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10 years of **Phytopharmacovigilance** in France

Review of the only organisation of its kind in Europe for post-MA vigilance of plant protection products

September 2025

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Preamble

Ten years of phytopharmacovigilance in France
Review of the only organisation of its kind in Europe for post-MA vigilance of plant protection products

ANSES has been running the phytopharmacovigilance scheme ever since it was set up under the French Act on the future of agriculture, food and forestry of 2014, supported by a network of 20 partners. To mark the tenth anniversary of the scheme, ANSES decided to publish a review to give some perspective to the actions and results of the work carried out under this vigilance scheme. By highlighting the unique features of phytopharmacovigilance, this review sheds light on the health issues specific to plant protection products and the importance of adopting a "One Health" approach to understanding the associated risks, for humans and ecosystems alike.

In addition to this activity review, ANSES has drawn three main lessons from its look back at the last 10 years:

Phytopharmacovigilance (PPV) is essential to effective management of the health and societal risks associated with plant protection products.

Why? Because the risk assessments carried out before products are placed on the market, even if they can draw on considerable data and efforts at European and national levels, do not remove the need to show humility in the face of real-life observations and be receptive to new knowledge: not everything can be predicted or modelled.

By allowing products to be banned or their conditions for use to be amended in light of lessons learned in the field, PPV meets not only a health imperative, but also a societal and political one. Indeed, many of the debates around plant protection products stem from a lack of assurance that all their effects have been controlled, particularly those in the medium or long term on human health, water quality and the impact on natural environments.

This link in the risk management chain is all the more essential since, unlike other economic activities that generate risks, no systematic surveillance by the MA holder is legally required, whereas in other contexts (e.g. classified facilities for environmental protection), it is a key lever for verifying the prudence of *ex ante* forecasts against the reality observed on the ground.

PPV thus helps to guide the collective effort to control risks by weighing up the information provided by the academic literature and the results of real-life measurements, and by drawing attention to and helping to fill gaps in data.

It usefully supplements and substantiates public policies designed to limit the use of plant protection products to only what is strictly necessary, at national level with the Ecophyto plans, as well as at European Union level.

A groundbreaking French organisation, the PPV scheme reflects an ambitious "One Health" attitude that regularly benefits ANSES as both an assessor and a signatory to decisions on the authorisation, revision and withdrawal of marketing authorisations for plant protection products.

This ambitious vigilance scheme is unique in several respects.

Firstly, PPV concentrates on all the potential effects from applying these products: on the health of workers and the general population, but also on the flora and fauna that are not targets of plant protection treatments and, more generally, on environments and ecosystems. This ability to take a broad view is rooted in the quality of the network of partners it mobilises and the diversity of those who contribute to it through their reporting: professionals in the sector (companies marketing the products, users) or in human and animal health, but also the general public through the online reporting form.

Secondly, whereas most vigilance schemes are good at detecting obvious and immediate adverse effects, this one endeavours to capture chronic effects, i.e. those that occur in the longer term, following moderate and repeated exposure. As well as being attentive to health signals, it regularly funds initiatives to improve its "sensors" by supporting work on the methods and mechanisms used by the network's partners to collect information.

Lastly, PPV is a theme inextricably linked with ANSES's other entities, and the scheme regularly provides input for the Agency's risk assessment activities and regulatory decisions on plant protection products, playing a part at all levels of risk governance. It contributes through:

- identifying signals by analysing the literature, in particular on underestimated hazards;
- encouraging and preparing for changes in the conditions for monitoring the environment and different media, by deploying studies or measurement campaigns in air, food, etc. (CNEP, TDS, etc.);
- calling for existing MA decisions to be reconsidered, with a view to withdrawing them or regulating them more strictly (e.g. metam-sodium, S-metolachlor);
- taking another look at the *ex-ante* assessment models applied to the examination of authorisation applications and the decision rules, to ensure that they continue to provide protection from adverse effects observed in real life (e.g. accumulation of S-metolachlor in environmental water, atmospheric dispersion of prosulfocarb);
- classifying and processing reports from the research community (e.g. on SDHIs) or civil society, particularly with regard to local situations (e.g. the report concerning the commune of Preignac).

To fulfil its mission, the PPV scheme can count on a dedicated, highly committed team, active in-house dialogue, a group of mobilised experts and a diverse community of partners. Other ANSES vigilance schemes, such as toxicovigilance, also provide occasional sources of feedback from the field.

While PPV has made a real contribution to managing the risks of plant protection products in recent years, it could do more – and more quickly – if clearly identified changes were made.

PPV is related to the pharmacovigilance implemented for medicines, another class of products that harness modes of action based on targeted toxicity for therapeutic purposes. There are two notable differences: in human and veterinary medicine, prescription and vigilance requirements are the rule rather than the exception, and are governed by European provisions.

In view of this comparison, but also of some of the limitations encountered by the PPV scheme during its first decade of activity, one solution would be to provide access to data on the application of plant protection products (products used – their type and quantity – by crop and plot) in a form that is easy to use, i.e. digitised. Such data, collected over the long term, would save a great deal of time and improve the precision of the PPV surveillance and vigilance work. This is because its scientific results are repeatedly penalised by the need to circumvent the lack of information by setting up complex, lengthy and costly investigations based on approximations of exposure sources and levels. More generally, the PPV scheme's output makes a valuable contribution to the debate on data and database interoperability, as well as to the creation of new datasets built with this in mind, in order to promote the identification of links between environmental data and health, whether it concerns humans, animals, plants or the environment.

The next step forward would be to encourage the move away from a purely French scheme to a Europe-wide network. The wider the scope of field experience it scrutinises, the more effective the vigilance system. Broadening it to the European level would provide new perspectives and data on a wider variety of climates, soils, uses, etc. This development would be especially relevant since the system for assessing and authorising plant protection products already benefits from complementary national and European skills. Steps in this direction have been taken with the public authorities and the European Food Safety Authority (EFSA), in particular.

As well as their advantages in terms of improved control over the use of plant protection products and greater transparency in the side effects of their use, these changes would enable PPV to free up resources and build its strength for its core mission: to have a powerful tool at its disposal for encouraging the ongoing adjustment of authorisations for products available on the market.

Lastly, in line with its "One Health" approach, the PPV scheme will focus in coming years on gaining insights into how best to safeguard soil health and groundwater quality, and preserve biodiversity.

Pr Benoit VALLET

Ten years of phytopharmacovigilance in France

Review of the only organisation of its kind in Europe for post-MA vigilance of plant protection products

Scientific and technical support REPORT

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Phytopharmacovigilance, plant protection products, pesticides, adverse effects, monitoring, vigilance, signals, warnings, reporting, observational data, exposure, residues, human health, animal health, plant health, epidemiology, biodiversity, environment, food, resistance.

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Summary

Phytopharmacovigilance consists in identifying signals of adverse effects on human, animal and plant populations and the environment associated with the use of plant protection products, and reporting them to the various bodies responsible for assessing and managing risks. To do this, the PPV scheme collects and analyses data, and classifies the nature of the signals accordingly. These data come from the network of phytopharmacovigilance partners and the literature monitoring conducted by ANSES, which mainly focuses on research into chronic health effects. The PPV scheme also receives reports directly from professionals and private individuals.

On several occasions, signals of adverse effects assessed by phytopharmacovigilance have led ANSES to amend the conditions for use in marketing authorisations (MAs), or even to withdraw the MAs, in application of Article 44 of European Regulation (EC) No 1107/2009.

Phytopharmacovigilance produces summaries of the surveillance and vigilance data available for active substances, in particular when their MAs are periodically re-examined and in addition to the *a priori* assessments updated in this context. These summaries can help highlight any specific problematic situations that were not identified through the representative uses predefined at European level for conducting European re-assessments of active substances.

Phytopharmacovigilance also funds research in situations where the data collected as mentioned above are not sufficient for analysing and classifying signals of adverse effects. The funded projects concern the production of surveillance data for a given environment, or the analysis of existing data. They may also investigate ways to improve how the phytopharmacovigilance partners operate.

Phytopharmacovigilance can also inform its partners of the needs that have been identified in terms of surveillance data, for example, based on its work to prioritise the substances to be monitored.

This document presents a review of all the phytopharmacovigilance activities concerning all the aspects mentioned above, carried out since the scheme became operational on 1 July 2015.

France's phytopharmacovigilance scheme is the only one of its kind in Europe. Its extension to the other Member States, with the aim of sharing surveillance data and improving the identification of adverse effect signals at European level, is one of the strategic orientations of the phytopharmacovigilance scheme for the period 2024–2028.

Acronyms and abbreviations

500 ENI	:	Programme monitoring unintended effects on 500 plots
AASQA	:	Approved Air Quality Monitoring Association
AFNOR	:	French Standards Institute
AHS	:	Agricultural Health Study
AMLP	:	*Alerte des Médecins sur les Pesticides* association
AMPA	:	Aminomethylphosphonic acid
MA	:	Marketing authorisation
ANSES	:	French Agency for Food, Environmental and Occupational Health & Safety
AP-HP	:	Paris Public Hospital System
ARS	:	Regional Health Agency
BNCI	:	National database of poisoning cases
BNPC	:	National database on products and compositions
BNV-D	:	National database of sales of plant protection products by approved distributors
BRGM	:	Bureau of Geological and Mining Research
CAPTV	:	Poison Control and Toxicovigilance Centre
CAPAE-Ouest	:	Animal and Environmental Poison Control Centre for Western France
CEP	:	National Expert Committee for the Prioritisation of Aquatic Micropollutants
RAC	:	Committee for Risk Assessment (ECHA)
CESCO	:	Centre for Ecology and Conservation Sciences
CGAAER	:	High Council for Agriculture, Food, and Rural Areas
CGEDD	:	General Council for the Environment and Sustainable Development
CH(R)U	:	(Regional) University Teaching Hospital
IARC	:	International Agency for Research on Cancer
CLP	:	Classification, Labelling and Packaging
CNRS	:	National Centre for Scientific Research
CDPCI	:	Committee for Ethical Standards & Prevention of Conflicts of Interest
CRPM	:	French Rural and Maritime Fishing Code
CRPPE	:	Regional Occupational and Environmental Disease Centre
CSTB	:	Scientific and Technical Centre for Building

DD(ec)PP	:	Departmental Directorate for Protection of the Population
DEB	:	Directorate for Water and Biodiversity
DGAL	:	Directorate General for Food
DGALN	:	Directorate General for Land-Use Planning, Housing & Nature
DGCCRF	:	Directorate General for Competition, Consumer Affairs and Fraud Control
DGEC	:	Directorate General for Energy and the Climate
DGPR	:	Directorate General for Risk Prevention
DGS	:	Directorate General for Health
DGT	:	Directorate General for Labour
DMS	:	N,N-dimethylsulfamide
DMSA	:	N,N-dimethylsulfamic acid
DRAAF	:	Regional Directorate for Food, Agriculture and Forestry
DROM	:	French Overseas *Départements* and Regions
TDS	:	Total diet study
ECHA	:	European Chemicals Agency
ECOACS	:	Studies compiled on the unintentional effects of plant protection products
DW	:	Drinking water
EFSA	:	European Food Safety Authority
EPIC	:	Public industrial and commercial entity
ESCo	:	Collective scientific expert appraisal
ESTEBAN	:	Health study on the environment, biomonitoring, physical activity and nutrition
FNE	:	*France Nature Environnement* association
GIS	:	Scientific Interest Group
PPV WG	:	"Phytopharmacovigilance" Working Group
HCERES	:	High Council for Evaluation of Research and Higher Education
HBM4EU	:	Human Biomonitoring for Europe
HBM-GV	:	Human Biomonitoring Guidance Value
Ifremer	:	French Research Institute for Exploitation of the Sea
IGAS	:	General Inspectorate of Social Affairs
Ineris	:	National Institute for Industrial Environment and Risks

INRAE	:	National Research Institute for Agriculture, Food and the Environment
Inserm	:	National Institute of Health and Medical Research
InVS	:	Institute for Public Health Surveillance
IODA	:	Database for computerising and organising bee data
Irstea	:	National Research Institute of Science and Technology for Environment and Agriculture
ITSAP	:	Technical and Scientific Institute for Beekeeping and Pollination
LCSQA	:	Central Laboratory for Air Quality Monitoring
MRL	:	Maximum residue limit
NHL	:	Non-Hodgkin lymphoma
LVD	:	Departmental veterinary laboratory
MNHN	:	Natural History Museum
MSA	:	National Health Insurance Fund for Agricultural Workers and Farmers
OBSLAG	:	Observatory of Mediterranean Lagoons
OFB	:	French Biodiversity Agency
OMAA	:	Observatory for Honeybee Mortality and Weakening
ONCFS	:	National Office for Hunting and Wildlife
OQAI	:	Indoor Air Quality Observatory
OQEI	:	Indoor Environment Quality Observatory
ORP	:	Pesticide Residues Observatory
PAN	:	Pesticide Action Network
RMQS	:	Soil Quality Measurement Network
RNCE	:	National Register of Childhood Cancers
RNV3PE	:	National Network for Monitoring and Prevention of Occupational and Environmental Diseases
RTU	:	CAPTVs' emergency telephone hotline
SAGIR	:	Wildlife Disease Surveillance Network
SDHI	:	Succinate dehydrogenase inhibitor
SICAP	:	Poison control centres' shared information system
SSP	:	Department of Statistics and Foresight Analysis
STOC	:	Temporal monitoring of common birds
TFA	:	Trifluoroacetic acid
UIPP	:	French Crop Protection Industry Association

US EPA	:	United States Environmental Protection Agency
Vmax	:	Maximum health value

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1 Presentation of the phytopharmacovigilance scheme

Article L.253-8-1 of Act no. 2014-1170 on the future of agriculture, food and forestry, enacted on 13 October 2014, provided for "the establishment of a scheme for monitoring the adverse effects of plant protection products on humans, farm animals (including honeybees), crops, biodiversity, wildlife, water and soil, air quality and food, as well as on the emergence of resistance to these products". Under the same text, the implementation of the PPV scheme, as it is known, was entrusted to ANSES.

In anticipation of the Act's entry into force, the Agency organised a consultation, from mid-April to mid-October 2014, of ministries, stakeholders and the main operators of permanent schemes that could contribute to this vigilance scheme (ANSES, 2015). The objectives of this consultation were to:

- identify all the permanent schemes that could contribute to the new PPV scheme;
- identify similar reference surveillance schemes, particularly internationally;
- identify the priority phytopharmacovigilance needs to be taken into account;
- consult stakeholders on the organisational procedures for this PPV scheme.

At the end of the consultation:

- all phytopharmacovigilance scheme partners were defined. The list was drawn up in the Ministerial Order of 16 February 2017 on the bodies participating in phytopharmacovigilance, issued in application of Article R.253-46-4 of the Rural and Maritime Fishing Code (CRPM). The scope of these bodies has since changed, leading to the Order being amended;
- the resources that would enable these partners to meet phytopharmacovigilance expectations were identified;
- the size of the ANSES team responsible for organising the PPV scheme was defined.

The PPV scheme became operational on 1 July 2015.

