PHYTOPHARMACOVIGILANCE

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

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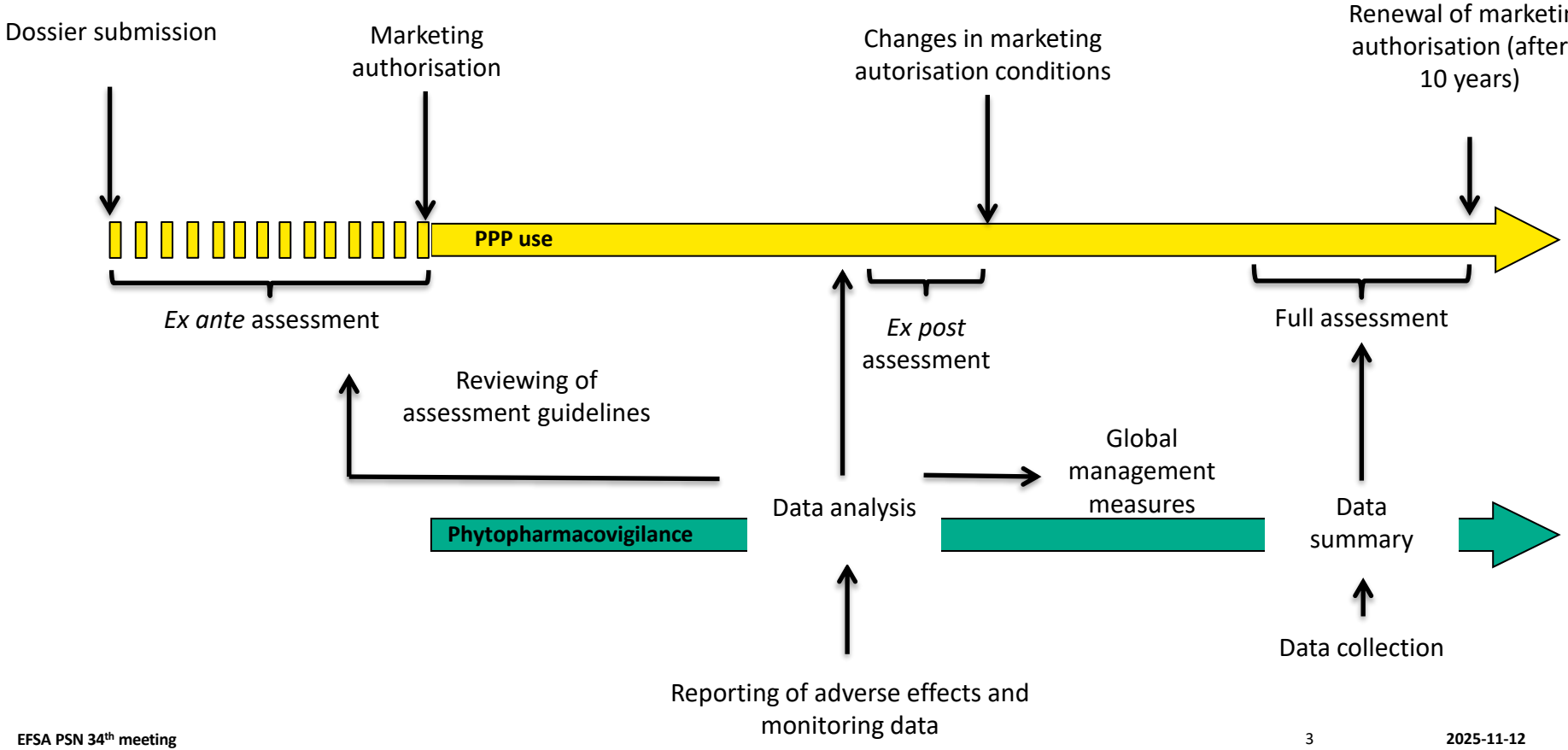
EFSA PESTICIDE STEERING NETWORK 34TH MEETING

INVESTIGATE, EVALUATE, PROTECT

National legal framework of phytopharmacovigilance

- 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

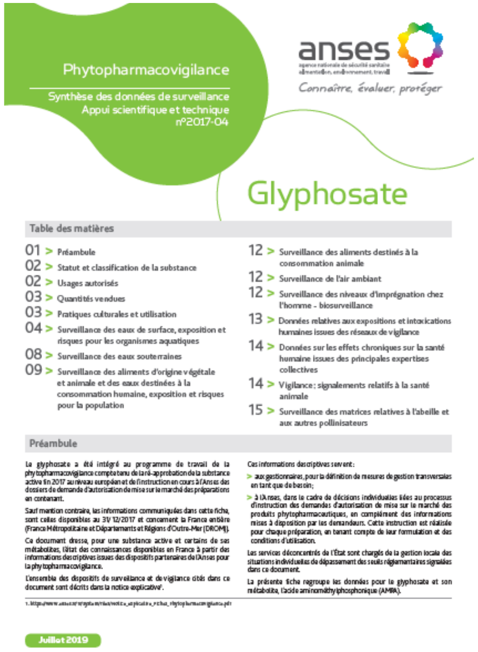
- Toxicovigilance in agricultural workers (MSA)
- Toxicovigilance in the general population (CAPTV)
- Agrican cohort (François Baclesse Centre)
- Chronic occupational diseases (ANSES-RNV3PE)
- BDMAs (MSA)

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)



Year by year, at the national scale

How much the substance is searched | How much the substance is quantified | How much the substance exceeds toxicological thersholds

Glyphosate	Zone : Métropole							
	Description des résultats de surveillance			Risque chronique			Risque aigu	Potabilité
Année	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)

