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PHYTOPHARMACOVIGILANCE

**THE VIGILANCE SYSTEM THAT COLLECTS AND ANALYSES
MONITORING DATA ON PLANT PROTECTION PRODUCTS**

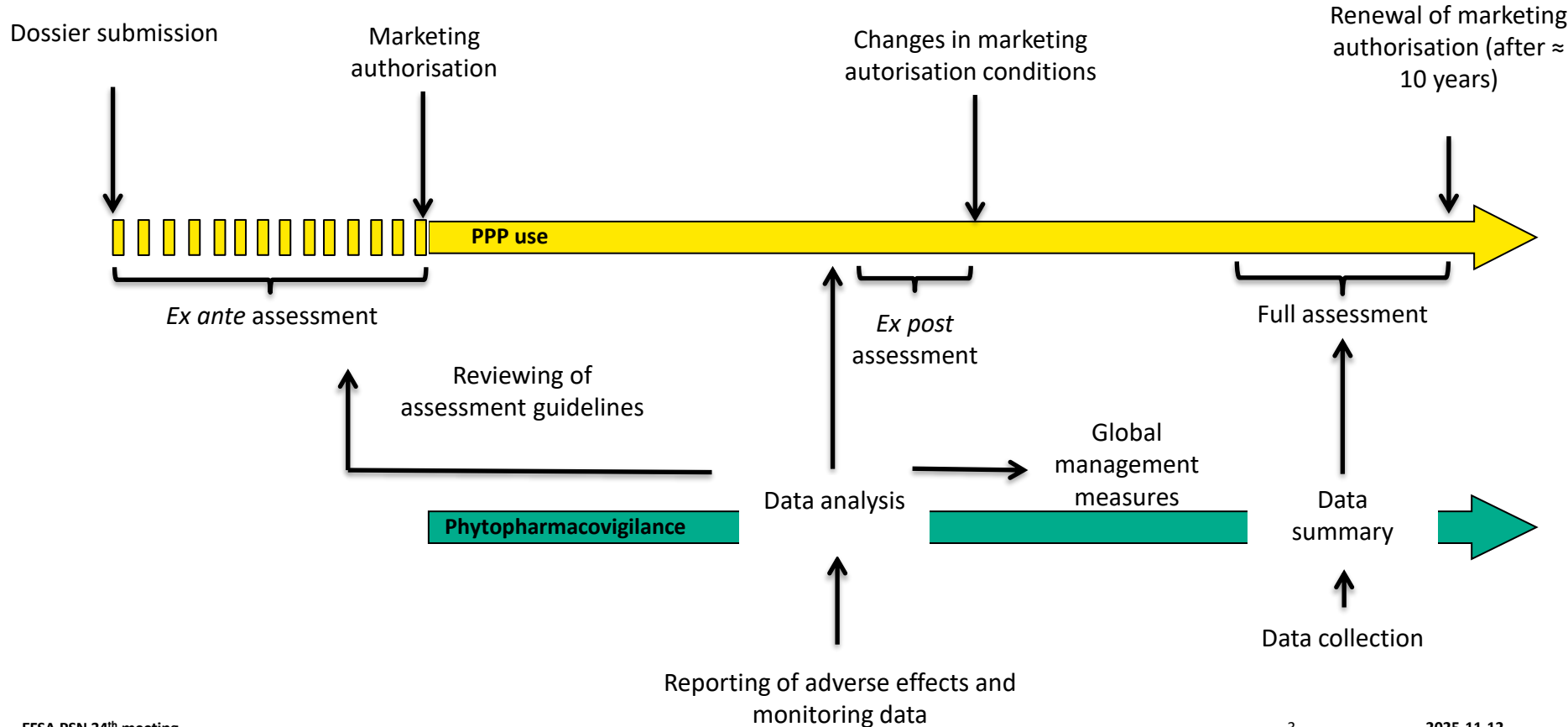
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EFSA PESTICIDE STEERING NETWORK 34TH MEETING

INVESTIGATE, EVALUATE, PROTECT

- French Act on the future of agriculture, food and forestry of 13 October 2014
 - Monitor the adverse effects of plant protection products available on the market, covering the contamination of environments, exposure and its impacts on living organisms and ecosystems, and phenomena of emergence of resistance
- Part of the « Stratégie Ecophyto 2030 », the current French National Action Plan, transposition of the Sustainable Use of Pesticides Directive (2009/128/EC)
- Indirectly funded by a tax on sales of plant protection products payable by the marketing authorisation holders

