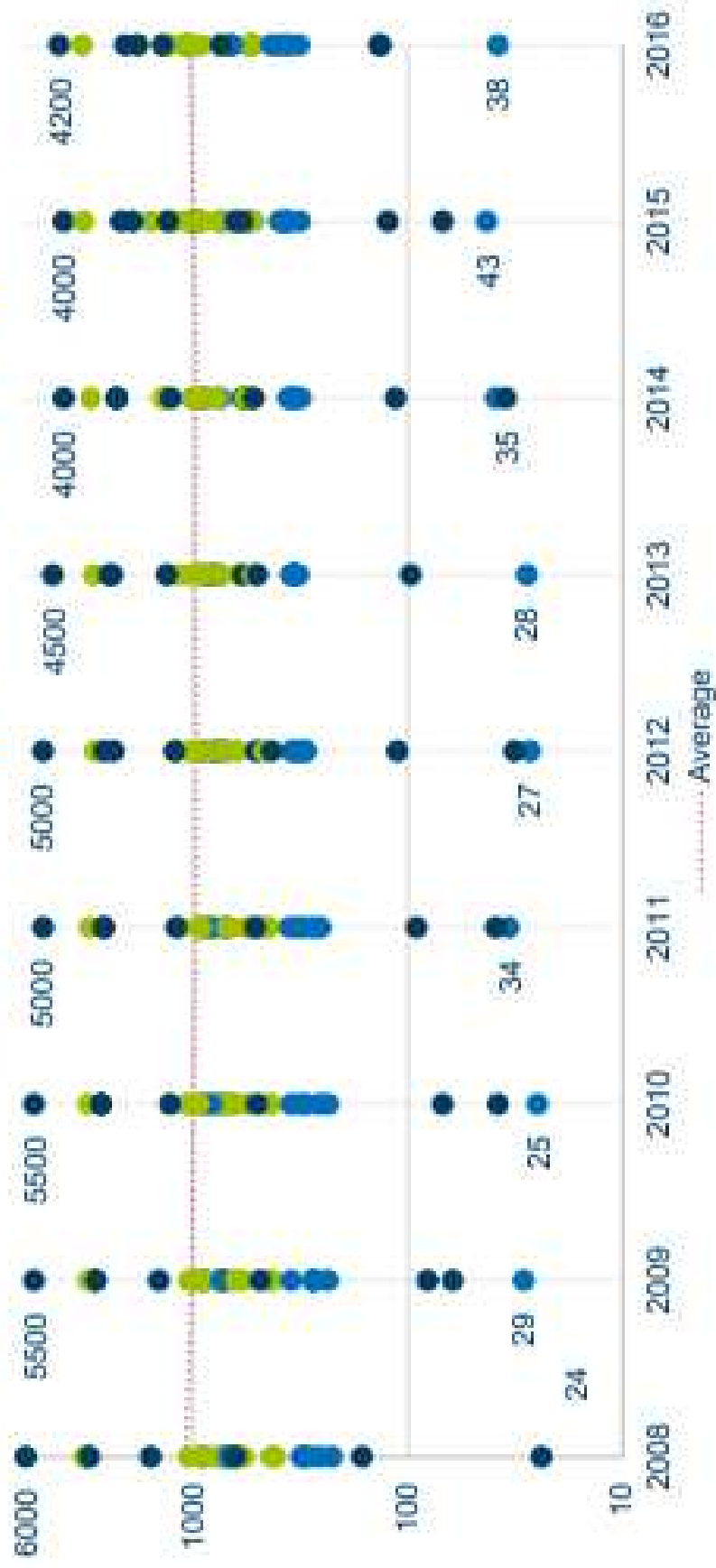


Table 2.3 Overview timelines, staff and fees of 21 MSs under Directive 91/414/EEC.

Country	Time for product authorisation (in months)			Staff	Average fee for application (in EUR)		
	Average	Legal	Diff.		EU	National	MR
Spain	54	12	42	28	150,000	2,000	1,350
Italy	45	12	33	58	52,000	1,500	3,615
Sweden	42	12*	30	26	450,000	13,500	6,000
Greece	36	N/A	--	29	80,000	6,000	5,000
Portugal	30	N/A	--	16	100,000	5,350	680
Denmark	30	24*	6	20	223,000	0	
Belgium	27	N/A	--	28	150,000	1,000	1,000
Netherlands	26	11	15	65	250,000	28,000	8,000
Germany	24	12	12	285	143,000	31,000	13,750
Poland	24	16	8	44	30,000	32,500	
Czech Republic	24	24	0	41	70,500	17,000	5,100
Slovakia	24	18	6	25	135,000	3,000	200
Romania	18	12	6		50,000	10,000	
Hungary	18	18	0	23	55,500	13,000	550
Ireland	18	N/A	--	21	200,000	5,000	2,500
France	16	12	4	108	200,000	40,000	15,000
Austria	12	15	-3	52	320,000	19,800	7,200
Lithuania	12	12	0	9	78,000	5,800	2,900
Latvia	12	15	-3	8	49,800	2,900	1,150
Estonia	12	13	-1	6	23,100	500	320
UK	10	7*	3	250	166,000	9,000	4,500

* Target timeline, not legal; N/A: not applicable, no legal or target timeline available.

Number of PPPs available in MSs and EEA countries between 2008 and 2016



Conclusions (extracted)

Synthesis of the key findings per evaluation criteria

Effectiveness

- ☐ The total number of available active substances has not significantly changed since the entry into force of Regulation 1107/2009
- ☐ Compared to 2010, data show an increase of authorized PPPs in most countries
- ☐ The approval criteria for active substances in Regulation 1107/2009 are among the most stringent in the world
- ☐ Several aspects of the Regulation may affect the competitiveness of EU agriculture
- ☐ The mutual recognition process is not functioning as intended. Legal timelines are widely exceeded.
- ☐ Emergency authorizations are steadily increasing
- ☐ The availability of PPPs for minor uses is negatively affected by a lack of clarity in the rules for authorization and harmonization between MS.
- ☐ Farmers perceive that alternatives are not fully capable of guaranteeing the same efficacy as traditional PPPs.