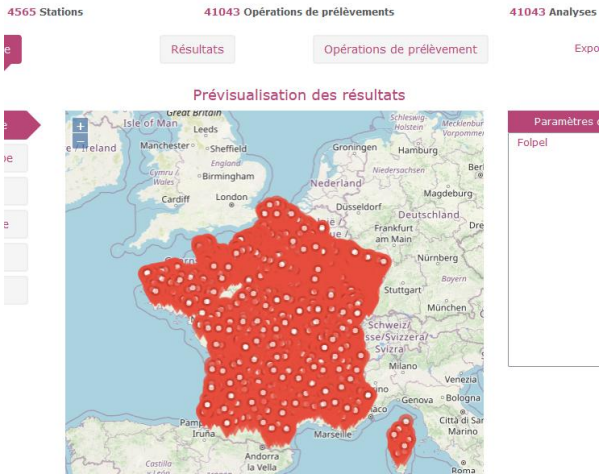
Monitoring data transmission for the peer reviewed assessment of active substances approvals

Example of folpet

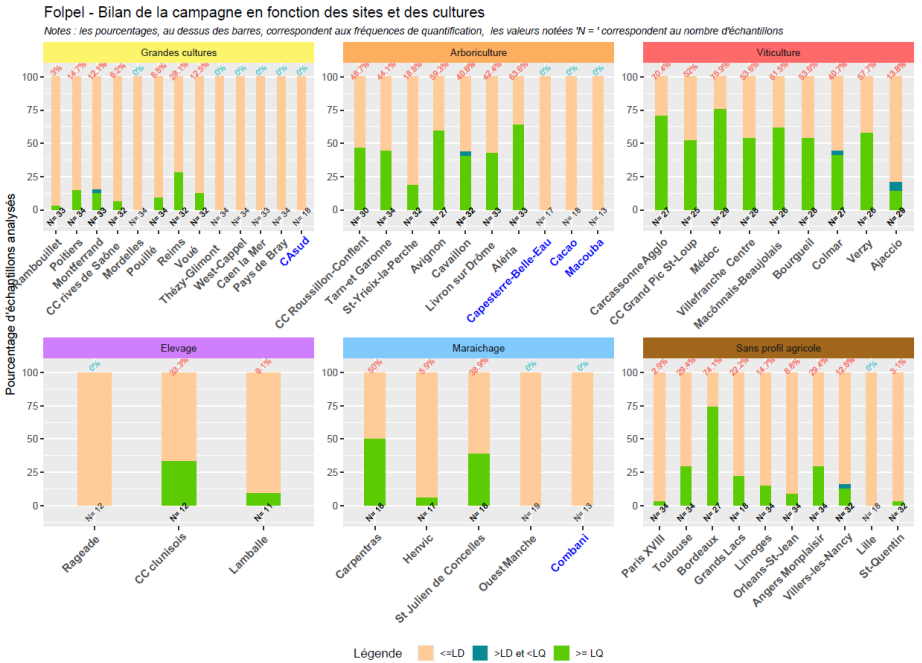
Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5

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



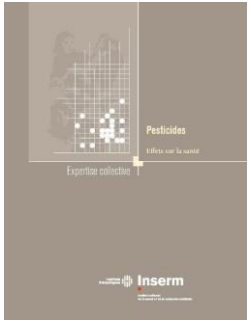
PPV data submission at EU level

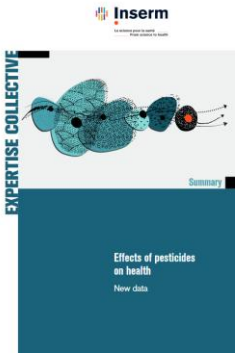
Most relevant step? →

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 + Data taken solely from the Inserm 2013 collective report	Validated signal + Data taken solely from the Inserm 2013 collective report					
	Fetal growth			Data taken solely from the Inserm 2013 collective report						
	Autism spectrum disorder (ASD)			Validated signal						
Domestic exposure	Non-Hodgkin lymphoma (NHL)			Data taken solely from the Inserm 2013 collective report						
Occupational exposure	Non-Hodgkin lymphoma (NHL)			Alert + Data taken solely from the Inserm 2013 collective report	Alert + Data taken solely from the Inserm 2013 collective report	Validated signal	Data taken solely from the Inserm 2013 collective report	Data taken solely from the Inserm 2013 collective report	Data taken solely from the Inserm 2013 collective report	
	Prostate cancer				Validated signal					
	Hypothyroidism				Validated signal					
	Leukemia		Validated signal		Validated signal					
	Sperm damage	Data taken solely from the Inserm 2013 collective report		Data taken solely from the Inserm 2013 collective report						
	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

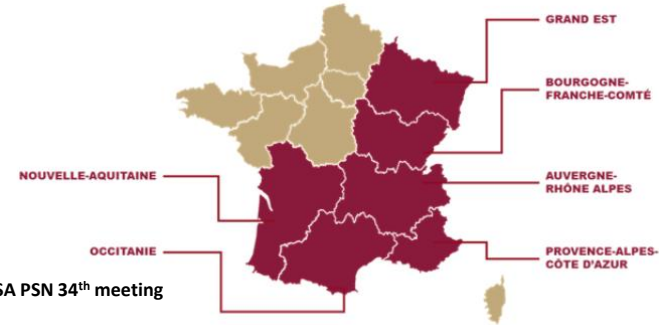
➔ Necessary to monitor the progress of the evaluation of the active substance to share the PPV data at the most relevant time

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	March-August 2022
Non-treatment period	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

Conclusions and outlooks

- **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

THANK YOU FOR YOUR ATTENTION