Phytopharmacovigilance in the global PPP regulation framework



20 partner monitoring and vigilance schemes

Monitoring of environmental media

- Surface water (Ministry of Ecology, OFB, BRGM)
- Groundwater (BRGM)
- Coastal water (Ifremer)
- Drinking water (Ministry of Health)
- Soil (GIS SOL)
- Food and feed (Ministry of Agriculture)
- Ambient air (AASQAs and LCSQA/INERIS)
- Indoor air (OQEI/CSTB)
- Human blood concentrations (*Santé publique France*)
- Bee matrices (ITSAP – Bee Institute)

Plant pest resistance (Ministry of Agriculture)

Sale and use of PPPs

- Sales (OFB)
- Surveys of cropping practices (Ministry of Agriculture)

Effects on human health

- Toxicovigilance in agricultural workers (MSA)
- Toxicovigilance in the general population (CAPTV)
- Agrican cohort (François Baclesse Centre)
- Chronic occupational diseases (ANSES-RNV3PE)
- BDMAs (MSA)

Effects on animal health

- Veterinary toxicovigilance (CAPAE-Ouest, VetAgroSup)
- Toxicovigilance in wildlife (OFB)
- Acute mortality of adult bees (Ministry of Agriculture)
- 500 ENI network (Ministry of Agriculture)

Phytopharmacovigilance fact sheets for an active substance

- 61 files published since 2017
- Only in French (but lots of tables with figures)


How much the substance is searched

How much the substance is quantified

How much the substance exceeds toxicological thresholds

Phytopharmacovigilance

Synthèse des données de surveillance
Appui scientifique et technique
n°2017-04



Glyphosate

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Préambule

Le glyphosate a été intégré au programme de travail de la phytopharmacovigilance complexe dans le cadre de la mise à disposition de la substance active en 2017, au moment où les données de surveillance des résidus de la substance active ont été mises à disposition.

Sauf mention contraire, les informations communiquées dans cette fiche, sont celles disponibles au 31/12/2017 et concernent la France entière (France Métropolitaine et Départements et Régions d'Outre-Mer (DROM)).

Ce document décrit, pour une substance active et certains de ses métabolites, l'état des connaissances disponibles en France à partir des informations descriptives issues des dispositifs nationaux de la phytopharmacovigilance.

L'ensemble des dispositifs de surveillance et de vigilance relatifs à la substance sont décrits dans la notice explicative.

Ces informations descriptives sont :

- aux gestionnaires, pour la définition de mesures de gestion transversales en tant que de bon sens ;
- à l'usage, dans le cadre de décisions individuelles liées au processus d'octroi des autorisations de mise sur le marché des produits phytopharmaceutiques, en complément des informations mises à disposition par les demandeurs. Cette information est relative pour chaque préparation, en tenant compte de leur formulation et des conditions d'utilisation.

Les services déconcentrés de l'Etat sont chargés de la gestion locale des données individuelles de dépassement des seuils réglementaires signalés dans ce document.

La présente fiche regroupe les données pour le glyphosate et son métabolite, l'acide aminométhylphosphonique (AMPA).