Conclusions (extracted)

Synthesis of the key findings per evaluation criteria

Efficiency

- ☐ There is no common agreement among the stakeholders regarding the efficiency of the risk assessment and risk management processes under Regulation 1107/2009.
- ☐ The costs of MS approval and authorisation procedures are estimated at approximately EUR 44 million annually, while the costs for industry are estimated at more than EUR 300 million for approvals and renewals of active substances.
- ☐ The costs for extensions of authorisations for minor uses represent about 20% of the costs for PPP renewals. Stakeholders.
- ☐ PPP renewal procedures with candidates for substitution (Art. 50) are approximately 10% costlier than the standard procedures.

Conclusions (extracted)

Synthesis of the key findings per evaluation criteria

Relevance

- ☐ There is a growing societal and consumer demand for an EU agriculture that is more sustainable, with a reduced impact on the environment.
- ☐ EU farmers need to address societal demands while remaining competitive. Farmers fear a decrease in the availability of PPPs in the coming years, alongside insufficient innovative methods to maintain their competitiveness

Coherence

- ☐ Overall, the Regulation has had some success in establishing a coherent policy in the area of pesticides.
- ☐ For the most part, EU legislation is considered to be consistent with international rules and agreements.

2nd Workshop on the study supporting the REFIT evaluation of the pesticide regulations

Date: 16 May 2018
Time: 09:30 – 17:00
Location: Albert Borschette Congress Centre
Participants: List of attendees (available in annex 1)

Session 3: Relevance, coherence and EU added value of the two Regulations.

The Contractor presented the main findings for the evaluation questions that assess the relevance, coherence and EU added value of Regulations (EC) No 396/2005 and 1107/2009.

Several participants shared their concerns as regards the availability of PPPs for farmers in the future. New active substances placed on the market have fewer uses whereas active substances that have disappeared from the market, covered many uses. At the same time, the EU may lose active substances in the near future that may not be replaced by new active substances. It is difficult for companies to find different modes of action and farmers may therefore experience difficulties in the future. As regards low-risk substances, one issue is that many active substances considered as low-risk in the market are approved as low-risk only after a lengthy approval process.

The conclusions from the study highlight that there is a growing societal and consumer demand for an EU agriculture that is more sustainable, with reduced impact on the environment. Some of the participants agreed with this finding. One Member State stressed that in the future, precision techniques and non-chemical alternatives will become more important. Integrated Pest Management will become the norm. However, farmers may still need PPPs to grow their crops thus having access to a range of pesticides will still be needed. One participant called for a more holistic regulatory framework.

Annex 1. Participants

Belgium
Denmark
Estonia
Finland
France
Germany
Hungary
Ireland
Latvia
Lithuania
Netherlands
Norway
Poland
Slovakia
Sweden
United Kingdom



European
Commission

*Scientific Advice
Mechanism (SAM)*

EU authorisation processes of

Plant Protection Products

*Group of Chief Scientific Advisors
Scientific Opinion S/2018*



Research and
Innovation



Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market

European
Implementation
Assessment

STUDY

EPRS | European Parliamentary Research Service

Ex-Post Evaluation Unit

PE 615.668 - April 2018



Directive 2009/128/EC on the sustainable use of pesticides

European
Implementation
Assessment

STUDY

EPRS | European Parliamentary Research Service

Editor: Milan Remáč

Ex-Post Evaluation Unit

PE 627.113 – October 2018

EN

Hedgerow



Stone fruits, October 2016 ES-Sunyer

Alguns temes en discussió

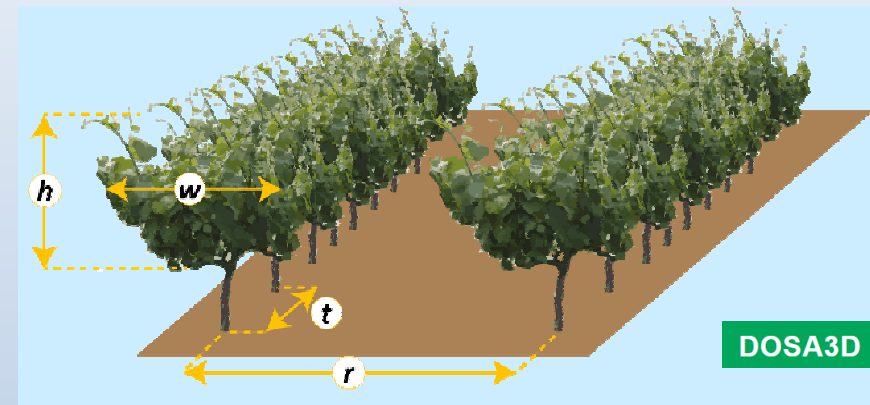
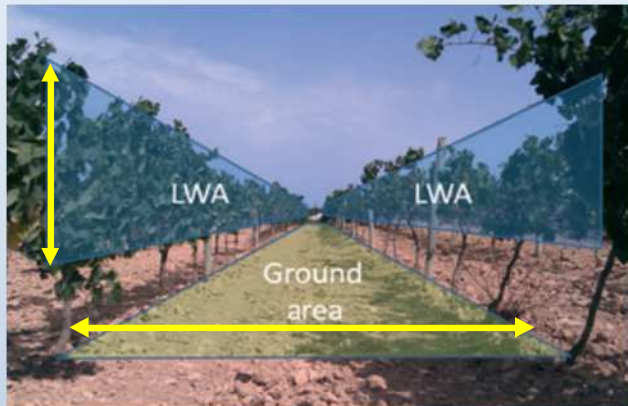
- Expressió de la dosi – EPPO - ECPA
- Ajust de la dosi - GenCat
- Classificació d'equips i components – DE, FR
- Avaluació eficàcia, metodologia - GenCat
- Mitigació de la deriva – NL, DE, UK
- Tractaments de precisió
- Registre, fitxa tècnica, etiquetes – SC6



Agència Fitos?