In accordance with Article L.1313-3-1 of the French Public Health Code, ANSES reports to Parliament on this legislated mandate, through the annual report provided for in this Article's paragraph 2.

1.1 Phytopharmacovigilance objectives

The PPV scheme's objectives are set out in Article R.253-46-3 of the CRPM:

- contribute to the definition of information collection schemes in partnership with services and bodies managing other surveillance or vigilance schemes;
- analyse the information gathered and conduct risk assessments;
- provide risk managers (ANSES's MA mission, supervisory ministries) with information on risks.

The terms of the CRPM and these objectives are consistent with certain provisions of Regulation (EC) No 1107/2009, as amended, in that they create an organisation for receiving

and analysing the information and notifications required under Article 56 of this Regulation, and they organise the collection of information that may lead to the activation of Article 44 of this Regulation. More broadly, the scheme also makes it possible to assess the merits of the conditions associated with the authorisations for the active substances and/or products.

However, it does not meet the requirements of Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides.

1.2 Phytopharmacovigilance governance

The PPV scheme is governed by its steering committees and the network of associated partners. Its activities are in line with multi-year strategic orientations.

In addition, in accordance with the terms of its fundamental principles of expert appraisal (ANSES, 2012), for its complex scientific work, ANSES relies on a group of scientific experts mandated for this purpose.

1.2.1 Strategic orientations of the PPV scheme

Phytopharmacovigilance is implemented as part of a general strategy that enables its activities to be identified, structured, prioritised and planned. The first of the scheme's strategic orientations were established for the period 2019–2021 (ANSES, 2019a). A review was carried out at the end of this period (ANSES, 2023a) and used as a basis for identifying new strategic orientations for the period 2024–2028 (ANSES, 2024a). The current document sets out the factors underlying these orientations.

1.2.2 Management of phytopharmacovigilance

As mentioned above, Parliament is the primary recipient of the report on the PPV scheme's mission, through the specific annual report on ANSES's responsibilities in the areas of plant protection products, fertilisers and growing media.

Under its prerogatives, Parliament has also interviewed the Agency about this mission on several occasions since it was set up, as part of information missions and even commissions of inquiry[1].

In addition, ANSES's governance bodies – the Committee for Ethical Standards & Prevention of Conflicts of Interest (CDPCI) and the Scientific Board – may also be called upon to analyse or question the operation of the Agency's scheme, with a view to issuing recommendations on improvements to be taken into consideration[2].

[1] For example: Descrozaille *et al.* (2023) on the commission of inquiry into the causes of France's inability to achieve the objectives of successive plans to control the human and environmental health impact of plant protection products, and in particular into the conditions under which the public authorities responsible for safeguarding health carry out their missions.

[2] For example: ANSES (2021a) on the summary of ANSES's Committee for Ethical Standards & Prevention of Conflicts of Interest on ANSES's ethical framework tested by "sensitive issues".

1.2.2.1 The interministerial steering committee for phytopharmacovigilance

An interministerial phytopharmacovigilance steering committee has been set up to ensure that the PPV scheme runs smoothly. Its tasks are to:

- define the scheme's strategic orientations, based on proposals by ANSES;
- support and monitor implementation of the scheme, guided by the strategic orientations;
- assess consistency between the topics of the study projects to be funded and the scheme's strategic orientations, and contribute to the use and dissemination of the results of these studies.

The phytopharmacovigilance steering committee is made up of representatives from ANSES and several ministries:

- for ANSES: the Director General or their representative;
- for the Ministry of Agriculture: the Director General for Food (DGAL) and the Secretary General or their representatives;
- for the Minister of the Economy: the Director General for Competition, Consumer Affairs and Fraud Control (DGCCRF) or their representative;
- for the Ministry of Health: the Director General for Health (DGS) or their representative;
- for the Ministry of Ecology: the Director General for Land-Use Planning, Housing and Nature (DGALN), the Director General for Risk Prevention (DGPR) and the Director General for Energy and Climate (DGEC) or their representatives;
- for the Ministry of Labour: the Director General for Labour (DGT) or their representative.

The committee is chaired by the DGAL or their representative, and the Directorate General for Food also provides the secretariat. It meets at least twice a year.

1.2.2.2 The in-house phytopharmacovigilance steering committee

Set up at ANSES's initiative, the in-house phytopharmacovigilance steering committee is responsible for:

- monitoring implementation of the work programme and milestones of the PPV scheme's strategic orientations;
- validating the research projects to be funded;
- validating dissemination/publication of phytopharmacovigilance deliverables;
- monitoring the financial resources committed to the phytopharmacovigilance budget.

It is made up of:

- for the ANSES General Directorate: the Managing Director General of the Science for Expertise Division and the Managing Director General of the Regulated Products Division, or their representatives;
- for the ANSES departments: the Risk Assessment Director, the Regulated Products Assessment Director, the Market Authorisations Director, the Strategy and Programmes Director, the Health Alerts & Vigilance Director, and the Administration and Financial Affairs Director, or their representatives.

This committee is chaired by the Managing Director General of the Science for Expertise Division or their representative.

1.2.3 PPV scheme partners

The phytopharmacovigilance network is primarily made up of the partners on the list defined by the Ministerial Order of 16 February 2017, as amended, on the bodies participating in phytopharmacovigilance, issued in application of Article R.253-46-4 of the CRPM. ANSES has signed framework agreements with these partners, which set out their obligations under the terms of Decree No 2016-1595 of 24 November 2016. In order to bring together the entities needed to "capture" all the data and signals, this network is supplemented by certain entities in ministries that manage other surveillance or vigilance schemes.

All the partners involved in phytopharmacovigilance are listed in Section 2.1. The Agency ensures that the network is complete in order to achieve the objectives set for the PPV scheme and, where necessary, submits requests to the ministries about any changes to the network.

ANSES holds regular meetings with all the network's partners.

1.2.4 Discussions with stakeholders

In its relations with stakeholders, the Agency favours multilateral exchanges. With plant protection products, this takes the form of thematic steering committees (for plant health and environmental health) and, more specifically, ANSES's platform for dialogue on plant protection products. This dialogue forum was set up in 2018 in order to improve information and provide a regular framework for multi-stakeholder exchange. It is open to the various stakeholders active in the field of plant protection products who have expressed an interest in taking part in and contributing to discussions: manufacturers or company federations, various associations (environmental protection, consumer protection, environmental health, victims and patients), technical institutes and professional federations, employee trade unions, agricultural unions, etc. Phytopharmacovigilance is a regular item on their meeting agendas.

With regard to bilateral requests, the ANSES Charter on relations with interested parties (ANSES, 2021b) also applies to phytopharmacovigilance. Bilateral exchanges taking place under this Charter are recorded in the register created to document them.

1.2.5 ANSES's in-house organisation for deployment of the scheme

The PPV scheme implemented by ANSES is one of several vigilance missions that have been entrusted to the Agency over the years. Quality control is managed as part of the "business" process dedicated to vigilance schemes, which falls within the scope of the Agency's ISO 9001-2015 certification. Although the PPV scheme was set up first, it is nonetheless aligned with the "Fundamental principles underlying vigilance schemes" formulated by ANSES (ANSES, 2024b).

Its deployment involves various units within the Agency, primarily the Phytopharmacovigilance Unit.

1.2.5.1 The Phytopharmacovigilance Unit and the other units involved

The phytopharmacovigilance mission at ANSES has been entrusted to the Risk Assessment Department's Phytopharmacovigilance Unit, within the Science for Expertise Division. This Division is separate from the one that carries out regulatory assessments of plant protection products and manages MAs.

Certain activities in support of phytopharmacovigilance are carried out in other ANSES departments, such as the Health Alerts & Vigilance Department and its "Toxicovigilance for regulated products" Working Group (for the use of data from the French poison control and toxicovigilance centres (CAPTVs)) and the Regulated Products Assessment Department (for the use of data from the Phyt'attitude scheme of the Agricultural Mutual Insurance Scheme (MSA)).

The staff of the Phytopharmacovigilance Unit have skills in epidemiology and exposure assessment in human health, animal health and plant health, metrology of food and environmental contamination, agronomy, and data management and statistical analysis.

1.2.5.2 The "Phytopharmacovigilance" Working Group

Mandated by ANSES and made up of competent and independent external experts appointed in a personal capacity (*intuitu personae*), the "Phytopharmacovigilance" Working Group (PPV WG) is coordinated by the Phytopharmacovigilance Unit and works to:

- contribute to the identification, characterisation and processing of adverse effect signals from all the phytopharmacovigilance data (i) provided by partners, (ii) generated by studies, or (iii) emerging from reports sent to the Agency or found in the scientific literature;
- identify new partners or datasets of interest on aspects not yet covered;
- suggest improvements to the descriptors of the data supplied by the partners, and participate in interpreting their health or environmental impacts;
- identify the need for studies to generate new data in application of the PPV scheme's strategic orientations, and participate in defining protocols and monitoring the work funded by the scheme.

1.3 A scheme unique in Europe

At the time of writing this report, 10 years after its launch, the PPV scheme set up in France remains the only one of its kind in Europe. This uniquely French approach is regularly highlighted by parliamentarians and general inspectorates (Potier, 2014; Delaunay *et al.*, 2017; Descrozaille *et al*., 2023). Of course, surveillance and vigilance data are also collected in other European Member States in application of various European regulatory frameworks, such as for monitoring the quality of foodstuffs, drinking water (DW) or environmental water. But what sets the French PPV scheme apart is the integration of these different surveillance and vigilance data relating to plant protection products within a dedicated organisation.

Although this organisation facilitates the implementation of Articles 44 and 56 of the European regulatory framework relating to MAs for plant protection products, Regulation (EC) No 1107/2009 does not actually require it to be set up.

Considering situations where the quality limit for various metabolites of the active substance S-metolachlor has been exceeded in DW (see 5.2.1.3) highlights the value of a post-MA vigilance scheme in characterising a situation that is neither occasional nor circumstantial. Gathering and comparing such signals from several countries where products incorporating the same active substance are used could have led to earlier collective vigilance and, consequently, could have accelerated or even pre-empted the re-examination process, and the ultimate finding of non-compliance with the uniform criteria of Article 29. This example illustrates the merits of proactive exchanges between countries in the analysis of real-life data for risk governance schemes, and is an argument in favour of setting up schemes similar to the French phytopharmacovigilance one in other European Member States, ideally with coordination at European level. Such a provision seems all the more relevant given that substance authorisations are regularly subject to conditions resulting from assessments that have not been entirely finalised, and requiring verification in the field. Exchanges with other European Member States and the European Food Safety Authority (EFSA) in this respect correspond to phytopharmacovigilance strategic orientation 4.5 for the period 2024–2028. ANSES has also worked to integrate this component of post-MA vigilance into the network for the assessment of plant protection products, through its participation in EFSA's Advisory Forum.

2 Sources of phytopharmacovigilance data and information

2.1 Surveillance and vigilance data provided by partner phytopharmacovigilance schemes

The main sources of data on which phytopharmacovigilance relies are the partner surveillance and vigilance schemes, since phytopharmacovigilance was conceived from the outset as a network of networks.

The partner schemes listed in the Ministerial Order of 16 February 2017 are as follows:

- the MSA's Phyt'attitude scheme, which mainly collects cases of acute and chronic effects among professional users, as well as the MSA's medical-administrative databases;
- the CAPTVs, which mainly collect cases of acute human poisoning in the general population;
- the regional occupational and environmental disease centres (CRPPEs), which collect chronic human cases in the occupational and general populations, brought together within the National Network for Monitoring and Prevention of Occupational and Environmental Diseases (RNV3PE);
- the "Anticipe" Interdisciplinary Research Unit for Cancer Prevention and Treatment (a unit of the National Institute of Health and Medical Research (Inserm), in collaboration with the François Baclesse Centre, University of Caen Normandy and Caen University Hospital Centre), which studies agricultural occupational exposure and its links with chronic effects on human health through the AGRICAN cohort;
- *Santé publique France's* surveillance of exposure and effects on human health;
- the "Surveillance for action" (SAGIR) network for monitoring the health of terrestrial vertebrate wildlife (birds, mammals, etc.), run by the French Biodiversity Agency (OFB) in partnership with hunting federations and departmental veterinary laboratories (LVDs), and which also works with the CAPAE-Ouest, the VetAgro Sup Toxicology Laboratory and the Chrono-environment joint research unit as part of the "Toxinelle" scientific interest group (GIS);
- the Animal and Environmental Poison Control Centre for Western France (CAPAE-Ouest) at the Nantes-Atlantic National College of Veterinary Medicine, Food Science and Engineering (ONIRIS VetAgroBio Nantes), which mainly collects cases of acute effects on domestic fauna (farm animals and pets), and which also works with the SAGIR network, the VetAgro Sup Toxicology Laboratory and the Chrono-environment joint research unit as part of the "Toxinelle" GIS;
- the Toxicology Laboratory of the Veterinary Testing Unit of the National Institute of Higher Education and Research in Food, Animal Health and Agricultural Sciences and the Environment (VetAgro Sup), which carries out toxicological analyses on wild and domestic animals, and which also works with the SAGIR network, the CAPAE-Ouest and the Chrono-environment joint research unit as part of the "Toxinelle" GIS;

- the Chrono-environment joint research unit of the National Centre for Scientific Research (CNRS) and the University of Bourgogne Franche-Comté, which works with the SAGIR network, the CAPAE-Ouest and the VetAgro Sup Toxicology Laboratory as part of the "Toxinelle" GIS;
- the "Pesticide Residues Observatory" programme for bee matrices, run by the Technical and Scientific Institute for Beekeeping and Pollination (ITSAP), which documents the exposure of bees and other pollinators to plant protection products;
- the Soil Quality Measurement Network (RMQS), run by the Info&Sol Unit of the National Research Institute for Agriculture, Food and the Environment (INRAE) as part of the "Soil" GIS;
- ambient air quality surveillance carried out by the approved air quality monitoring associations (AASQAs), with the support of the Central Laboratory for Air Quality Monitoring (LCSQA);
- surveillance of indoor air quality and dust, led by the Scientific and Technical Centre for Building (CSTB) and ANSES as part of the Indoor Environment Quality Observatory (OQEI).

The following partner schemes, managed by the ministries, are not listed in the Ministerial Order of 16 February 2017 but nevertheless participate in phytopharmacovigilance:

- the "500 ENI" biovigilance network for monitoring unintended effects, run by the Directorate General for Food (DGAL) and implemented by regional coordinating structures (chambers of agriculture, FREDON network and other agricultural players), and consisting of around 500 plots on which biodiversity is monitored;
- surveillance of acute mass mortality in adult honeybees, run by the DGAL and implemented by the Departmental Directorates for the Protection of the Population (DD(ec)PPs);
- monitoring of pest resistance to plant protection products as part of the National Biological Surveillance (SBT) programme run by the DGAL;
- surveillance and control of food and feed quality, run by the DGAL;
- control of drinking water quality, run by the DGS and implemented by the Regional Health Agencies (ARSs);
- surveillance of surface and ground water quality, run by the Directorate for Water and Biodiversity (DEB) and implemented by the water agencies, for which data are available via the Naiades portals of the DEB, the OFB and the Bureau of Geological and Mining Research (BRGM), and the BRGM's ADES, respectively;
- surveys of cropping practices coordinated by the Ministry of Agriculture's Department of Statistics and Foresight Analysis (SSP).