Year by year,
at the national
scale

Glyphosate		Zone : Métropole						
Année	Description des résultats de surveillance			Risque chronique			Risque aigu	Potabilité
	Points paramètre : N (%)	Nb analyses	Analyses quantifiées : N (%)	Point(s) où moy. ann. > NQE/VGE : N (%)	Point(s) où moy. ann. > PNEC : N (%)	Moy. ann. max. en µg/L	Analyses où quantif. > MAC : N (%)	Dépassements du 2 µg/L : N (%)
2005	367 (74,3)	2 424	979 (40,4)	0	0	4,287	0	19 (0,78)
2006	596 (70,1)	4 352	688 (15,8)	0	0	2,402	0	11 (0,25)
2007	849 (49,6)	5 185	1 070 (20,6)	0	0	20,088	1 (0,02)	28 (0,54)
2008	1 016 (70,4)	5 742	1 605 (28)	0	0	4,619	0	26 (0,45)
2009	1 153 (58,7)	7 236	1 749 (24,2)	0	0	4,965	0	41 (0,57)
2010	1 472 (75,6)	7 951	1 543 (19,4)	0	0	2,5	0	24 (0,3)
2011	1 521 (77,4)	9 383	2 689 (28,7)	0	0	8,627	0	22 (0,23)
2012	1 634 (68,8)	8 497	2 741 (32,3)	0	0	11,008	0	27 (0,32)
2013	1 868 (67,4)	12 242	4 596 (37,5)	0	0	6,392	0	30 (0,25)
2014	2 026 (72,2)	13 961	5 375 (38,5)	1 (0,05)	0	70,151	1 (0,01)	38 (0,27)
2015	2 535 (82)	18 485	7 890 (42,7)	0	0	10,262	0	56 (0,3)
2016	2 757 (94,4)	17 954	9 230 (51,4)	0	0	7,65	0	82 (0,46)
2017	2 766 (96,7)	18 874	9 567 (50,7)	0	0	10,875	1 (0,01)	125 (0,66)
2018	2 834 (91,6)	19 120	8 870 (46,4)	0	0	9,271	0	119 (0,62)
2019	2 568 (95,5)	17 374	7 156 (41,2)	2 (0,08)	1 (0,04)	258,201	2 (0,01)	50 (0,29)
2020	2 358 (98,2)	14 934	5 838 (39,1)	0	0	4,061	0	38 (0,25)
2021	1 307 (97,7)	4 595	2 027 (44,1)	0	0	1,437	0	10 (0,22)

Monitoring data transmission for the peer reviewed assessment of active substances approvals

Example of folpet

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)

No monitoring data available

Surface water (indicate location and type of study)

No monitoring data available

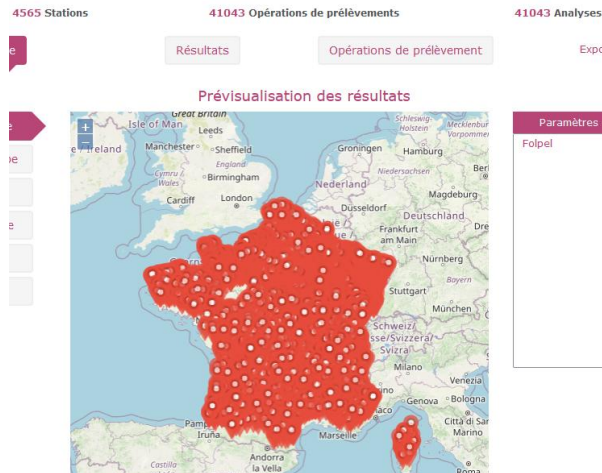
Ground water (indicate location and type of study)

No monitoring data available

Air (indicate location and type of study)

No monitoring data available

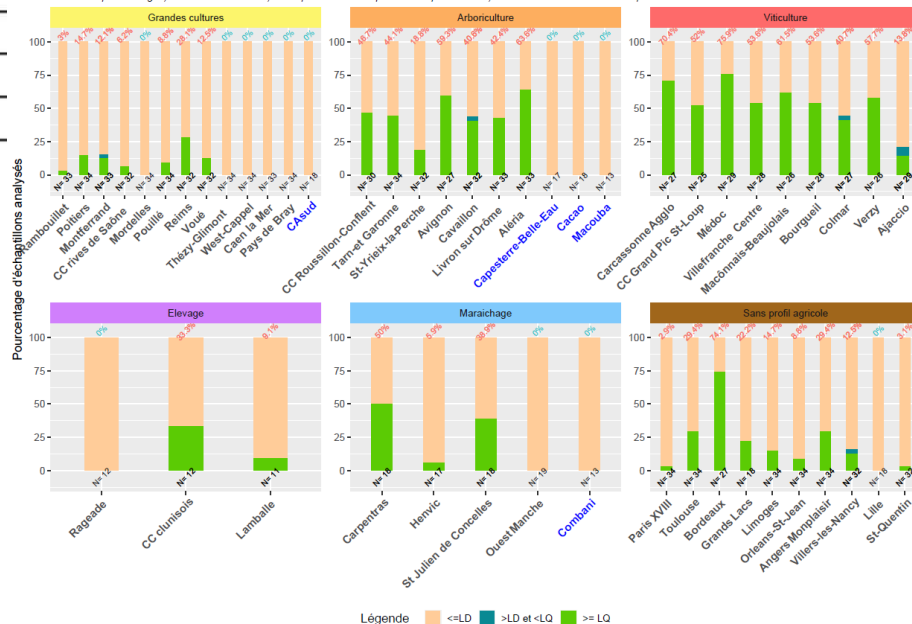
Folpet in surface water



Results of the national exploratory campaign to measure pesticides in ambient air