- **ANSES** www.anses.fr Agència Francesa de Salut i Seguretat Alimentària, Ambiental i Ocupacional
- **AGES** www.ages.at Agència Austríaca de Salut i Seguretat Alimentària
-

- Expressió de la dosi – EPPO - ECPA

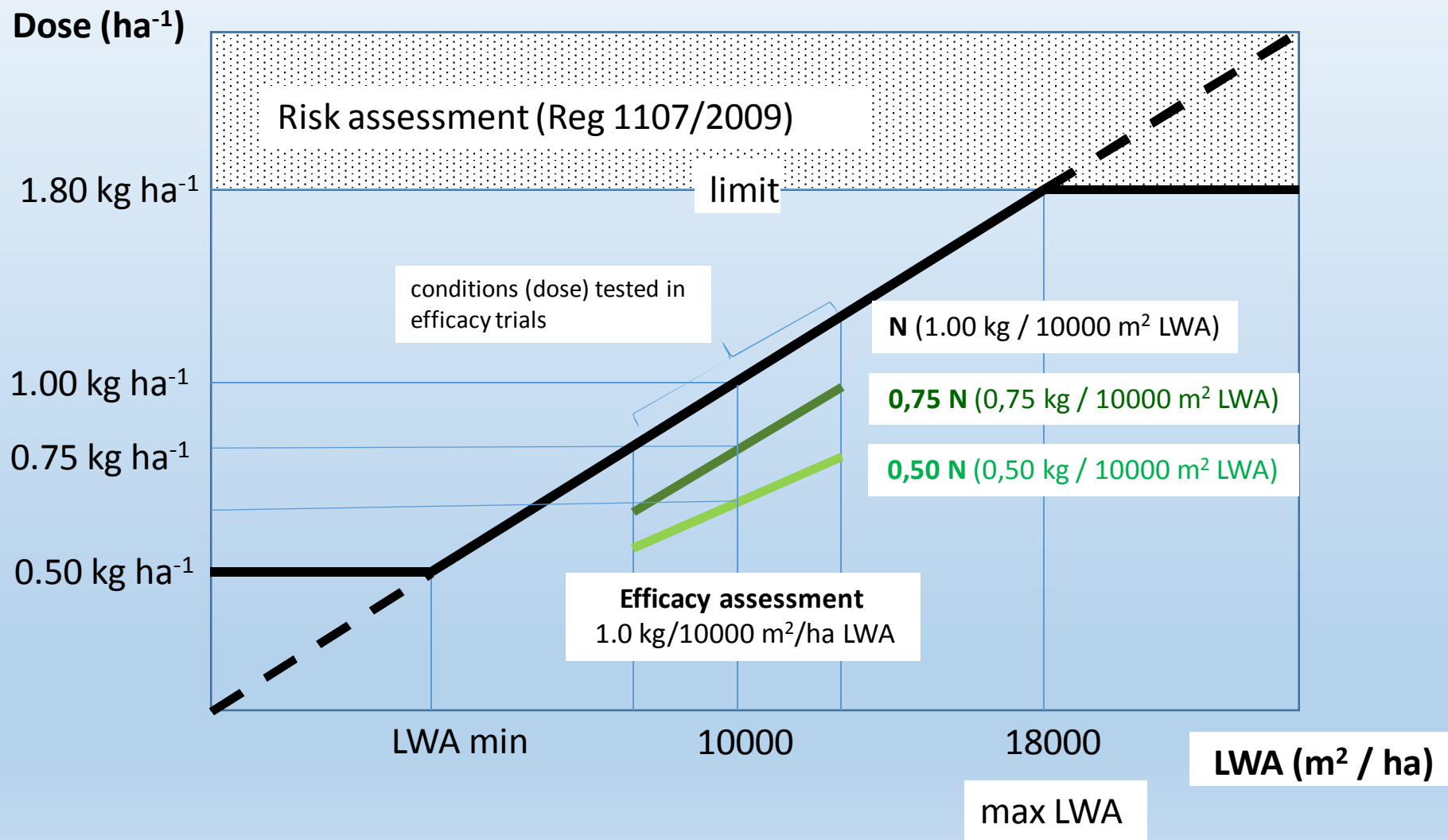


Leaf Wall Area (LWA) = superfície de paret foliar (m²/ha)

$$LWA = \frac{2 \times \text{alçada capçada} \times 10000}{\text{amplada carrer}}$$

h = 0,9 m; r = 3,0 m
LWA = 6.000 m² / ha

Dose ground and LWA on efficacy assessment trials



Dose adjustment in humans

Pharmaceuticals: dose adapted to the body weight of the person



**15 kg
child**



**55 kg
lady - teacher**



**100 kg
worker**

- Ajust de la dosi en cultius 3D

DOSA3D CALCULADORA BROQUETS CALIBRATGE DOCUMENTS CRÈDITS CONTACTA REGISTRE ACCÉS CA ▾



**Volum de caldo i dosi optimitzada
en cultius de tres dimensions (3D)**

 Generalitat de Catalunya
Departament d'Agricultura,
Ramaderia, Pesca i Alimentació

 Universitat
de Lleida

www.dosa3d.cat

<http://ruralcat.gencat.cat/web/guest/sanitat-vegetal>





Ús sostenible dels productes fitosanitaris



Què entenem per ús sostenible dels productes fitosanitaris?

Àmbits d'actuació

Normativa

Presentacions

Preguntes més freqüents

Reconeixement com a persona assessora en gestió integrada de plagues

Directe a

- Comunicació d'assaigs d'experimentació amb productes fitosanitaris
- Carnet d'aplicador i manipulador de productes fitosanitaris
- Model de quadern d'explotació en gestió integrada de plagues en l'àmbit de l'agricultura professional
- Pla d'acció nacional per a l'ús sostenible de productes fitosanitaris
- Guies GIP - Gestió Integrada de Plagues
- Jornades tècniques

Enllaços relacionats

- La gestió integrada de plagues. 2014  [429,97 KB]

DOSA3D

Volum de caldo i dosi optimitzada en cultius de tres dimensions (3D)

DOSA3D - Reference trials



16_V01 Ull de Llebre

17_V01 Cabernet S

17_V01

13_F04

10_F04

18_V01 Merlot

10_F02

10_F03

16_V01

10_F05

18_V05 Chardonnay

18_V05

18_V03 Xarel·lo

18_V07 Xarel·lo

18_V04 Muscat

18_V03

18_V07

18_V02 Xarel·lo

18_V04

18_V06 Macabeu

18_V06

18_O01

17_O01

18_C02

17_C02

17_C06

17_C05

18_C05

Golfo de San Jordi

Golfo de San Jorge

Data SIO, NOAA, U.S. Navy, NGA, GEBCO
Image Landsat / Copernicus



Generalitat de Catalunya
Departament d'Agricultura,
Ramaderia, Pesca i Alimentació