Lastly, although not listed in the Ministerial Order of 16 February 2017 and not managed by a ministry, the following partner schemes also participate in phytopharmacovigilance:

- surveillance of the quality of coastal waters, run by the French Research Institute for Exploitation of the Sea (Ifremer);
- the national database of sales of plant protection products by approved distributors (BNV-D) administered by the OFB.

ANSES thus has access to surveillance data on plant protection product residues in the environment and in foods, data on acute and chronic adverse effects on human and animal health, and data on resistance developed by pests (Figure 1).

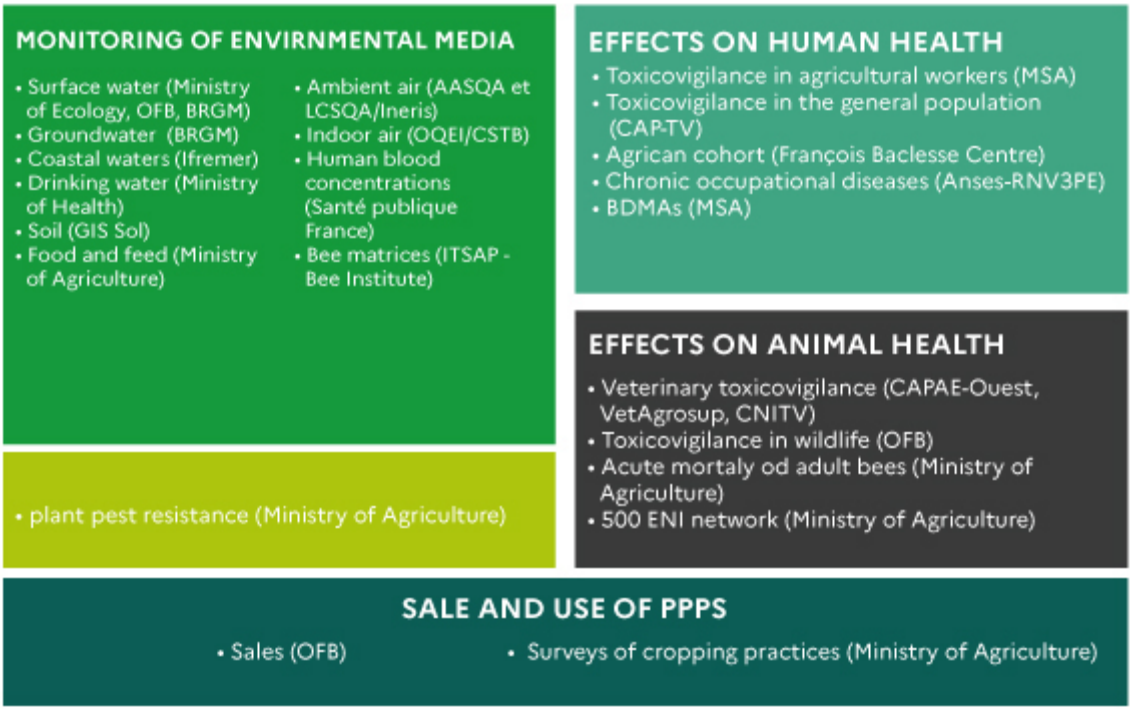

Figure 1: Surveillance and vigilance data provided by partner phytopharmacovigilance schemes

A detailed description of these data provided by the partners can be viewed in the explanatory note to the phytopharmacovigilance "active substance" data sheets produced by ANSES (ANSES, 2017a). For a given active substance and its degradation products (metabolites), these sheets summarise the data on its presence in food and the environment, and on exposure and adverse effects attributable to it, under real conditions of use (see Section 4).

The challenge for phytopharmacovigilance is to get the partner networks to cover all the types of adverse effects provided for by the Act, i.e. adverse effects on humans (agricultural and non-agricultural occupational populations, general population including sensitive groups such as children and the most exposed populations such as people living near crops), farmed animals (including honeybees), crops, biodiversity (animal and plant; aquatic, telluric and terrestrial), the quality of water (raw inland surface and ground water, coastal water and mains-supplied water), air (outdoor and indoor), soil and food, as well as on the emergence of resistance in pests.

Since the PPV scheme was set up, shortcomings have been addressed following the identification of gaps in the data (see Section 6 on studies funded by phytopharmacovigilance). This was the case, for example, with data on contamination of the general population (*Santé publique France's* health study on the environment, biomonitoring, physical activity and nutrition (ESTEBAN)), data on pesticide residues in ambient air (national exploratory campaign to measure pesticides in ambient air (CNEP) by the LCSQA and the AASQAs), data on pesticide residues in soil (PhytoSol study by INRAE) and data on pesticide residues in the air and dust of homes (PestiLoge study by the CSTB).

There are still major gaps in knowledge on the effects on biodiversity and the exposure of wildlife, as was pointed out in the collective scientific report by INRAE and Ifremer on the impacts of plant protection products on biodiversity and ecosystem services (Leenhardt *et al.*, 2022).

In any case, the PPV scheme is able to fund occasional measurement campaigns that can then help encourage the establishment of more long-term surveillance (strategic orientation 2.2 "Identify new priority needs for the production of useful data and knowledge for the phytopharmacovigilance mission"), something it has already done on various occasions and that has led, for example, to the inclusion of a partner for monitoring soil quality.

Regarding data on the use of plant protection products, which are essential for interpreting phytopharmacovigilance data, in the absence of an accessible centralised register of how these products are used, ANSES relies on sales data from the BNV-D and the results of the SSP's surveys of cropping practices. However, sales are only proxies for use, while the surveys are only carried out on a sample of farms over a multi-year period. To meet the objectives of the phytopharmacovigilance mission, it is essential that ANSES has access to all the data on the actual use of plant protection products.

2.2 Reporting by professionals and private individuals

Another source of data and information for phytopharmacovigilance comes from adverse effect reporting. Reports can be made spontaneously by individuals. On the other hand, in application of Article 56 of Regulation (EC) No 1107/2009, notification is mandatory for holders of MAs and parallel trade permits for plant protection products, manufacturers, importers, distributors, self-employed professional users, advisors and trainers of plant protection product users.

2.2.1 The various possible channels enabling professionals and private individuals to submit reports to the phytopharmacovigilance network

If someone wishes to declare an adverse effect associated with the use of a plant protection product, they should preferably go directly to the dedicated phytopharmacovigilance partner, depending on the nature of the adverse effect. Alternatively, or if there is no vigilance scheme for the type of adverse effect in question, the person may contact ANSES, which also has a reporting portal[3]. If the report falls within the scope of a partner's activities and prerogatives, ANSES transfers it to them without delay. These partners have the necessary skills for conducting an initial analysis of the adverse effect reports in their field of activity.

The following vigilance schemes work in partnership with phytopharmacovigilance and are qualified to directly receive and process reports:

- The CAPTVs provide teleconsultations, toxicological expertise and urgent medical assistance through an emergency telephone hotline (RTU), in the event of human exposure to any product or substance. Each teleconsultation is recorded in the poison control centres' information system (SICAP) in the form of a medical record. These records include an assessment of causality (i.e. an estimate of the strength of the causal link between exposure and the observed health effects) and precise

[3] https://www.anses.fr/fr/content/signaler-un-effet-indesirable-lie-lutilisation-de-produits-phytopharmaceutiques

documentation of the agent(s) involved and the exposure context, as well as the medical consequences of the poisoning, where follow-up was necessary.

- The MSA's Phyt'attitude scheme records, analyses and validates information on accidents or incidents occurring during the use of plant protection products or from contact with treated crops. Based on the principle of voluntary reporting of symptoms, it mainly captures acute events affecting human health associated with the use of plant protection products. This scheme is intended for professional users of these products.
- The Ministry of Health's adverse health event reporting portal[4] is available to anyone wishing to submit a report. Professionals subject to the reporting obligation have a dedicated area for submitting their reports on this same portal.
- For chronic diseases, reports are recorded by the CRPPEs. During medical consultations, patients are asked about the various risk factors to which they may have been exposed and to which the disease is potentially attributable. All the data from these consultations are stored in the RNV3PE database.
- The OFB's SAGIR network monitors the health of terrestrial vertebrate wildlife (birds, mammals, amphibians, reptiles), game species and protected species. It focuses on early detection and monitoring of abnormal health signals (mortality, morbidity or abnormal demographic signals) and diseases in space and time, as well as early detection of the emergence of new infectious agents or toxic substances.
- The CAPAE-Ouest is an animal and environmental toxicology information service that is available to answer any questions on suspected poisoning of animals, whether domestic or wild.
- The CAPAE-Ouest, the OFB and its SAGIR network, the VetAgro Sup Toxicology Laboratory and the Chrono-environment joint research unit (supervised by CNRS and the University of Bourgogne-Franche-Comté) are all members of the "Toxinelle" GIS, whose main purpose is to carry out toxicovigilance expert appraisals and research work. In this context, the GIS acts as a forum for exchanging reports.
- In the event of acute mass mortality of adult honeybees, all reports should be submitted to the DD(ec)PPs, with the exception of regions where the Observatory for Honeybee Mortality and Weakening (OMAA) is deployed.
- Lastly, decentralised state services can also receive reports of adverse effects due to plant protection products, particularly in regions where specific reporting channels have been set up, such as Nouvelle-Aquitaine, Pays de la Loire and Brittany.

2.2.2 Descriptive review of the reports from professionals and private individuals received directly by ANSES between 2015 and 2024

Although it is not the preferred reporting channel, ANSES receives some reports of adverse effects associated with the use of plant protection products. Between 2015 and 2024, 61 such reports were received. Figure 2, Figure 3 and Figure 4 show the types of reporting parties, the topics covered by the reports and the annual number of reports, respectively.

[4] https://signalement.social-sante.gouv.fr/psig_ihm_utilisateurs/index.html#/accueil

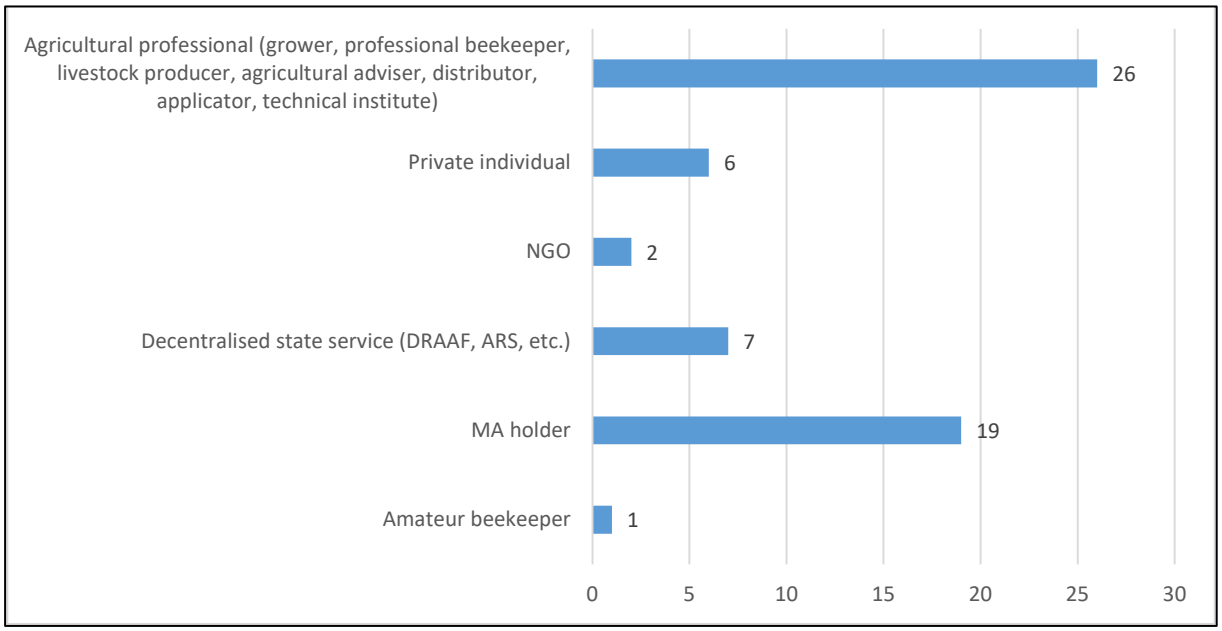

Figure 2: Types of professionals or individuals reporting adverse effects suspected of being associated with the use of plant protection products, directly to ANSES

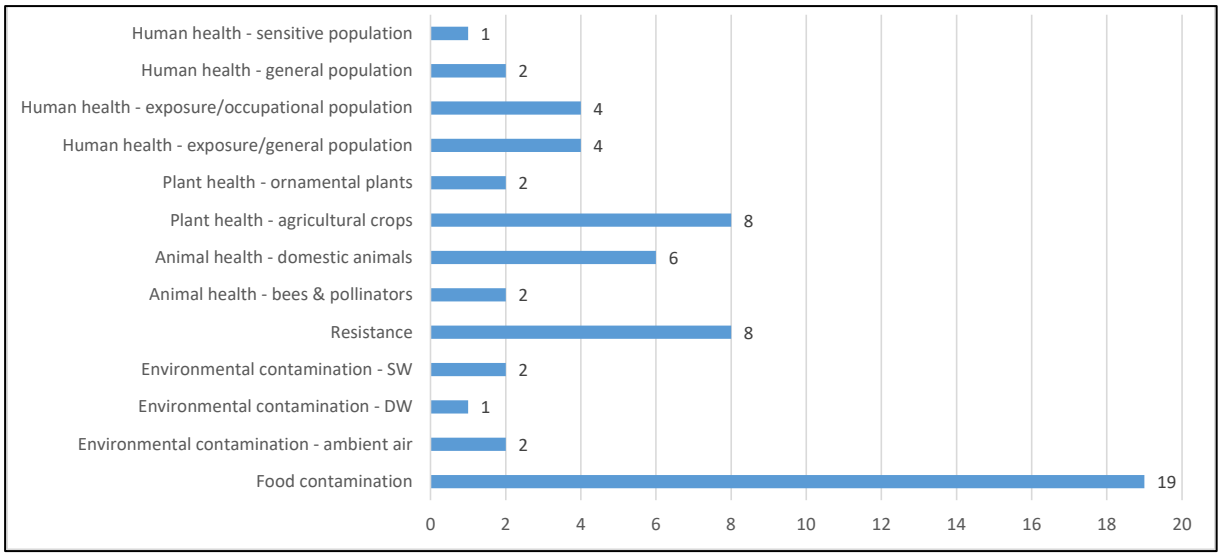

Figure 3: Types of topics or affected environmental media that have been the subject of reports of adverse effects suspected of being associated with the use of plant protection products, made directly to ANSES by professionals or individuals