Folpet - Bilan de la campagne en fonction des sites et des cultures

Notes : les pourcentages, au dessus des barres, correspondent aux fréquences de quantification, les valeurs notées 'N' = ' correspondent au nombre d'échantillons

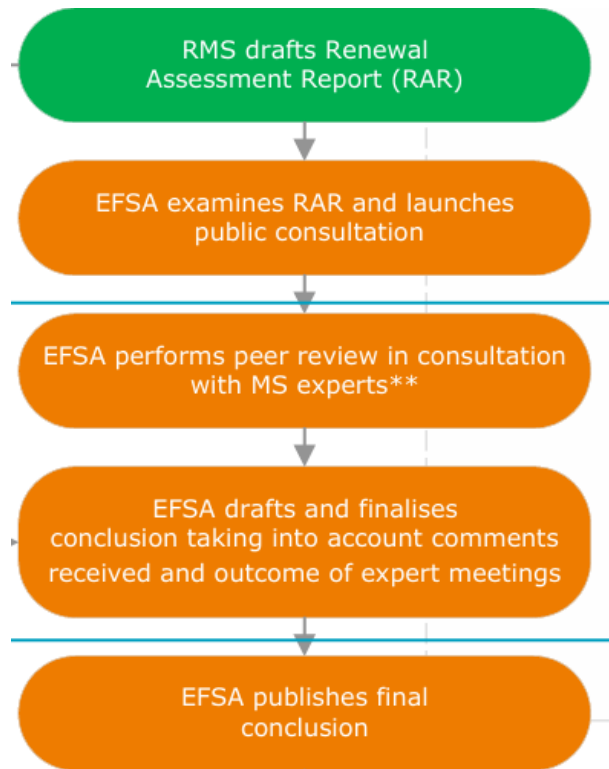


PPV data submission at EU level

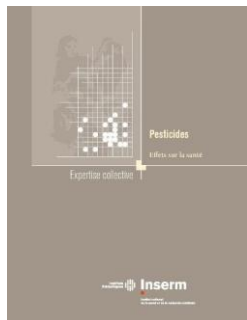
Most relevant step? →

PPV fact sheets for active substances identified through a prioritization process to be defined (e.g., based on level of use criteria and the inherent hazard of the substance)

In order to contribute to the re-evaluation of active substances at the European level



Analysis of INSERM collective expert review on effects of pesticides on health: methods



		Level of presumption of link		
		Strong ++	Moderate +	Weak ±
Exposure accuracy	Approved active substance or family of active substances containing at least one approved substance	Alert	Validated signal	Weak signal
	Non-approved active substance or family of active substances containing only non-approved substances	Signal not qualified		
	Pesticides (without distinction)	Out of the PPV scope		

Analysis of INSERM collective expert review on effects of pesticides on health: Alerts & validated signals

Exposure	Health outcomes	Pyrethroids	Deltamethrin	OP	Malathion	Glyphosate	2,4-D	Carbamates	Triazines	Phenoxy herbicides
Prenatal exposure	Children's motor or neuropsychological development	Alert		Alert	Validated signal					
	Fetal growth			Validated signal						
	Autism spectrum disorder (ASD)			Validated signal						
Domestic exposure	Non-Hodgkin lymphoma (NHL)			Validated signal						
Occupational exposure	Non-Hodgkin lymphoma (NHL)			Alert	Alert	Validated signal	Validated signal	Validated signal	Validated signal	
	Prostate cancer				Validated signal					
	Hypothyroidism				Validated signal					
	Leukemia		Validated signal		Validated signal					
	Sperm damage	Validated signal		Validated signal						
	Cognitive disorders in adults			Alert						
	Soft tissue and visceral sarcomas									Validated signal