Seminario

Dosis en tratamientos fitosanitarios del viñedo y los frutales

31 de mayo (Tarragona) y 1 de junio (Lleida) de 2018

Informe y conclusiones

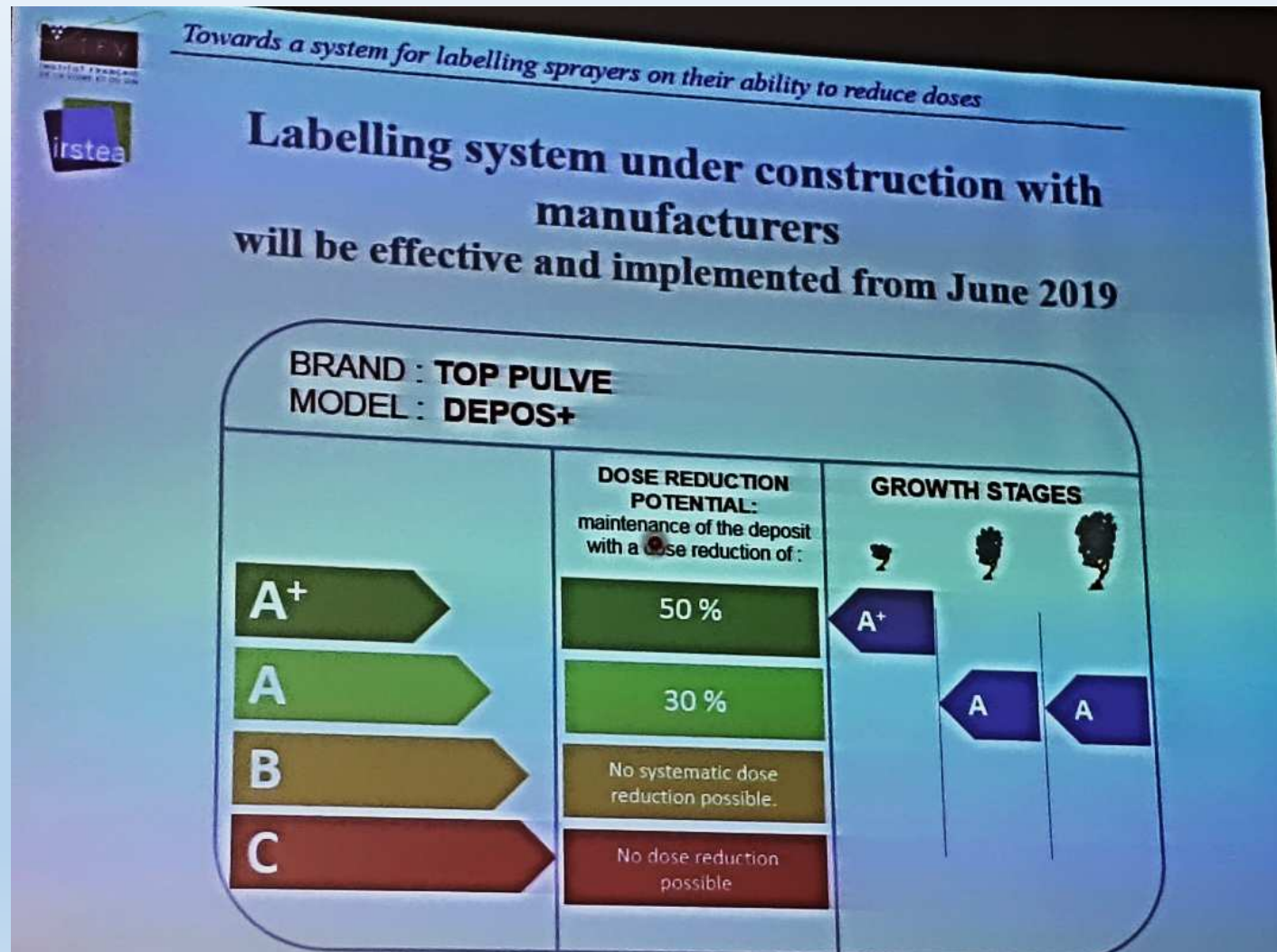




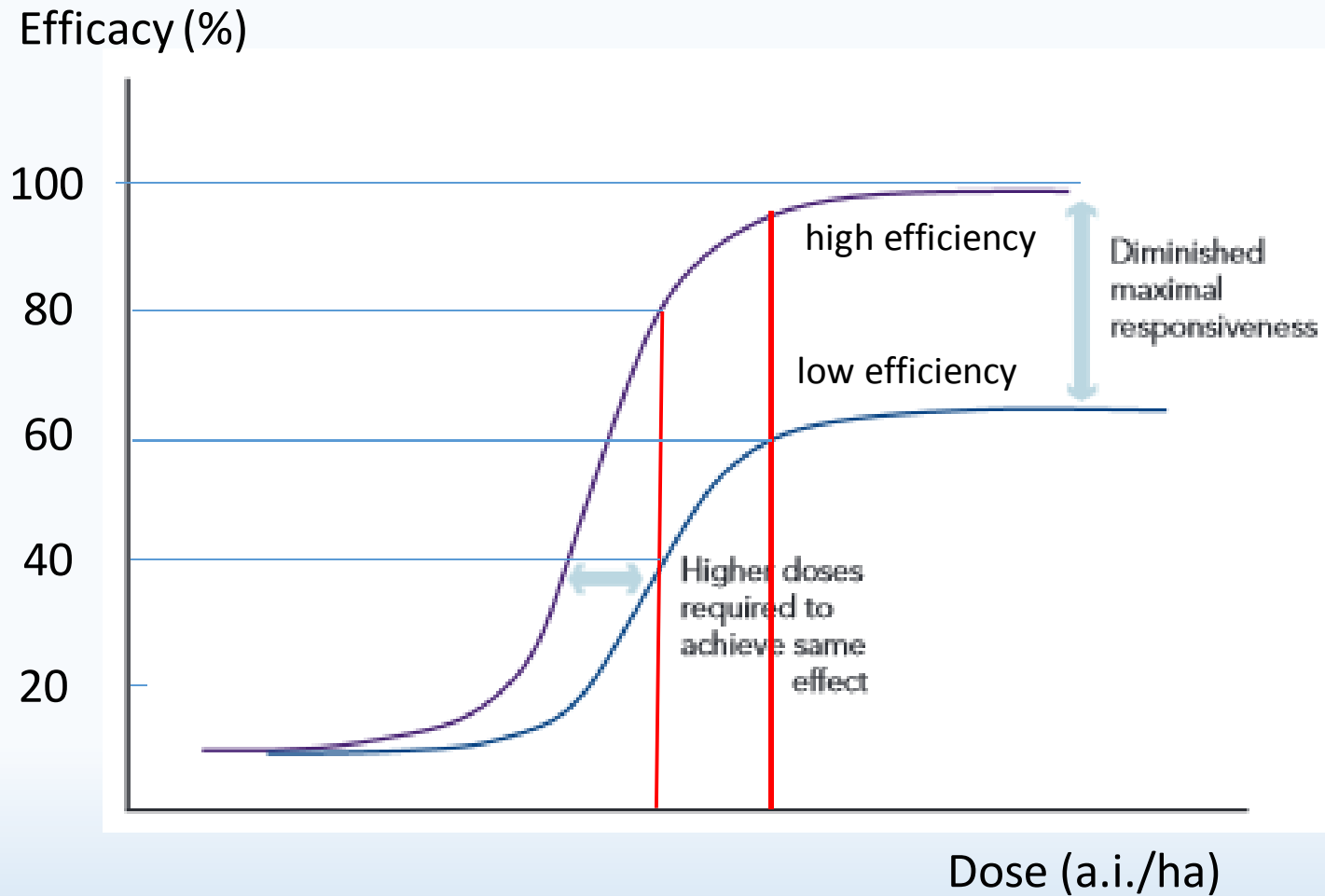
Conclusiones

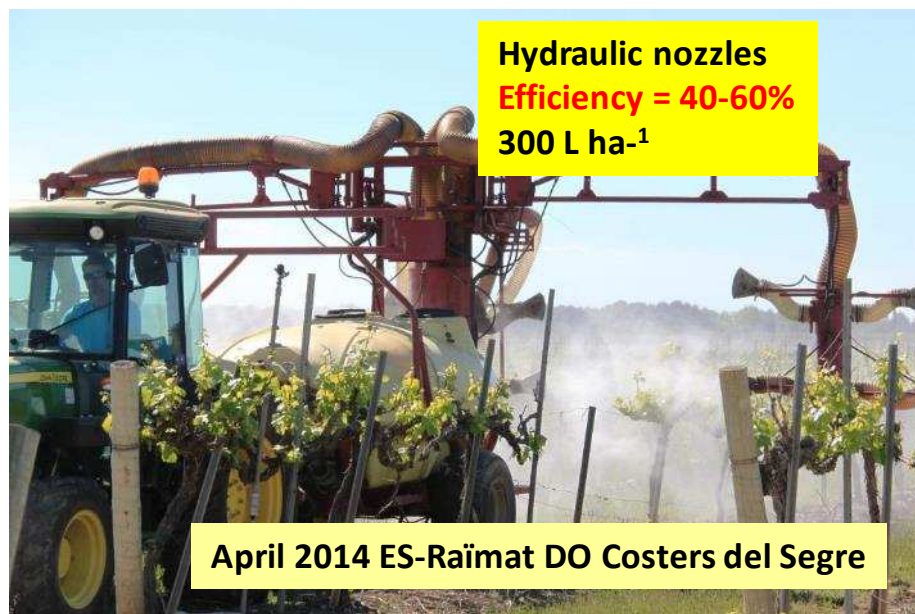
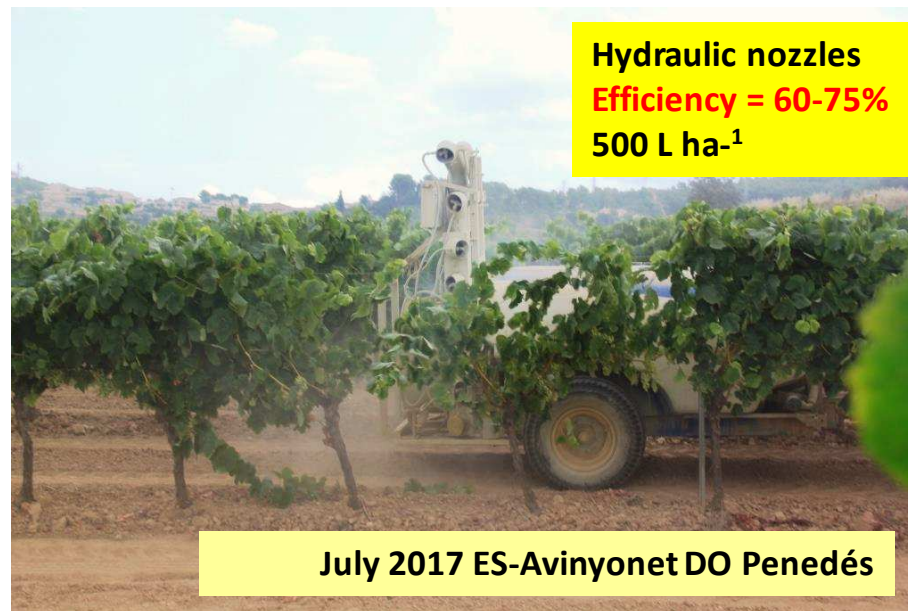
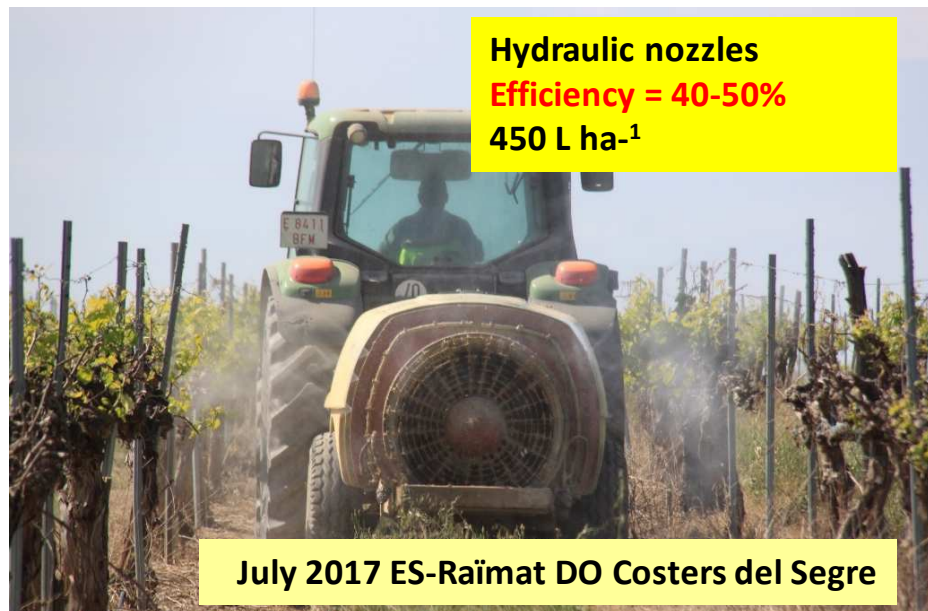
1. Los formatos actuales de expresión de la dosis, informando solamente sobre la concentración del caldo (%) o sobre la cantidad de producto por unidad de superficie cultivada (kg o litros de producto por hectárea), deben complementarse y evolucionar hacia criterios de mayor rigor.
2. La concentración (%), unida siempre a un intervalo de volúmenes de caldo (L/ha) es percibida como un sistema de expresión bien adaptado a los condicionantes de la viticultura y la fruticultura próximas.
3. El sistema leaf wall area (LWA), recomendado para en frutales de pepita y viñedo, representa un avance significativo en la estandarización de la dosis en los ensayos oficiales de eficacia. Facilita la evaluación zonal y el reconocimiento mutuo en el Sur de Europa.
4. Ajuste de la dosis: En el ajuste de la dosis se pueden tener en cuenta otros parámetros como por ejemplo: la anchura de la copa, el estadio vegetativo del cultivo y la técnica de aplicación.
5. Los sistemas DOSA3D y DOSAVIÑA para el establecimiento de volúmenes de caldo ajustados son de gran utilidad. También pueden ser útiles otros datos adicionales sobre las condiciones del tratamiento como la asistencia de aire, la presión de trabajo y la velocidad de avance.
6. Sería conveniente disponer de un único sistema de ajuste reconocido oficialmente.
7. La etiqueta de los productos fitosanitarios podría mejorarse incorporando, por ejemplo, instrucciones específicas como el volumen de caldo a aplicar, el tipo de pulverización, y el tipo de boquilla.
8. El contenido de la etiqueta debe ser diáfano, no sujeto a interpretación subjetiva y fácilmente llevable a la práctica, reflejando las técnicas actuales de aplicación de productos fitosanitarios.