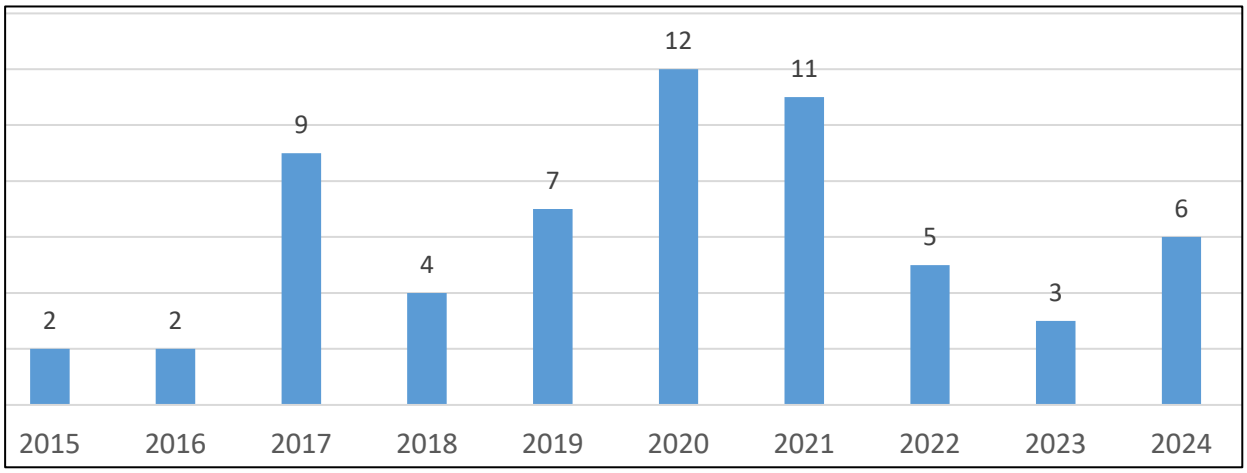

Figure 4: Annual number of reports of adverse effects suspected of being associated with the use of plant protection products, made directly to ANSES by professionals or individuals

The phytopharmacovigilance reports submitted directly to ANSES represent only a minority of the total number received by the national PPV scheme, which ANSES runs and whose partner vigilance schemes also act as reporting channels. There will therefore be limitations to any quantified review of the reports received directly by ANSES and the lessons that can be drawn from them. If such a review is to better reflect the PPV scheme's ability to capture events of adverse effects associated with the use of plant protection products occurring in the field, it will therefore need to take account of all the reporting channels in the phytopharmacovigilance network. An event is considered to have been "captured" by the PPV scheme if the information has been saved in a database and made accessible to ANSES. The establishment of such a comprehensive review, carried out on a regular basis to monitor developments, is included in the outlook for phytopharmacovigilance (strategic orientation 1.1 "Consolidate the network of surveillance and vigilance partners so that they are fully involved in the reporting of adverse effects associated with the use of plant protection products"). As a reminder, the decree setting out the partners' obligations states that alerts must be sent to ANSES without delay. In 10 years of operation, ANSES has received 19 reports classified as alerts.

Once these reviews have been drawn up, lessons can be learned about any trends in the reporting of adverse effects associated with the use of plant protection products. General or targeted actions can then be decided to encourage reporting (strategic orientation 1.1).

2.3 Literature monitoring

Reporting by phytopharmacovigilance partners or by natural or legal persons is not the only means of identifying adverse effects associated or potentially associated with a plant protection product. The scientific literature is also an important source of data, particularly on long-term effects that can only be studied by research teams. For this reason, a system was set up for the systematic and continuous collection of data from the scientific literature and grey literature[5]. It also relies on societal and media monitoring carried out by ANSES.

[5] According to the AFNOR definition, grey literature includes any "typed or printed document, often of a provisional nature, reproduced and distributed in fewer than a thousand copies, outside commercial publishing and distribution channels".

As well as being a source of information for identifying potential signals, this monitoring system within the PPV scheme can also identify sources of data for supplementing the phytopharmacovigilance substance data sheets (see Section 4), as well as methods and protocols that could encourage funded research projects (see Section 6).

Figure 5 shows the main objectives and procedures for the scientific monitoring set up under the PPV scheme.

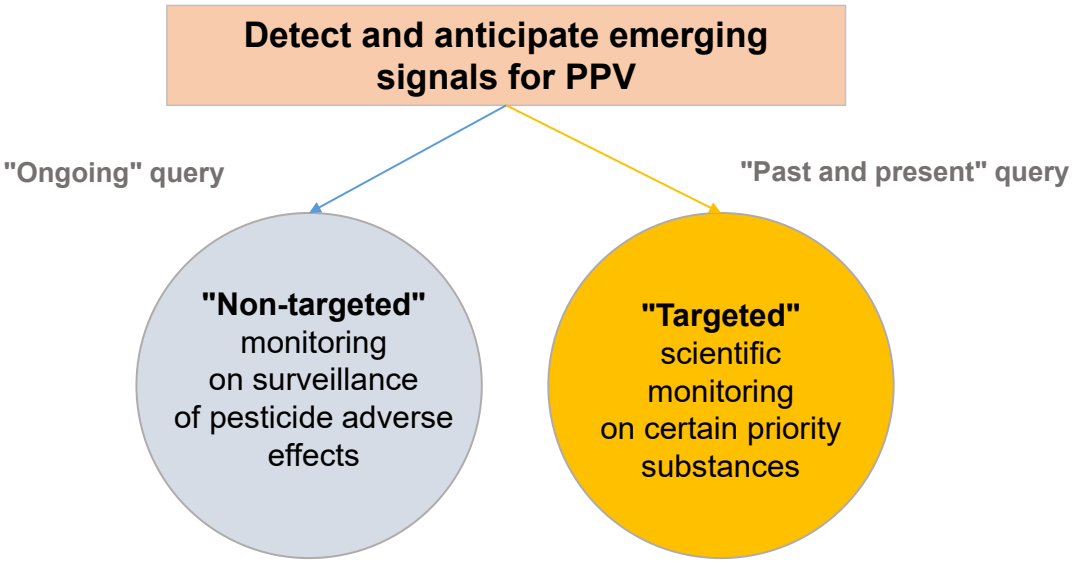

Figure 5: Main objectives and procedures of the monitoring system set up for phytopharmacovigilance

This report only describes the elements, structure and procedures for setting up "non-targeted" monitoring. "Targeted" monitoring involves a traditional literature search, as part of a specific investigation, and is therefore not described in this document.

2.3.1 Data collection system put in place for the literature monitoring system

2.3.1.1 Targeting the scope of the literature monitoring system

The first step in setting up literature monitoring is to define its scope (i.e. the topics, types of studies, tools and protocols to be covered) in order to meet the phytopharmacovigilance objectives. As part of this step, inclusion and exclusion criteria are defined for setting up relevant queries by topic. Table 1 below lists all the criteria used in the PPV scheme's literature monitoring system.

Table 1: Scope of the PPV scheme's literature monitoring system

	Exclusion criteria for literature monitoring	Inclusion criteria for literature monitoring
Study type	Studies of toxicological and physico-chemical properties Models for *a priori* assessment *Anopheles* resistance to insecticides used to combat malaria Case studies (human health) Human poisoning Strictly biocidal and veterinary use	Epidemiological studies (descriptive, ecological, cohort and case-control) Exposure studies (local/national) Meta-analyses and systematic literature reviews Biomarkers of contamination Methodological studies (statistics, development of analytical methods, protocols) Data mining using health data from medical-administrative databases
Substance status	Substances not used or usable in France	-
Geographical area	No exclusion criteria	-
Language	-	French and English, with the exception of reports on measurement campaigns for which documents in other languages may be collected, in particular publications from neighbouring countries (Spain, Italy, Belgium, Luxembourg, Germany, Switzerland, Andorra, Monaco) or further afield (Brazil, Suriname, Netherlands)

Given the PPV scheme's objective of monitoring the adverse effects of plant protection products after they have been marketed and under conditions of use corresponding to those in the field, ANSES prioritises the monitoring of observational studies. Development of analytical methods (all matrices combined) and *a posteriori* risk assessment studies are also included within the scope of the PPV scheme's literature monitoring system.

2.3.1.2 Tools and sources to be queried

Once the scope of the monitoring has been established, the second step is to identify and select the sources to be queried (sourcing). It is essential to identify the most relevant sources for monitoring purposes. Source selection is complex, as it is important to avoid unnecessarily multiplying the sites to be queried.

Sourcing is an iterative step in the process. All the sources are discussed again and may be constantly updated. Figure 6 below lists all the sources used by the PPV scheme's literature monitoring system.

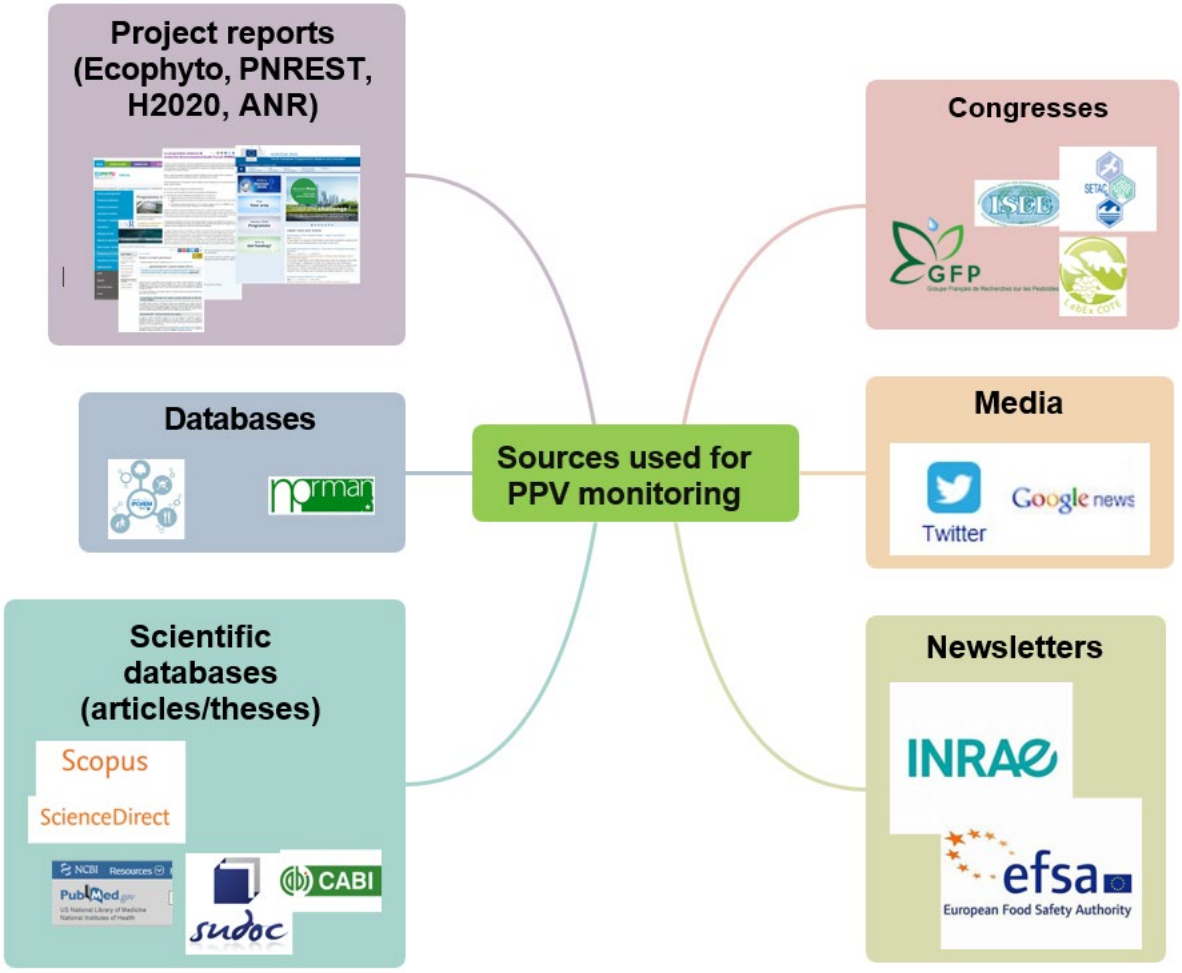

Figure 6: List of sources and tools used in the PPV scheme's literature monitoring system

The results of queries to the Scopus, ScienceDirect and PubMed databases are received in a continuous stream.

Grey literature documents can be collected by searching websites. In this monitoring system, the grey literature consists of reports (dissertations, theses, activity reports, etc.) in French. This search is not exhaustive, but already provides a broad overview of the main French players involved in research and management of plant protection products.

Congress proceedings (presentations, articles, abstracts, posters, etc.) can be retrieved through the monitoring system. This congress monitoring is particularly important because it is a way of anticipating research results before they are published in journals. Indeed, publications in A-ranked journals[6] often appear well after the end of a study, due to the time needed to write and publish scientific articles.

Media coverage is also monitored via news review websites, in-house press reviews and the societal monitoring carried out by ANSES's Social Sciences, Economics & Society Department.

[6] For the HCERES, an A-rank scientific output is a publication in an international peer-reviewed journal or "a journal considered to be of a very high standard by the community in certain disciplines".

2.3.1.3 Classification of articles collected by the PPV scheme's literature monitoring system

All the articles collected by the scheme's monitoring system are stored in Zotero[7].

Once these articles have been stored, they are classified into three categories based on phytopharmacovigilance needs and objectives. The principle of this classification has been validated with the PPV WG.

Table 2 below shows the three classification categories used in the PPV scheme's literature monitoring system.

Table 2: Terminology used for classification in the PPV scheme's literature monitoring system

Classification	Description
A potential signal *(S?)*	Corresponds to a study whose protocol is deemed sufficiently robust and that reports on an adverse effect attributable to a plant protection substance or substance class, which is still poorly documented or which provides new results in relation to existing knowledge.
If the analysed article does not provide any information that is new or could be interpreted as a signal, it is considered to be "of interest" to PPV (IPPV), corresponding to two categories:	
Interest to PPV *(IPPV (S-))*	Corresponds to a study whose protocol is not sufficiently robust, even though it reports an adverse effect attributable to a plant protection substance or substance class.
Interest to PPV *(IPPV (M))*	Corresponds to a study that does not report an adverse effect attributable to a plant protection substance or substance class, but whose protocol is of interest for an ongoing and/or a future funded study.

2.3.2 Descriptive review of the articles collected by the monitoring system

The PPV scheme's literature monitoring system "captured" 2062 articles between 2017 and 2024. Figure 7 below shows the number of articles captured for each topic under this monitoring system, between 2020 and 2023.