Alert

Validated signal

Data taken solely from the Inserm 2013 collective report

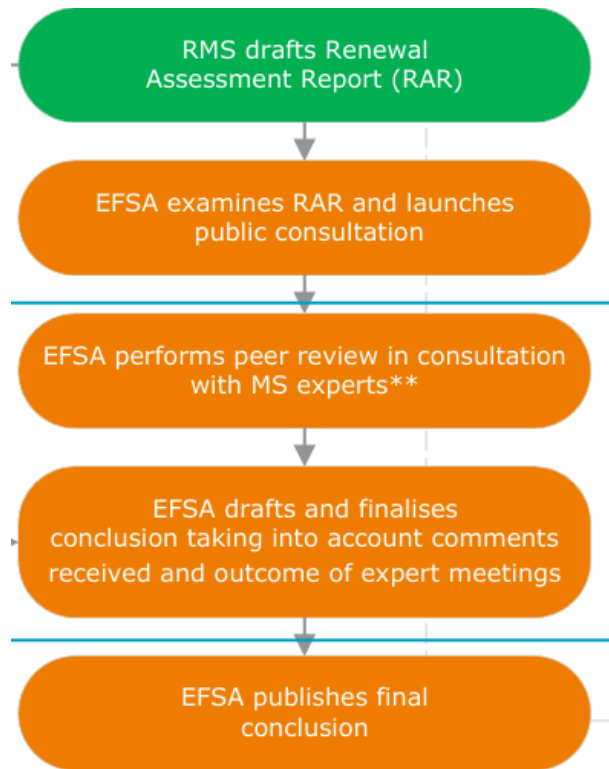
PPV alerts submission at EU level

Most relevant step? →

Alerts & validated signals for malathion and authorized pyrethroids (summary of the analysis)

+ PPV fact sheets for each pyrethroid active substance.

In order to contribute to the re-evaluation of active substances at the European level.



PPV alerts submission at EU level

AS	Expiry of approval	RMS
Malathion	2026/01/31	RMS=CZ
Esfenvalerate	2026/05/31	SA CfS, RMS=AT, coRMS=PT
Deltamethrin	2026/08/15	RMS=AT, coRMS=SE
Lambda-cyhalothrin	2026/08/31	RMS=EL, coRMS=FR
Tau-fluvalinate	2027/01/31	RMS=DK, coRMS=DE
Tefluthrin	2027/05/31	RMS=HU, coRMS=DK
Cypermethrin	2029/01/31	RMS=BE, coRMS=DE

➔ Necessary to monitor the progress of the evaluation of the active substance to share the PPV data at the most relevant time

PestiRiv: a study on the exposure to pesticides of people living in wine-growing areas



1 946 adults (18-79 y/o) and 742 children (3-17 y/o)

Number of samples analysed:



Urine
3 484



Hair
1 890



House dust
790



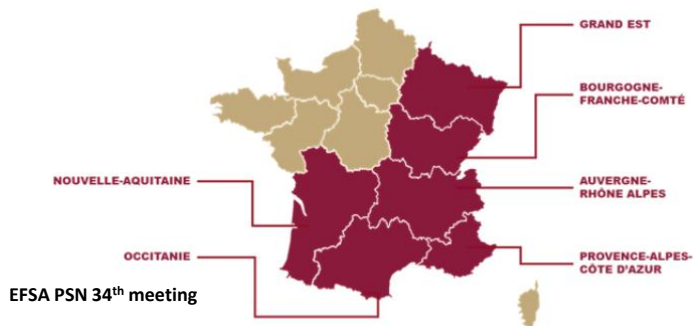
Indoor air
333



Outdoor air
1 557



**Garden fruits
and
vegetables**
106



October 2021-February 2022

Non-treatment period

March-August 2022

Treatment period

Key findings of the study



Urine



Hair



House dust



Indoor air



Outdoor air

Higher exposure in wine-growing areas than in areas far from any crop

In wine-growing areas: higher exposure during treatment periods than during non-treatment periods

Key findings of the study

Factors influencing pesticide exposure in wine-growing areas

- **Mainly agricultural practices:** exposure increases with the amount of pesticides used, and when the distance between housing and vineyards decreases
- **Contact with the environment:** exposure increases with the amount of time the home is ventilated and with the amount of time spent outdoors
- **Certain everyday habits and home improvements reduce exposure:**
 - taking the shoes off
 - cleaning home at least once a week
 - drying the laundry indoors
 - ventilation system
 - peeling fruit from the garden and limiting the consumption of eggs from domestic chicken coops

- **A scheme still young ...**
 - Phytopharmacovigilance set up in 2015
- **... But publish results and useful for PPP regulation**
 - AS fact sheets, analysis reports, funded studies results, *10-year report*
- **A network of networks**
 - 20 partners providing and analyzing data
- **Still unique in the EU**
 - In the integrated way France has set up
- **PPV data and alerts submission at the EU level**
 - Relevant moments and recipients



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THANK YOU FOR YOUR ATTENTION