- Classificació d'equips i components – DE, FR



Dose response curve for two spraying efficiency levels

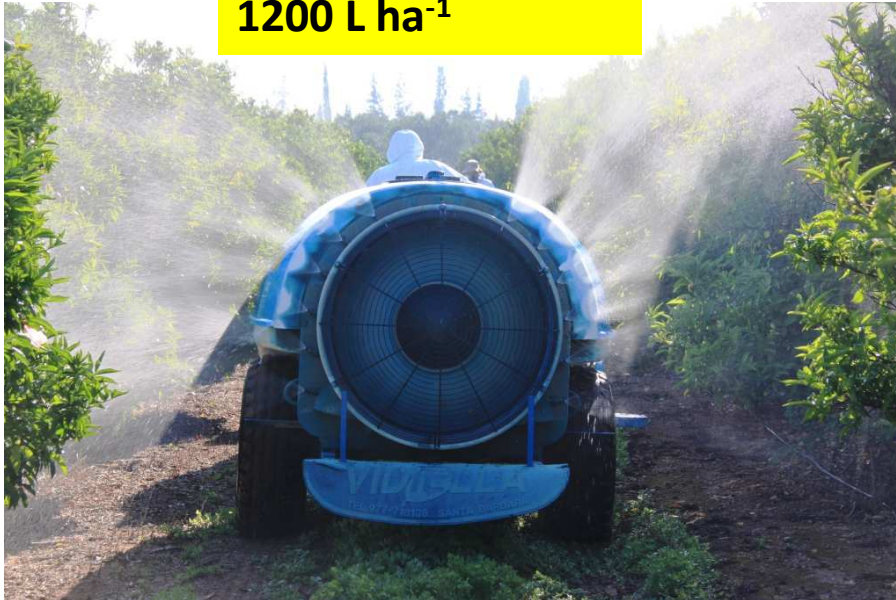




ABS

Efficiency = 40-55%

1200 L ha⁻¹



August 2014 ES-Tortosa

ABS w/ deflectors

Efficiency = 60-70%

800 L ha⁻¹



July 2013. ES-Alcarràs



Generalitat de Catalunya
Departament d'Agricultura,
Ramaderia, Pesca i Alimentació