[7] https://www.zotero.org/

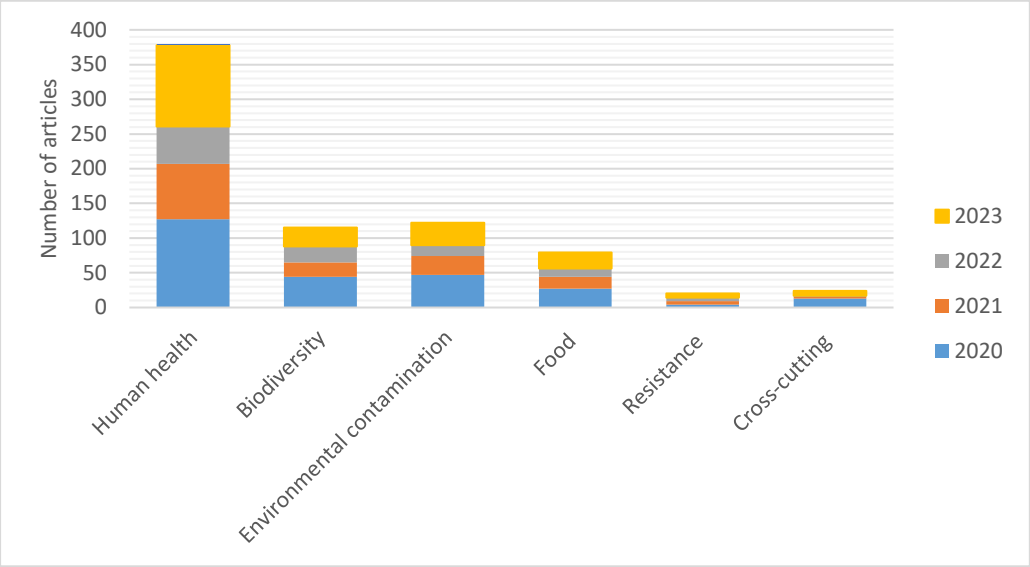

Figure 7: Number of articles captured by topic under the PPV scheme's literature monitoring system between 2020 and 2023

To facilitate the identification of signals and the exploitation of relevant articles, the working procedure for the PPV scheme's literature monitoring system has undergone gradual improvements: transition from the EndNote bibliographic management tool to Zotero, updating of literature queries, clarification of the scope and criteria for signals, etc.

Other developments are planned, in particular improving the exploitation of article analyses with a view to facilitating their subsequent re-querying (strategic orientation 1.3 "Improve the storage of collected and analysed scientific literature in a way that facilitates its re-exploitation").

3 Prioritisation of substances to be screened for in environmental media

3.1 General framework for prioritising substances in preparation for a measurement campaign

Phytopharmacovigilance is made possible through the reporting of surveillance data on different matrices (e.g. water, food) from national surveillance networks, whether regulatory or not. Cross-referencing the number of potential substances to be monitored with the various matrices results in a huge volume of data and a very high associated cost.

Before measuring substances in the environment, food or other biological matrices, it is therefore necessary to select the most relevant substances, i.e. to prioritise them. This prioritisation step is all the more important in the case of prospective measurement campaigns, when a matrix is not already subject to surveillance (e.g. soil before the start of the PhytoSol campaign, housing before the PestiLoge campaign) or is being monitored inconsistently across the country (e.g. ambient air before the CNEP). Any prospective measurement campaign should therefore include a prior step to prioritise the substances to be screened for.

In recent years, a number of studies have been published on the different prioritisation methods. These methods generally apply to all types of substances and combine different criteria, while explicitly including in the prioritisation process substances for which a criterion cannot be met due to a lack of available information.

The prioritisation of substances generally leads to three types of list being drawn up:

- A list of priority substances to be measured, for which data acquisition is relevant and necessary;
- A list of non-priority substances, in light of the available scientific knowledge;
- A list of substances that cannot be prioritised due to a lack of knowledge, for example, on their physico-chemical or toxicological characteristics. These substances will have to undergo further investigations before their definitive classification can be decided.

In France, an official prioritisation method for surface water has been in use by the OFB and Ineris since the early 2010s, as part of the National Expert Committee for the Prioritisation of Aquatic Micropollutants (CEP). This method is essentially based on the work of the NORMAN network[8]. This prioritisation method is now widely recognised, particularly by EU bodies but also by the French bodies responsible for surveillance (DEB and the water agencies). This method (Dulio and Andrès, 2012) was groundbreaking in the field of environmental water surveillance and has become a benchmark for prioritising chemicals (not just plant protection active substances) in other matrices.

This prioritisation method has therefore been used by the PPV scheme as a basis for its work since 2015 due to its operational, consistent and traceable nature. However, it has been modified and tailored to suit the specific objectives for each prioritisation exercise on plant protection active substances carried out by ANSES.

[8] European network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances

These prioritisation exercises have been defined on the basis of discussions with ANSES expert groups, by analysing the tools available and any modifications that need to be made. They are generally based on three steps:

- an *a priori* (or theoretical) prioritisation process;
- an *a posteriori* (or empirical) prioritisation process;
- in some cases, these two processes can be combined in a third step to produce a categorisation of substances.

In most cases, the *a priori* prioritisation of plant protection active substances is based on the following three criteria, which make up the meta-criterion "potential for quantities, emissions and persistence in the environment":

- the quantities of substances theoretically used in the region in question;
- their persistence in the environment (or residence time);
- their hazard potential for human or animal health, assessed by calculating a hazard score relating to chronic (or sometimes acute) effects.

For some prioritisation exercises, in particular those in preparation for the CNEP, the *a priori* prioritisation process was carried out using a specific tool: Sph'Air, developed by Ineris in 2005 to rank the pesticides to be screened for in ambient air. Data from the BNV-D are used to prioritise substances in terms of their uses.

Regarding the chronic hazard properties, most of the data come from European assessments of plant protection active substances. However, data produced outside the European regulatory framework by national or international bodies (IARC, Inserm, US EPA) are used when they are able to fill gaps in knowledge. As the prioritisation exercises are not intended to conduct a detailed quantitative assessment of the health risks, they do not draw on in-depth literature work to characterise the toxicity of the substances.

Regarding *a posteriori* prioritisation, the criteria used include presence in environmental media and the extent to which regulatory or health threshold values are exceeded. This has also enabled the PPV scheme to fully exploit the numerous surveillance data that were already produced by its partners but were often inconsistent across the country (differences in temporal monitoring, partial geographical coverage, etc.).

Moreover, it should be noted that for the most recent prioritisations, new criteria have been added to the usual ones. In particular, certain substances were considered to be priorities from the outset, regardless of their status at the end of the prioritisation process. This made it possible to select substances or substance classes for which the acquisition of new knowledge had been recommended following ANSES's collective expert appraisals, such as the one on the assessment of the warning signal regarding the toxicity of succinate dehydrogenase inhibitor (SDHI) fungicides (ANSES, 2019b).

3.2 Examples of substance prioritisations carried out in the context of phytopharmacovigilance

Since 2015, the PPV scheme has led or contributed to the design and implementation of around ten prioritisation exercises, examples of which are shown below (Table 3).

Table 3: Examples of substance prioritisation work carried out or supported by the PPV scheme

Environmental medium	Objective	Method	Indicators used	Substances identified as priorities	Reference
Ambient air	CNEP	*A priori* and *a posteriori*, classification by rank	Modelling of emissions, hazard, sales, occurrence	90	ANSES (2017)
Indoor air and dust	PestiLoge measurement campaign as part of the CNL2	*A priori* and *a posteriori*, classification by rank	Hazard, occurrence, sales, use (Pestihome)	92	ANSES (2018)
Soil	PhytoSol measurement campaign as part of the RMQS	*A priori* and *a posteriori*, classification by order	Hazard, occurrence, sales, indicator of a substance of concern	134	ANSES (2019c)
Food	TDS3	*A priori* and *a posteriori*	Hazard, sales, occurrence	127	ANSES (2019d)
Multi-compartment: urine, hair, dust, indoor air, food, ambient air	PestiRiv study	*A priori* and *a posteriori*	Hazard, sales, occurrence	48	*Santé publique France*, ANSES (2021)
Groundwater	Metabolites to be included in a possible prospective study in DW	*A priori* and *a posteriori*, classification by order	Risk assessment results (EFSA and ANSES), sales, physico-chemical properties, occurrence, analytical feasibility	122	ANSES (2022a)
Biomonitoring	ALBANE study	*A priori* and *a posteriori*	Hazard, occurrence, compilation of other prioritisations	395	ANSES (2022b)
Wildlife	Substances to be measured in the biological matrices of wild mammals	*A priori* and *a posteriori*, classification by order	Hazard, sales, risk	20	Bedouet *et al.* (2022)

3.3 Limitations and prospects for prioritising substances

Regarding the regulatory status of substances, only those that are still authorised or were only recently banned are systematically selected for prioritisation. However, depending on the objective of the study or the long-term surveillance to be set up, prohibited substances of concern may have been retained for prioritisation, particularly when the data were incomplete (e.g. lindane in indoor air) or not widely available (e.g. chlordecone in ambient air in the DROM).

The main limitation of these prioritisation exercises remains the initial list of substances, which in most cases contains few or no degradation products. Over the next few years, therefore, it will be necessary to consolidate the lists of potential degradation products, collect *a priori* and *a posteriori* data on them, and incorporate them into these prioritisations. In addition, the European NORMAN network has updated its prioritisation method over the last few years to include data produced by non-targeted analytical methods in the prioritisation scheme, which could therefore address this problem.

It is important to remember that the prioritisation lists described above were drawn up without taking account of the analytical feasibility criterion, which is only considered after the substance prioritisation work. The lists of substances ultimately screened for in the studies may then be reduced, particularly when specific sampling (e.g. sensors in the air) is needed to obtain a specimen of the substance, or when the analysis of a substance proves to be incompatible with a multi-residue method.

Eventually, the PPV scheme should implement these methods and set up a prioritisation system that can also support its partners in long-term surveillance. These methods will then have to be automated, to enable any new knowledge on substances to automatically trigger changes (up or down) in classification in the various categories (strategic orientation 1.2 "Continue including the priority issues for phytopharmacovigilance in the orientations for partner surveillance and vigilance schemes, in the fields necessary for the phytopharmacovigilance mission").

4 Summary sheets of surveillance and vigilance data for active substances and their degradation products

For a given active substance and its degradation products (metabolites), phytopharmacovigilance substance sheets summarise the data on their presence in food and the environment, and on exposure and adverse effects attributable to them, under real conditions of use.

Data on their presence in food and the environment (soil, water, ambient air, indoor air, dust, bee matrices) are summarised in the form of annual and national indicators that show the level of screening for the active substance and its degradation products, the level of quantification, and the extent to which they exceed regulatory ecotoxicological or toxicological quality threshold values in a given medium.

Other information besides data on food and environmental contamination is also reported:

- The results of major studies such as *Santé publique France's* health study on the environment, biomonitoring, physical activity and nutrition (ESTEBAN) concerning contamination of the general population in mainland France, and ANSES's total diet studies (TDSs) concerning dietary exposure;
- The conclusions for the active substance concerned in the collective export reports by Inserm (on human health), and INRAE and Ifremer (on biodiversity);
- Cases recorded by partner vigilance schemes (CAPTV for the general population and Phyt'attitude for agricultural workers covered by the MSA scheme);
- Sales data (BNV-D) and surveys of cropping practices (SSP) to enable impact data to be compared with data on pressure.

Where available, information on metabolites subject to risk assessments reported in EFSA peer reviews is also provided.

On the other hand, literature data and regional data are not reported, except when they compensate for an absence of data from the phytopharmacovigilance partners.

The information sources used to complete these summary data sheets are presented in an explanatory note published on the ANSES website (ANSES, 2017a).

4.1 Objectives and timetable for drawing up phytopharmacovigilance substance data sheets

Following the European re-approval of active substances used in plant protection products, MA holders submit applications to the Member States for the re-assessment of preparations containing them. Phytopharmacovigilance substance data sheets are systematically drawn up for the active substances contained in these preparations. These sheets provide additional information for the overall risk assessment process as provided for in Regulation (EC) No 1107/2009.

In this context, the data sheets are used to verify that the phytopharmacovigilance data do not call into question the *a priori* risk assessment of the active substance carried out at European

level, or possibly to identify problems specific to French situations that had not been fully taken into account during this assessment (which only examines representative use scenarios). As such, they are mainly intended for ANSES's Regulated Products Division and the ministries.

Phytopharmacovigilance substance data sheets can also provide information on active substances with the highest levels of contamination and adverse effects. These sheets were therefore drawn up for 14 active substances as part of ANSES's work on plant protection substances considered to be of concern in the report on the use of plant protection products in December 2017 (ANSES, 2020a).

Regardless of the context in which they were produced, all phytopharmacovigilance substance data sheets are expected to be published, as they are also intended to inform civil society.

4.2 Review of phytopharmacovigilance substance data sheets

Since 2017, 59 phytopharmacovigilance substance data sheets have been produced and published[9]. For two of them (flumioxazin and glyphosate), two data sheets were produced to better keep track of changes in the expiry dates of the active substances.

Table 4: Number of phytopharmacovigilance substance data sheets published per year

Publication year	Number of data sheets published
2018	23
2020	22
2021	5
2022	4
2023	4
2024	1
General total	59

Phytopharmacovigilance substance data sheets are updated at the same rate as the re-approval of active substances, i.e. every 10 years or so.

4.3 Prospects for substances to be considered when drawing up phytopharmacovigilance substance data sheets

Work is currently under way to prioritise the active substances to be considered when drawing up phytopharmacovigilance data sheets, based on a combination of criteria such as the quantities used and the date of the last European assessment, or relating to the intrinsic hazard

[9] https://www.anses.fr/fr/content/fiches-de-phytopharmacovigilance-ppv

of the active substance. With this in mind, these data sheets could be drawn up as part of the European re-assessment of active substances whose approval is due to expire, i.e. in advance of the current procedure. The aim here is to contribute fully to the European re-assessment of active substances by sharing the surveillance and vigilance data available in France with EFSA and the ministries (which have a vote at the European Commission). This approach was partially adopted for glyphosate, with a data sheet produced and shared with the ministries ahead of the vote on its renewal at European level in 2023.

Monitoring the re-assessment of active substances whose approval is about to expire means examining active substances that have not been re-assessed for almost 10 years (which is the general approval period). In some cases, an active substance may have been on the market for more than 10 years without having been submitted for re-assessment. For these active substances, it would seem appropriate to draw up a phytopharmacovigilance substance data sheet to support the request for a re-assessment.

For information, as of 31/08/2024, 195 active substances had an approval dating back more than 10 years. Among the active substances that have not yet been submitted for re-assessment, priority should be given to those for which it is most urgent to draw up a phytopharmacovigilance substance data sheet (strategic orientation 4.5 "Continue reporting phytopharmacovigilance results at the European level").

5 Identification of phytopharmacovigilance signals

The purpose of collecting data and information for phytopharmacovigilance is to identify signals to be reported to the various bodies responsible for assessing and managing the risks associated with the use of plant protection products. After specifying what constitutes a signal for phytopharmacovigilance, this section gives examples of how signals are processed by the PPV scheme.

5.1 How are signals and alerts defined for phytopharmacovigilance?

ANSES runs and operates seven vigilance schemes: veterinary pharmacovigilance, the RNV3PE, nutrivigilance, phytopharmacovigilance, toxicovigilance, cosmetovigilance and tatoovigilance. While these seven vigilance schemes share the common aim of identifying adverse effects with a view to their prevention, they differ in their respective areas of coverage and in the way they operate, mainly in terms of data sources, admissibility criteria and calculation of causality. Apart from these differences, the vigilance schemes coordinated by ANSES need to be governed by common principles. For this reason, ANSES has drawn up a document setting out the fundamental principles underlying the vigilance schemes it coordinates (ANSES, 2024b). It applies to all the vigilance activities carried out by the Agency and gives the following definitions:

- A **signal** is defined as information drawing attention to a potential risk and/or information requiring monitoring. This may be an event in France or in another country that has been identified in a scientific article or any other media outlet or network;
- **Reporting** is the act of issuing and transmitting a signal to one of ANSES's vigilance schemes. This may involve, for example, the transmission of information on an adverse effect of a product, within a regulatory or non-regulatory framework, whether the report is submitted by an affected user or a professional who has observed the effect;
- An **alert** refers to a sufficiently validated signal considered, after an initial risk assessment, to pose a threat to the health of human, animal or plant populations or the environment, and to require an appropriate response for its prevention;
- A **weak signal** is one that, following an analysis, does not constitute an alert, but requires vigilance to be continued or stepped up, or further investigation. This term is also used to refer to statistical signals obtained from non-targeted data mining, which can only be classified as alerts on the basis of more in-depth analysis;
- Certain **validated signals** (for example when a regulatory threshold has been exceeded, defining non-compliance), which are not considered to be health alerts, may nonetheless require management measures to be taken with a view to preventing the occurrence of a health risk situation in the longer term. The need to act is less urgent than for an alert.

5.1.1 Signals and alerts for phytopharmacovigilance

The definitions of signals and alerts presented above need to be translated into criteria that can be applied to the analysis of data and information (strategic orientation 3.1 "Set out the common principles of what constitutes an alert and a signal for phytopharmacovigilance, specifically for the different partner schemes"). On the one hand, the criteria must be precise (quantitative if possible) to guarantee consistency and objectivity in the classification of signals by the phytopharmacovigilance scheme. On the other hand, the criteria must not be too rigid and must allow for the possibility of incorporating unforeseen factors that would be difficult to manage using criteria established *a priori*. Indeed, the very essence of a vigilance scheme is that it is not limited to alerts on what is expected, but also remains open to the unexpected. The definition of the criteria presented below strives to keep this subtle balance.

5.1.1.1 For data measured in the environment (water, soil, air), or in food, or on exposure

In general, although with specific features depending on the matrix, data from measurements in the environment or food can give rise to signals or alerts for various reasons:

- a high frequency of detection/quantification, regardless of the concentrations;
- a high frequency of cases in which a regulatory (not health) threshold is exceeded;
- a high frequency of cases in which a health threshold is exceeded;
- a high frequency of concentrations of a substance in a matrix – higher than expected by the *a priori* assessment;
- the first time a substance is detected in a given matrix and/or in a given region and/or in a given month, etc.;
- insufficient screening or no screening for a substance in a matrix, even though it has been associated with a signal in a specific research context or in another country in a similar situation to France.

Classification of the signal or alert will take the following factors into account:

- stability of the frequencies or upward/downward trends;
- frequencies or concentrations higher or lower than the usual frequencies or concentrations;
- quantities of the substance used (high or low, stable, decreasing or increasing).

Work is in progress with the PPV WG to determine what should be considered "high" in the various criteria listed above, i.e. to set thresholds to use as a basis for classifying the various types of signal. The same applies to upward trends, which require the use of time trend analysis methods (strategic orientation 1.4 "Improve the identification of emerging phenomena requiring reporting").

5.1.1.2 For data on acute health effects

Insofar as the health effects observed, whether in human, animal or plant populations, can be attributed to exposure to plant protection products, there are several possible reasons for considering cases of poisoning, morbidity or mortality as signals:

- any event when it concerns serious cases;
- when there is a repetition, in time and/or space, of less serious events in similar circumstances (same substance, same industry sector, same exposure, etc.).

5.1.1.3 For data on chronic health effects

In epidemiological studies, whether in human, animal or plant health, causality is based on statistical associations between health effects and exposure, as well as on the biological plausibility of the health effect being caused by the exposure.

With regard to the "health effects" part, classification of the signal will depend on the severity.

With regard to "exposure", given the many plant protection products to which people are exposed, it often cannot be attributed to a particular substance but is related to plant protection products more broadly, in a general and indistinguishable way. However, as phytopharmacovigilance mainly targets feedback on substances, it is important for a signal to be related to a specific substance, or at least to a class of substances.

When an epidemiological study is published, it needs to be positioned in relation to existing studies:

- if this is the first study to demonstrate an association between a human disease or an effect on biodiversity and a substance, the study can be classified as a signal in terms of its novelty;
- a study can consolidate the results of existing studies and cause all the available knowledge to be transformed into a signal;
- a study may contradict the results of existing studies and therefore possibly weaken what was previously identified as a signal.

ANSES also carried out a specific analysis of Inserm's collective expert review on the human health effects of pesticides (ANSES, 2025). The higher the level of evidence and the more the exposure concerned a specific substance still in use, the more the disease/substance association constituted a phytopharmacovigilance signal.

5.1.1.4 For data on resistance

Once a plant protection product has been applied to a plant to repel a pest (mainly an insect, weed or fungus), this pest may develop resistance to this product. In the area of plants, the PPV scheme considers a signal to be:

- the first observation of resistance in France;
- the widespread presence of resistant populations compromising the effectiveness of treatments.

5.1.2 Possible actions following signals and alerts identified by the PPV scheme

Signals and alerts identified by the PPV scheme can lead the players concerned to take risk management measures:

- if the adverse effects occurred despite correct use of the plant protection product, the conditions for use laid down in the MA (dose and frequency of use, special restrictions, etc.) may be revised;
- if the adverse effects occurred due to an accident without any obvious negligence, it is important to understand the causes to prevent them from happening again;
- if the adverse effects occurred as a result of misuse, whether unknowingly or deliberately, information and training initiatives to raise awareness of the risks associated with the use of plant protection products can be rolled out among users.

If an epidemiological study in a human population reveals an association between a disease and exposure to an active substance, this information is then added to the body of toxicological knowledge and may lead to a revision of the toxicological classification established in accordance with Regulation (EC) No 1272/2008 (the CLP Regulation).

Signals identified by the PPV scheme can also encourage in-depth or complementary investigations and, where data gaps have been identified, the production of new data, either through surveillance or research.

5.2 Representative examples of signals and alerts identified by the PPV scheme, and action taken

5.2.1 Signals and alerts based on data from measurements in the environment or in food, or on exposure

5.2.1.1 Prosulfocarb residues in non-target crops

The PPV scheme received and analysed several reports concerning the undesirable presence of prosulfocarb in apples, watercress and rocket, in particular, even though this herbicide is not used on these crops. Although they exceeded the maximum residue limit (MRL), the concentration levels measured in foodstuffs did not exceed the risk thresholds for consumers. However, due to the abnormal presence of such residues on non-target crops, some products were downgraded and can no longer be marketed. Analysis of the data showed that the contamination came from neighbouring cereal and potato crops, where prosulfocarb had been used for weed control.

Following this analysis, the PPV scheme (ANSES, 2017c) concluded that this constituted a validated signal. Surveillance of prosulfocarb in foodstuffs from these non-target crops was stepped up, and ANSES decided to strengthen the conditions for using the products in 2017 and then in 2018 by making treatment conditional on having no sensitive agricultural crops ready to be harvested within a radius of 1 km. In 2023, this analysis was updated with new

data on the presence of prosulfocarb in foodstuffs (ANSES, 2023b). The presence of prosulfocarb on non-target crops in excess of the MRLs is still observed.

5.2.1.2 Quantification of terbuthylazine in watercourses

The presence of terbuthylazine in surface water was reported by the Brittany regional directorate for food, agriculture and forestry (DRAAF) and also described in a scientific communication from a study in the Brie region (AquiBrie, 2019). This herbicide in the triazine group, intended to control weeds in maize, was re-authorised in 2017 and has been contaminating water bodies since 2018. Although the terbuthylazine concentrations very rarely exceed the ecotoxicological threshold value, the high detection frequency (up to 20%) warranted the special attention paid to its surveillance in surface water, groundwater and DW.

Following the analysis, the PPV scheme (ANSES, 2021c) concluded that this constituted a validated signal. ANSES decided to restrict application to once every three years (instead of two years previously), at a distance of at least 20 metres from water sources and leaving a five-metre strip of vegetation along their edges.

5.2.1.3 Quality standards in drinking water exceeded by metolachlor metabolites

This report was forwarded by the DGS in early 2021. Over the past few years, in their surveillance of drinking water quality, the ARSs have shown that metolachlor ESA (CGA 354743) and metolachlor OXA (CGA 51202), two metabolites of S-metolachlor, are among the five compounds most frequently implicated in non-compliant situations (pesticides found at concentrations above quality limits). Since 2019, surveillance has also revealed the frequent presence of metolachlor NOA 413173 (SYN 547627), another metabolite of S-metolachlor.

Although the concentrations of these metabolites never exceeded the maximum health value (Vmax), the high detection frequency (up to 20%) and their ubiquitous presence warranted the special attention paid to their surveillance, in both DW and water resources (surface water and groundwater).

On the basis of its analysis, the PPV scheme (ANSES, 2021d) concluded that this constituted a validated signal. ANSES decided to amend the MAs for plant protection products containing S-metolachlor, mainly by reducing the doses used.

5.2.1.4 Ifremer's OBSLAG project on Mediterranean lagoons

Pesticide contamination of lagoon waters was studied by Ifremer in 2017–2019 (Munaron *et al.*, 2020) and 2020–2021 (Munaron *et al.*, 2022) as part of the OBSLAG Pesticides project, which sought to conduct a review of the issue of pesticides in Mediterranean lagoons in terms of the individual and/or cumulative risk they pose to these ecosystems. Since there are very few data on the contamination of French lagoons by plant protection substances, any new data are of great interest for phytopharmacovigilance. Moreover, some substances reached concentration levels that exceeded the ecotoxicological thresholds derived for the specific needs of the study by the Ifremer team that conducted it.

As this was the first large-scale study of pesticides in French lagoon areas, these data constituted a weak signal in terms of the novelty for phytopharmacovigilance. However, following an analysis by ANSES of the robustness of the ecotoxicological thresholds derived by Ifremer, the classification of the signal was revised downwards.

5.2.1.5 Presence of trifluoroacetic acid (TFA) in groundwater

Germany and Denmark reported TFA levels exceeding the threshold value of 0.1 µg/L in groundwater and DW. TFA has been identified as a metabolite of flufenacet, fluazinam, flutolanil, saflufenacil, trifloxystrobin and oxyfluorfen. It can also be formed from certain active substances with a trifluoro group (CF_3). This CF_3 group is not specific to plant protection active substances and can therefore be produced from chemicals used for purposes other than plant protection.

In France, as of 15 April 2021, the PPV scheme had no surveillance data for this metabolite in any of the three compartments (groundwater, surface water, DW). ANSES suggested to its partners responsible for monitoring environmental and drinking water that they include TFA surveillance in the procedures for prioritising substances to be monitored. Methods for analysing TFA were subsequently developed by the reference laboratories for environmental water (AQUAREF) and DW (ANSES's Nancy Laboratory for Hydrology). The first official measurements were planned for 2025.

5.2.1.6 Presence of N,N-dimethylsulfamide (DMS) and N,N-dimethylsulfamic acid (DMSA) in groundwater

In a press release published in January 2023[10], the Pesticide Action Network Europe (PAN Europe) reported that the Danish Environmental Protection Agency was considering banning the use of cyazofamid, after measuring excessive concentrations of DMS and DMSA, two compounds considered to be metabolites of this active substance, in groundwater. Its first point was that DMS had not previously been identified as a possible degradation product of cyazofamid following its recent re-assessment under Regulation (EC) No 1107/2009. Regarding the presence of these two compounds in French groundwater, DMS has been monitored since 2016. In 2021, the frequency of quantification was around 2% – an increase – while the frequency at which the 0.1 µg/L quality standard was exceeded was of the same order of magnitude. DMSA, on the other hand, has not yet been screened for in French groundwater.

In view of the multiple authorised uses of the active substance cyazofamid in France and the situation in Denmark, ANSES suggested to its partners responsible for monitoring environmental and drinking water that they strengthen their surveillance of DMS and also include DMSA.

5.2.2 Signals and alerts from data on acute health effects

5.2.2.1 Acute metam-sodium poisoning

Several operations to treat lamb's lettuce crops with products containing this active substance caused a series of clustered poisonings of local residents and walkers in Maine-et-Loire in 2018, to the extent that the "White Crisis Plan" was triggered at Angers University Hospital. The exceptionally hot, dry weather conditions in autumn of that year favoured the volatilisation of the degradation substance of metam-sodium buried in the ground.

[10] https://www.pan-europe.info/blog/denmark-ban-groundwater-polluting-fungicide-after-18-years-use

Subsequently, a retrospective analysis of the cases recorded in the CAPTV database found that occasional metam-sodium poisonings had been occurring regularly for years, although none on the scale of the 2018 event. These adverse effects corroborated the findings of an unfavourable assessment conducted as part of the planned regulatory re-examination of MAs for products containing metam-sodium.

5.2.3 Signals and alerts from data on chronic health effects

5.2.3.1 Cluster of paediatric cancers among people living in wine-growing areas

In 2015, the association *Alerte des Médecins sur les Pesticides* (AMLP) informed ANSES of a suspected cluster of paediatric cancers in Preignac, a wine-growing municipality in the Bordeaux region. The epidemiological investigation conducted by the regional unit of *Santé publique France* was statistically inconclusive (Castor *et al.*, 2013), given the low number of cases due to the small geographical area and time scale covered by the investigation.

Although not conclusive, the suspected cluster of paediatric cancers in the vicinity of agricultural crops was considered to be a weak signal. In addition, the issue of risks associated with pesticides for people living near crops was considered to be important, as these populations are in principle more exposed and therefore potentially more at risk. Lastly, there were few international data available to study them. For this reason, two major national studies were launched by the PPV scheme, one on health (GEOCAP-Agri, see Section 6.2.4.1) and the other on exposure (PestiRiv, see Section 6.2.4.2).

5.2.3.2 Increased risk of cancer of the liver and intrahepatic bile ducts and chronic lymphocytic leukaemia following long-term occupational exposure to dicamba

The article by Lerro *et al.* (2020) concerns an updated assessment of the association between the use of dicamba and the incidence of cancer in the US Agricultural Health Study (AHS) prospective cohort study. In particular, it shows an increased risk of cancer of the liver and intrahepatic bile ducts and chronic lymphocytic leukaemia.

This epidemiological study highlighted a possible carcinogenic risk following long-term cumulative exposure of 10 years or more. As with any observational study of actual exposure situations, it did not rule out the possible role of mixtures (e.g. a product containing dicamba and co-formulants), or that of occupational co-exposures (e.g. use of products systematically associated with products containing dicamba), but this would assume that these mixtures or co-exposures were stable over time for more than a decade. The level of confidence in these results, suggesting the possible role of the active substance dicamba, therefore remains high.