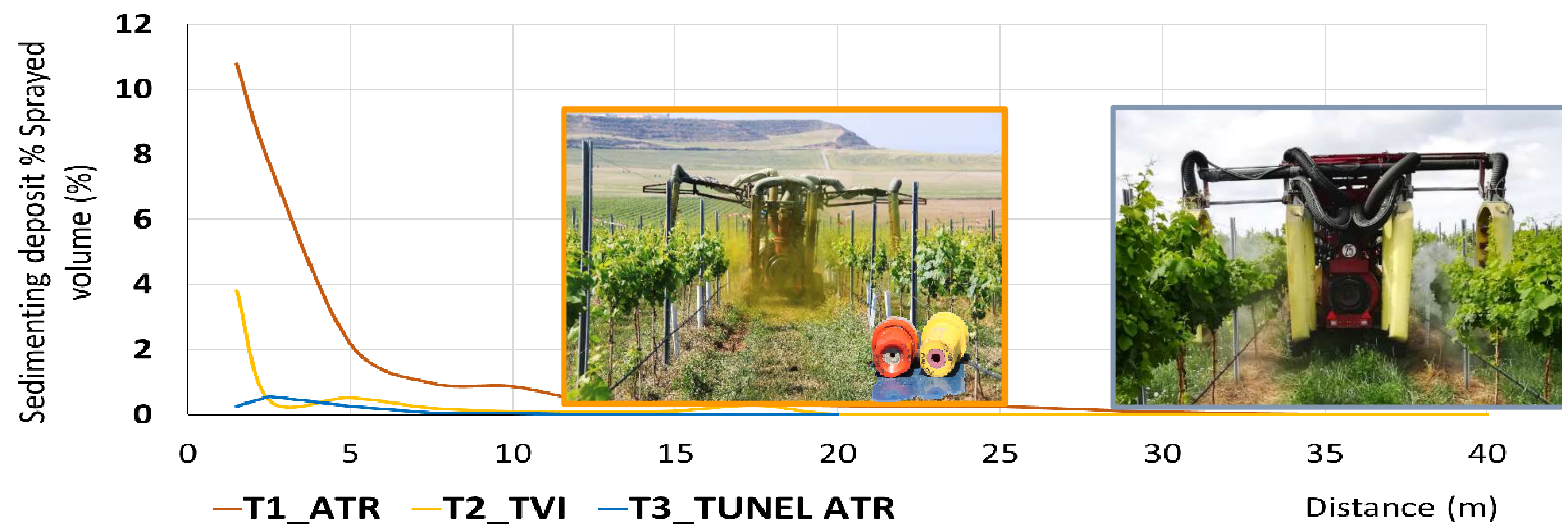
Universitat
de Lleida

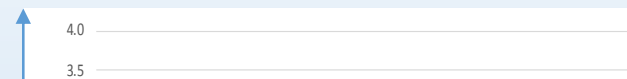
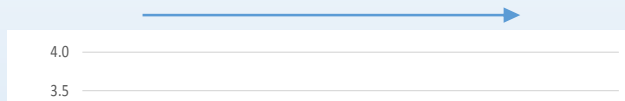
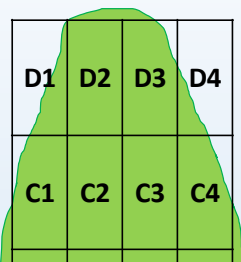
- **Avaluació eficàcia, metodologia**



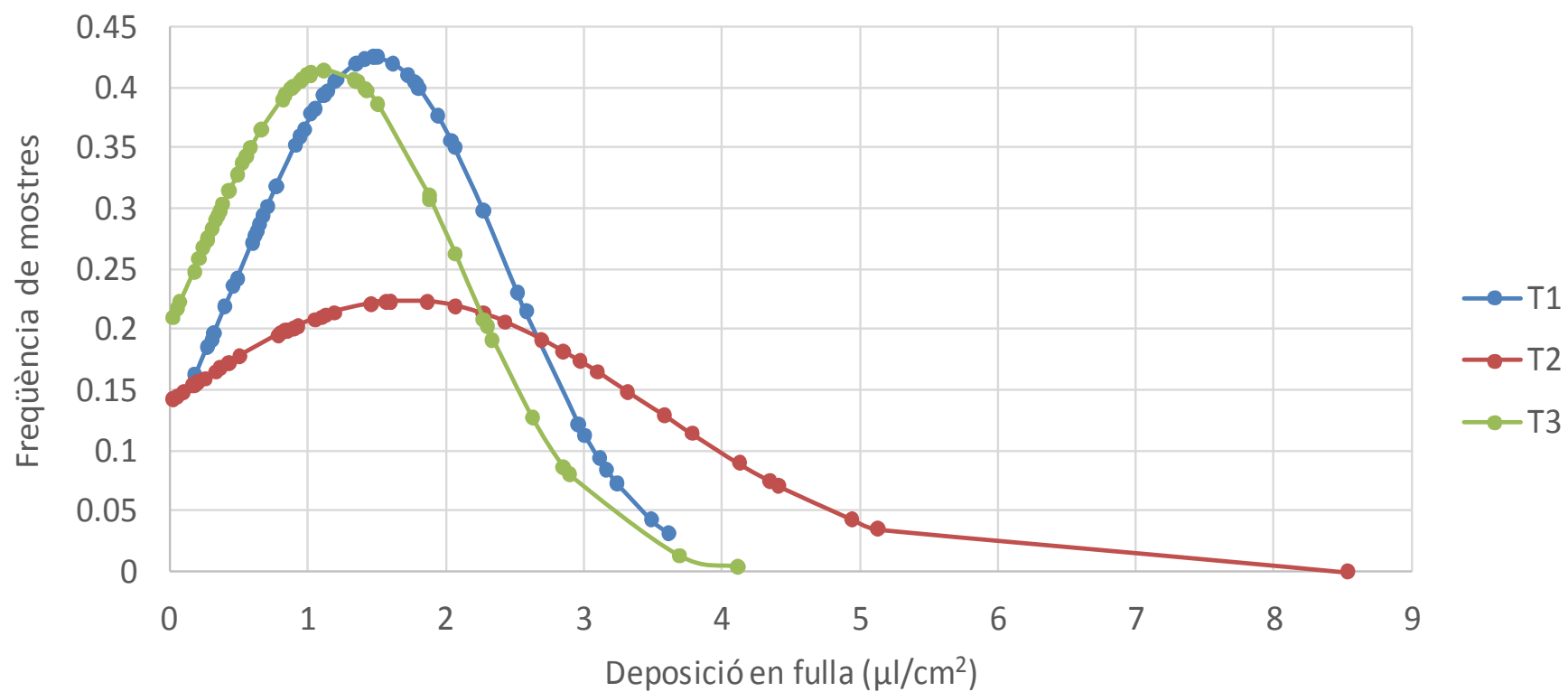
19 juliol 2018

- Mesura de la deriva (ISO 22866:2006)



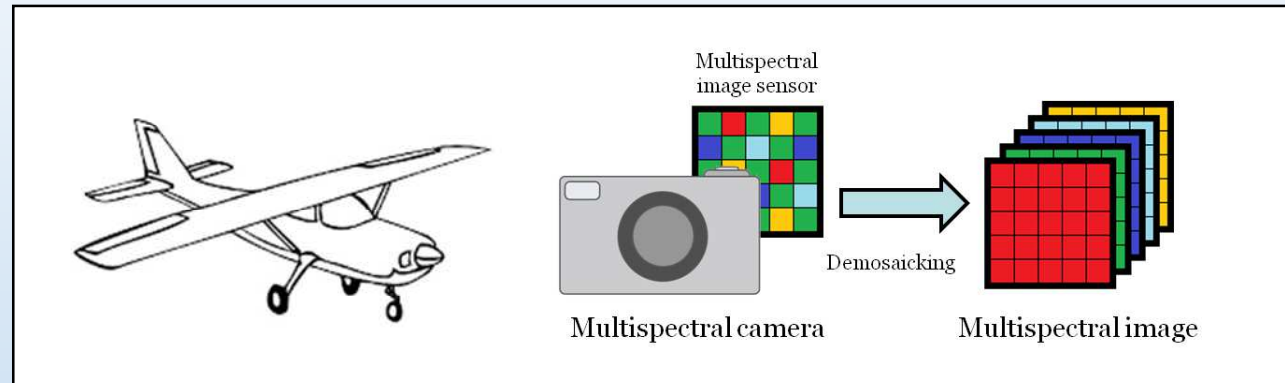


Anàlisi de la freqüència de la deposició en fulla (POMERA)