This study was conducted within the AHS prospective cohort in the United States. Because the exposure characterised by this study is specific to the situation in the United States, the lack of French data means that the existence of this association in the French context can neither be confirmed nor ruled out. In France, however, dicamba is still commonly used, and there is no sign of any reduction in professional applications. It was therefore considered that the article by Lerro *et al.* (2020) constituted a validated signal.

ANSES then ensured that the article by Lerro *et al.* (2020) was clearly identified by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), which is responsible for determining toxicological classifications for plant protection substances. The

RAC had indeed identified it, among other data, but had concluded that dicamba should not be classified as a carcinogen because the data were inconclusive overall (RAC, 2022).

5.2.3.3 Analysis of the results of Inserm's collective expert review on "Pesticides and health effects"

Phytopharmacovigilance analysed the results of Inserm's collective expert reviews of 2013 and 2021 on the links between exposure to pesticides and human health (Inserm 2013; 2021). The aim of this analysis was to identify signals, as defined by phytopharmacovigilance, in the results of Inserm's collective expert reviews on the human health effects of pesticides, and in particular the presumed links between pesticide exposure and the onset of a disease or health event.

For active substances or active substance classes approved for plant protection use, the analysis by ANSES's phytopharmacovigilance scheme of Inserm's collective expert reviews of 2013 and 2021 (ANSES, 2025) identified the following signals (see Section 5.1 for signal classification):

- Alerts:
  - internalising behaviour disorders in children and prenatal exposure to pyrethroids;
  - cognitive disorders in adults and occupational exposure to organophosphates;
  - non-Hodgkin lymphoma (NHL) and occupational exposure to organophosphates, specifically malathion;
  - impaired motor and cognitive capacities and sensory functions in children and prenatal exposure to organophosphates;
- Validated signals:
  - NHL and occupational exposure to glyphosate, 2,4-D, carbamates, triazines and organophosphates;
  - leukaemia and occupational exposure to deltamethrin and malathion;
  - prostate cancer and occupational exposure to malathion;
  - hypothyroidism and occupational exposure to malathion;
  - soft tissue and visceral sarcomas and occupational exposure to phenoxy herbicides and chlorophenols;
  - sperm damage and exposure to pyrethroids in the general population and occupational exposure to organophosphates;
  - impaired motor and cognitive capacities and prenatal exposure to malathion;
  - behaviour suggestive of autism spectrum disorders in children and prenatal exposure to organophosphates;
  - impaired foetal growth and prenatal exposure to organophosphates.

ANSES drew its conclusions and recommendations from these alerts and validated signals and will be informing the relevant stakeholders so that any corrective and preventive actions deemed necessary can be taken, with a shared public health objective. In this context, as it is preparing to take over coordination of the Green Data for Health (GD4H) scheme under the Fourth National Environmental Health Action Plan, the Agency reiterates its recommendation relating to long-term access to data on the use of plant protection products: making such

access possible would facilitate more effective and robust investigations into the reports submitted to the PPV scheme, similar to what is observed in pharmacovigilance for human medicine.

6 Studies funded by phytopharmacovigilance

The studies carried out under the PPV scheme are intended to generate new knowledge needed for performing its tasks. These studies are funded by a specific additional tax for "phytopharmacovigilance", based on revenues from sales of plant protection products by MA holders.

In particular, these studies supplement the information provided by the PPV scheme's partner bodies when this is insufficient, particularly for analysing the reports received.

All the studies funded by phytopharmacovigilance are listed in Table 7 in Annex 1. This review has examined some studies in greater detail to illustrate their contribution to phytopharmacovigilance (see Section 6.2).

6.1 Types of studies funded by phytopharmacovigilance

6.1.1 Purpose of studies funded by phytopharmacovigilance

Studies funded by phytopharmacovigilance provide answers to specific questions posed by the scheme. Unlike calls for research projects, they do not involve open research questions. Based on existing surveillance and vigilance schemes, the studies thus funded are designed to meet three objectives:

- consolidate and develop tools and methods:
  - consolidate existing schemes;
  - encourage the establishment of new schemes;
  - develop new methods for exploiting data;
- investigate reports:
  - investigate a report found in the literature;
  - investigate a report resulting from a declaration (by a partner or the reporting party);
- generate new knowledge on adverse effects.

6.1.2 Criteria for funding a phytopharmacovigilance study

The funding of a study by the PPV scheme is governed by a number of criteria. The studies must be in keeping with the scheme's strategic orientations. They must address national issues and therefore be carried out on sites and populations in France.

Table 5 lists the criteria that must be met for a study to be funded by the PPV scheme.

Table 5: Criteria for a study to be funded by phytopharmacovigilance

Criteria	Details
Study seeking to continue the investigation of a report for which the analysis was not sufficiently conclusive, despite a potential health issue	A report received or identified via: o the reporting portal; o a phytopharmacovigilance partner; o literature monitoring.
Observational study	Epidemiological studies in animal or human health (ecological, case-control or cohort studies). Excludes experimental laboratory or "quasi-experimental" studies.
Study for biological surveillance or surveillance of an environmental medium	Measurement campaign. Analytical feasibility study. Exploitation of a sample library.
Survey	Data collection. Mapping. Network feasibility.
Data processing	Data mining. Analytical method. Development of indicators. Tools for exploiting data.

The studies applying for funding from the PPV scheme are initially submitted for consultation to the PPV WG, which can offer recommendations on their study protocols. Following this consultation, these studies are assessed and selected by the in-house phytopharmacovigilance steering committee. This in-house committee may also be required to prioritise the studies, according to criteria relating to the severity and intensity of the adverse effect, the sensitivity of the population concerned and societal expectations.

The interministerial phytopharmacovigilance steering committee assesses the consistency between the studies to be funded and the PPV scheme's strategic orientations.

6.1.3 Quantified review of studies funded by phytopharmacovigilance

Since 2015, the PPV scheme has funded some 50 studies for a total of around €13 million.

Figure 8 shows the number of studies in progress or completed since 2015, as of 30/09/2024.

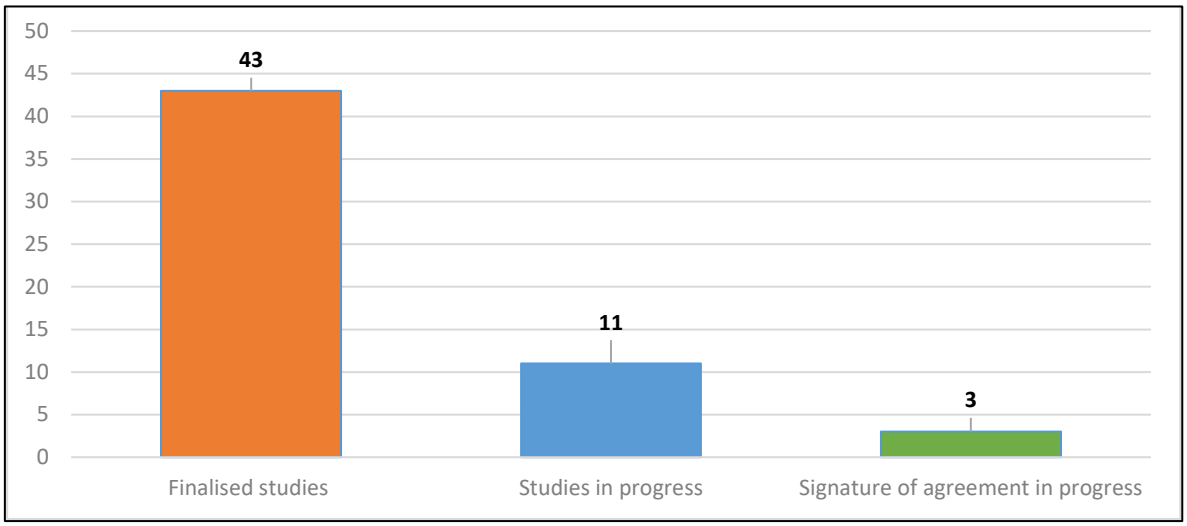

Figure 8: Progress of studies funded by phytopharmacovigilance since 2015, as of 30/09/2024

Each of these studies relies on collaborations with partners or service providers.

Below are examples of partners and service providers already involved in projects funded by phytopharmacovigilance:

- Agency: *Santé publique France*;
- Public industrial and commercial entities (EPICs): Ineris, CSTB, BRGM;
- Association: ATMO France;
- Universities: University of Grenoble, Sorbonne University;
- Research bodies: Inserm, CNRS;
- Agricultural technical institute: ITSAP;
- Service provider laboratories: LERES, Ianesco, GIRPA.

Studies in a great variety of fields have been funded by phytopharmacovigilance over the last 10 years. Figure 9 shows the number of studies by field.

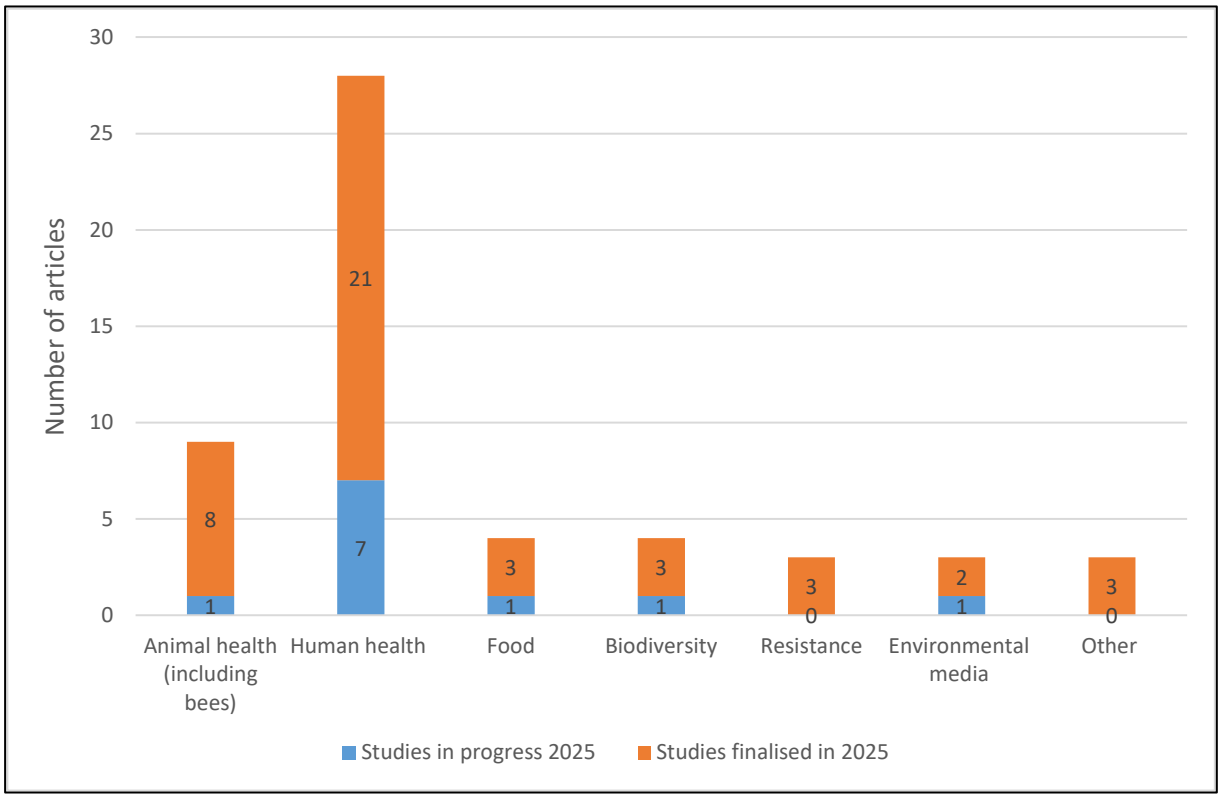

Figure 9: Research fields funded by phytopharmacovigilance

Table 6 shows the breakdown of studies according to the main types of objectives, as defined in Section 6.1.1.

Table 6: Breakdown of studies funded by phytopharmacovigilance according to the main types of objectives

Objectives of PPV studies	Number of studies funded	Number of studies in progress
Develop or consolidate schemes, tools or methods	**16**	**2**
Generate new data or knowledge	**21**	**5**
Investigate a report	**5**	**2**

6.2 Representative examples of contributions to studies by the PPV scheme

6.2.1 Develop or consolidate schemes, tools or methods

6.2.1.1 IODATOX: Design of IT tools to standardise data entry practices, and pool and exploit data on bees

ITSAP had developed the IODA database for computerising and organising bee data. However, it did not include data on contamination of bee matrices, in particular from the Institute's Pesticide Residues Observatory (ORP). In the absence of a centralised database, whenever ANSES requested data, ITSAP was obliged to consult the multiple sources of data from the various programmes it had managed and consolidate them all.

With funding from ANSES, an extension was added to the IODA database to cover data on contamination of bee matrices. Entry of data on this contamination is now standardised, as is data exploitation. In addition, an online display application (available to designated users, with secure access) can be used to generate contamination reports for bee matrices and retrieve raw data. Numerous criteria-based search tools can be used to study the contamination of bee matrices by a single substance or a cocktail of substances, or to study contamination as a whole. In the event of a signal relating to contamination of bee matrices, the application can also be used to identify the agricultural context around the colonies concerned.

6.2.1.2 VIGIPhyto: Toxicovigilance study on plant protection products in order to target priority products/substances for post-approval monitoring

The toxicovigilance scheme draws on information collected by the CAPTVs, whose information system (SICAP) contains two databases:

- The national database on products and compositions (BNPC), hosted by the Nancy CHRU and managed by the Nancy CAPTV; this brings together validated information on the composition of products and agents, useful to CAPTV doctors for their activities (emergency telephone hotline, toxicological information and expertise, and toxicovigilance);
- The national database of poisoning cases (BNCI), hosted by the Paris Public Hospital System (AP-HP) Lariboisière Saint-Louis Hospital Group; this lists all the poisoning cases known to the CAPTVs.

Given the main hierarchical organisation of products in the BNPC, which is according to use and not regulatory status, it was not possible to carry out an immediate automated search for all products classified as "plant protection products" in the regulatory sense. Thanks to funding from the PPV scheme, a secondary hierarchy was set up in the CAPTV database, making it easier to extract cases of poisoning associated with exposure to plant protection products. A few years later, this secondary hierarchy facilitated the establishment of an annual review of cases associated with plant protection products (ANSES, 2020b).

6.2.2 Generate new data or knowledge: boost surveillance or fund an occasional campaign

6.2.2.1 CNEP: National exploratory campaign to measure pesticides in ambient air

On 2 July 2020, ANSES published its initial interpretation work on health impacts, based on the results of the national exploratory campaign to measure pesticides in outdoor air (CNEP), conducted jointly by Ineris and the AASQA network and funded by the PPV scheme. During the national large-scale campaign launched in June 2018, 75 substances were measured over 12 months according to a newly harmonised protocol, and around 1300 analyses were produced for each of these substances. France is one of the few countries in Europe, besides Belgium, to have undertaken this kind of campaign for measuring pesticides in ambient air on a national scale.