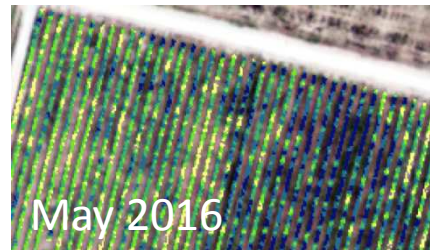
- Tractaments de precisió: dosi zonal

Data acquisition

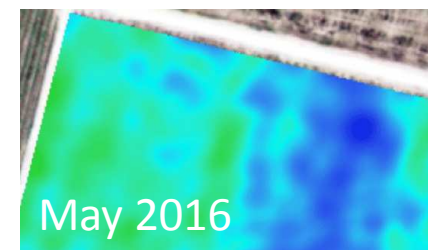


Data processing

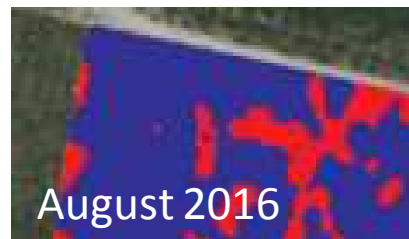
$$PCD = \frac{NIR}{R}$$



Delete interrow pixels



Raster map

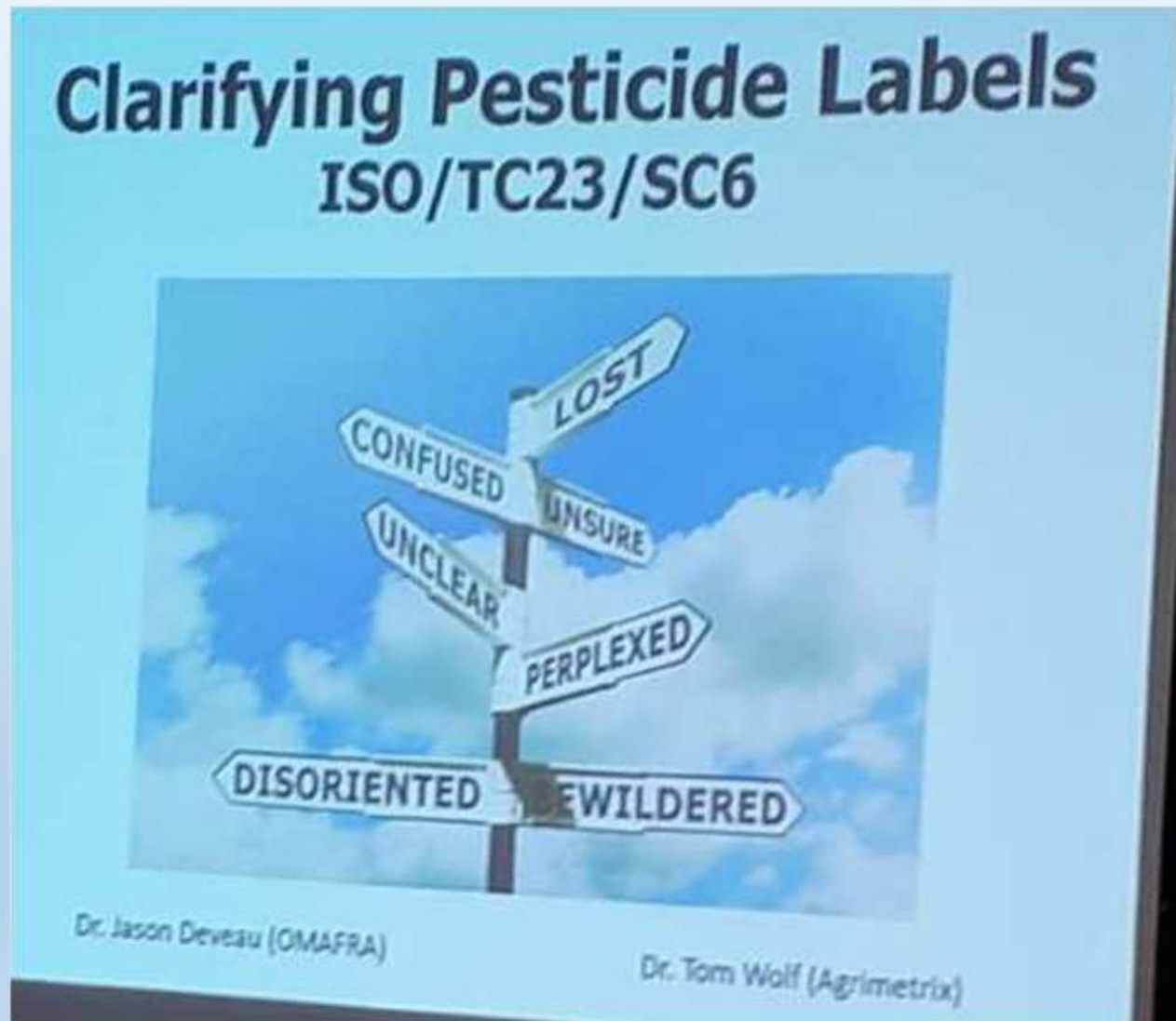


Two PCD classes



Final application map

- **Registre, fitxa tècnica, etiquetes – SC6**



Consideracions finals

- preocupació
- ocupació
- evolució legislativa
- harmonització
- + restriccions
- mitigació del risc
- + professionalització
- + especialització
- Rol experts-assessors





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Generalitat de Catalunya
Departament d'Agricultura,
Ramaderia, Pesca i Alimentació



Universitat
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