On the basis of the CNEP results, ANSES carried out initial interpretation work to assess the health impacts of 70 substances confirmed in outdoor air. This analysis identified substances requiring further consideration for possible inclusion in the national surveillance system for pesticides in air.

This initial work to interpret the health impacts was carried out using two approaches capitalising on measured concentration levels, the frequencies at which substances were measured in air, toxicity reference values, and the most unfavourable hazard classifications for each substance, by reviewing not only the databases created from regulatory dossiers but also the scientific literature.

The first health approach compared the results of air measurements with available toxicological data to provide initial health risk indicators. In the current state of knowledge, these did not show a major health issue in connection with the exposure of the general population via outdoor air, apart from areas with local emission sources. However, some uncertainties remained regarding the toxicity reference values used.

The second approach adopted by ANSES led to the prioritisation of 32 substances of interest for which additional expert appraisal work will be carried out in the near future; this will include chronic exposure routes to these substances other than via air. These investigations will make use of the latest available data, with regard to both toxicological values, and the hazards and health impacts of the various substances.

The CNEP findings have helped to guide choices made by the Ministry of the Environment's Bureau for Air Quality in terms of permanent national surveillance of pesticides in air.

6.2.2.2 PhytoSol: Validation of the technical feasibility of soil surveillance based on existing players and tools, in order to obtain an initial representative insight into the presence in regional soils of substances used in plant protection products

In 2018, as part of its phytopharmacovigilance mission, ANSES consulted INRAE's Info&Sols unit about setting up a prospective study on the measurement of plant protection substance residues in soil. This study drew on the RMQS, the institutional network for measuring soil quality in France.

The results of the study showed that virtually all the samples were contaminated with plant protection product residues, with between one and 33 active substances found in each sample. In total, 67 different active substances out of the 111 sought were found in the soil samples. The laboratories' analytical capabilities enabled very low concentrations of active substances

to be measured, with limits of quantification between 0.01 ng/g and 5 ng/g. Maximum concentrations of the 67 substances detected ranged from 0.03 ng/g for benalaxyl to 413 ng/g for indoxacarb. In addition, certain active substances were quantified at high frequencies, such as glyphosate and its metabolite AMPA, as well as fluopyram and fluxapyroxad, which were quantified at 70%, 83%, 69% and 68% of sites, respectively.

The PhytoSol study showed the reality of soil contamination by plant protection products. It therefore seemed appropriate to set up long-term surveillance of plant protection product residues in soil. This would make it possible to document soil contamination by active substances and metabolites, and monitor changes in this contamination over time and space in order to study the impact of plant protection products under the actual conditions in which they are used. Moreover, it was thought that this surveillance could usefully be attached to the RMQS, in order to guarantee its operational nature, draw on the INRAE teams' proficiency in the measurement protocol and streamline the associated budget.

ANSES therefore recommended that such surveillance be introduced in metropolitan France and the DROM from 2024. This would also enable France to pre-empt implementation of the future Framework Directive on Soil Protection. It would help improve understanding of the specific situation in France and make the case to the European Commission for any adjustments needed when the Directive is transposed into French law.

6.2.2.3 PestiLoge: Measurement of pesticides in air as part of the Second National Housing Campaign (CNL2)

Data on pesticide contamination of the indoor air matrix are still relatively limited. The aim of the PestiLoge study was to measure pesticide concentrations in air (gas and particulate phases) and in settled dust as part of the Second National Housing Campaign (CNL2) of the Indoor Air Quality Observatory (OQAI)[11]. The measurements were carried out in 2021–2022 on a sample of almost 600 homes, representative of homes in mainland France. A total of 81 substances were screened for in indoor air, and 92 in dust.

At this stage, the results, which are still only descriptive (although they have demonstrated the frequent presence of pesticides in indoor air and dust), have not identified any signals within the meaning of phytopharmacovigilance. But further work to come, led by the CSTB and/or ANSES, could help with this identification. This additional work could focus on analysing the associations between the pesticides found and proximity to crops, seasonality or the characteristics of homes and households.

The Agency will also be undertaking collective expert appraisals to study the feasibility of defining specific toxicity reference values for respiratory exposure, for the pesticides of greatest concern in the air. Data permitting, this work will also aim to conduct an assessment of the health risks associated with exposure to pesticides, taking the different sources and routes of exposure into account.

6.2.2.4 Assessment and interpretation of biological contamination of the general population by plant protection products – Data from the health study on the environment, biomonitoring, physical activity and nutrition (ESTEBAN)

ESTEBAN, run by *Santé publique France*, aimed primarily to measure the exposure of the general population to certain environmental substances, including pesticides (this part was funded by the PPV scheme). Participants were recruited between 2014 and 2016 to obtain a

[11] Now known as the Indoor Environment Quality Observatory (OQEI) since May 2024.

representative sub-sample of the general population aged between 6 and 74 years living in metropolitan France.

For the first time, the results described exposure to five classes of pesticides in children, through measurements in urine and blood, as well as exposure to new substances, including glyphosate, in adults. While the overall level of contamination of the population is falling, certain substances, although banned today, are still leading to non-negligible levels of exposure.

Based on the study results, exposure reference values were established for organochlorines, organophosphate metabolites, glyphosate and its metabolite AMPA, 2,4-D and pyrethroids. These reference values were used to identify any sub-populations overexposed to a given substance at a given time, compared with the population as a whole.

The exposure data were cross-referenced with the responses to the various questionnaires administered on lifestyles, food consumption and participant characteristics, in order to identify the determinants of overexposure, which varied depending on the substance.

To a certain extent, because the values are still provisional, interpretation of the health impact of pyrethroid contamination levels was carried out using human biomonitoring guidance values (HBM-GVs). An HBM-GV represents the concentration of a chemical or its specific metabolite(s) in human biological matrices (e.g. urine, blood, hair) below which, according to current knowledge, there is no expected risk to health. HBM-GVs have been provisionally established for several pyrethroid metabolites as part of the European HBM4EU initiative. When the contamination levels were compared with the HBM-GVs, it showed that the urinary concentrations of the pyrethroid metabolites studied were mostly lower than the HBM-GVs, with the exception of the metabolite 3-PBA.

6.2.3 Generate new data or knowledge: methodical analysis of data

6.2.3.1 MELASSES: Taking better advantage of groundwater surveillance

In 2020, ANSES commissioned BRGM to carry out a study aimed at taking better advantage of groundwater surveillance data for phytopharmacovigilance purposes.

Since the introduction of the PPV scheme, groundwater surveillance data have only been used in a general approach for the whole of France. Some more spatially detailed analyses are occasionally carried out, although these are according to administrative regions and lack any real hydrogeological relevance. Moreover, groundwater surveillance data had not yet been methodically analysed in relation to data on the use of plant protection products. The BRGM study aimed to fill these gaps.

BRGM's work highlighted a list of substances contaminating more than 10% of groundwater near the surface. A method was also developed to classify substances according to criteria of contamination of shallow aquifers and pressure associated with substance authorisations, and then to classify substances into three groups: high contamination for low potential pressure, contamination increasing with potential pressure and zero contamination regardless of the potential pressure. The signals revealed by this study still need to be analysed in detail.

6.2.3.2 PPBiodiv: Identify the potential effects of plant protection products on biodiversity

In 2019, ANSES commissioned the Centre for Ecology and Conservation Sciences (CESCO) at the Natural History Museum (MNHN) to conduct a study designed to exploit the citizen science data produced via the MNHN's Vigie-Nature platform.

Among the groups studied, CESCO analysed data from the Temporal Monitoring of Common Birds (STOC) programme to identify any possible pressure caused by the use of plant protection products on the biodiversity of common birds, taking account of other confounding factors likely to have an impact on bird populations, in particular those associated with agricultural intensification.

This study found a negative spatial correlation between the hazard quotient of plant protection products for bird species and the quantities of substances sold over a year. This negative correlation concerned 79% (n = 68) of the common bird species selected for analysis. This correlation was significant for 18 species (21%). The analyses carried out by the MNHN made it possible to separate the risk associated with plant protection products from any other agricultural factors, particularly those relating to the landscape.

For phytopharmacovigilance, this study constitutes a weak signal that needs to be confirmed and clarified in order to target:

- the agricultural contexts or substances posing the greatest risk to birds;
- the most sensitive species;
- the periods of exposure most likely to have an effect on bird populations.

6.2.4 Investigate a report

6.2.4.1 GEOCAP-Agri: Study of the link between the risk of paediatric leukaemia and living near vineyards

The study was undertaken in response to a series of cases of paediatric cancers suspected of being linked to exposure to plant protection products in the Nouvelle-Aquitaine region, following a request from the association *Alerte des Médecins sur Les Pesticides* (AMLP). It aimed to examine the potential links between paediatric cancers and the surface area of vineyards located near the children's homes. It was carried out by the CRESS research laboratory (Inserm/Paris Cité University) in collaboration with *Santé publique France*, throughout metropolitan France. The data used were:

- those of the National Register Of Childhood Cancers (RNCE) for the period 2006–2013;
- surface areas of vineyards and distances to the wine-growing plots located closest to the homes of children under 15 suffering from leukaemia in metropolitan France, which were calculated and then compared with the same data (vineyard surface areas, distances) for children of the same age who were not sick.

The study’s results did not show any clustering of cancer cases in metropolitan France. They also found that the presence of vineyards within 1 km of the home address was no more common for children with leukaemia than for healthy control children. The statistical analysis carried out by the researchers showed a moderate increase in the risk of acute lymphoblastic

leukaemia when the density of vineyards within a 1 km radius of the home address increased. The average increase in risk was 5 to 10% for a 10% increase in the vineyard surface area.

As part of the study, maps were produced to identify and quantify the surface area of vineyards in the vicinity of homes. A new study, called GEOCAP-Pest, was launched by Inserm in late 2023. It set out to compare these data with the plant protection substances used on each type of crop, for the main types of childhood cancer. The aim was to verify any correlations between the risk of cancer in children and their exposure to the plant protection substances used in farming activities carried out close to their homes. The researchers also planned to identify groups of products, chemical classes, or even active substances responsible for an increased risk.

6.2.4.2 PestiRiv: Study of pesticide exposure in people living near vineyards

Following an alert concerning a suspected increase in paediatric cancers in the Gironde municipality of Preignac, an epidemiological investigation was carried out by the regional unit of *Santé publique France*, which ultimately proved inconclusive. However, given the general concerns among the French population and public authorities about the health impact of pesticides, and the lack of French data on the actual exposure of people living near crops, *Santé publique France* and ANSES decided to launch the PestiRiv study. This is therefore the first study undertaken throughout metropolitan France to explore exposure to pesticides in wine-growing and non-wine-growing areas. It is an original study in that it will investigate the population's actual level of exposure, assessed through biological sampling (urine and hair), to all possible exposure sources: air (samples taken of air and dust from homes and outdoor air), food (including water), occupational activities including agricultural uses, and domestic uses. The primary objective is to find out whether exposure to pesticides differs between people living near grapevines and those living far from any crops. PestiRiv will seek to identify the sources that most contribute to pesticide exposure and determine how living distance from vines, the season, and the habits and behaviours of individuals may impact this exposure.

The field study was carried out between October 2021 and August 2022 and included almost 2000 adults aged between 18 and 79 years and almost 750 children over 3 years of age. The participants live in more than 250 study zones, representing contrasting local situations, in six regions: Auvergne-Rhône-Alpes, Bourgogne-Franche-Comté, Grand Est, Nouvelle-Aquitaine, Occitanie and Provence-Alpes-Côte d'Azur. In total, depending on the matrix, around 50 substances were screened for. The substances were selected because they were more or less specific to use in viticulture, with some of the highest sales volumes. The technical feasibility of measuring them, which varies according to the matrix, was also taken into account. The results of the study are expected in 2025.

6.2.4.3 PGL.EXPO: Study of the impact of environmental exposure to SDHIs on tumour risk in subjects at risk of hereditary SDH-related paraganglioma

Succinate dehydrogenase inhibitors (SDHIs) are fungicides used on arable crops (particularly cereals), as seed treatment, in viticulture, arboriculture, and on vegetable crops and ornamental plants. In 2019, Bénit *et al.* warned that SDHIs may inhibit all the SDHs tested (from fungi to humans) and be nonspecific by also inhibiting mitochondrial complex III, and that their toxicity may be aggravated in the event of mitochondrial dysfunction. ANSES conducted a collective expert appraisal in response to this alert, and concluded that "some residual uncertainties deserve to be highlighted, such as the absence, in the current state of the data brought to its attention, of any real signs of a health alert in terms of an increase in the incidence

of specific cancers associated with SDH-deficiency in humans not carrying a mutation (in exposed workers, for example), despite the fact that in some cases these compounds have been on the market for a long time". In order to resolve some of these residual uncertainties, the expert group recommended "testing the feasibility of retrospectively and prospectively monitoring changes in the incidence of known diseases involving SDHx mutations".

Hereditary paraganglioma is a rare genetic disease with an inherited predisposition to cancer associated with constitutional mutations in one of the autosomal dominant SDHx genes. Observation of the natural history of the disease in subjects on the French national register of hereditary paraganglioma (PGL.R) showed that disease penetrance and expressivity varied between subjects carrying the same mutation, suggesting that environmental or genetic factors contributed to its emergence. Exposure to SDHIs could be one of these factors, and the main aim of the PGL.EXPO study was to test this hypothesis. It was conducted jointly by the AP-HP, Inserm and the *Centre Léon Bérard* (CLB).

A feasibility study was initially carried out from December 2019 to June 2023, which led to the successful development of tools and a specific methodology. It demonstrated the feasibility (101 subjects included in 3 months, 81% participation rate among those included) of a national case-control study to acquire information on the existence of a morbid risk associated with exposure to SDHIs in carriers of a constitutional SDHx mutation, and specified the protocol. The study will therefore be continued by extending it to all the cases in the national PGL.R register (650 subjects) and to controls (650 subjects). The results of the study are expected in 2029.

7 Conclusions and outlook

In terms of governance for managing the health and environmental risks associated with the use of plant protection products, the PPV scheme, which identifies signals *a posteriori*, is an essential complement to the *a priori* risk assessments carried out on these products. This scheme increases the robustness of this governance through its ability to identify signals of adverse effects associated with the use of these products and report them to the various bodies responsible for assessing and managing risks.

To do this, the PPV scheme collects and analyses data, and classifies the nature of the signals accordingly. The data primarily come from the network of phytopharmacovigilance partners, which run surveillance schemes for the environment, food or populations, or vigilance schemes for human, animal or plant health. Another source of data is the literature monitoring conducted by ANSES, which mainly focuses on research into chronic health effects, as well as its monitoring of the results of environmental measurements obtained in other European countries. Lastly, the scheme receives reports directly from professionals and private individuals.

On several occasions, signals of adverse effects assessed by phytopharmacovigilance have led ANSES to amend the conditions for use in MAs or even to withdraw the MAs, in application of Article 44 of European Regulation (EC) No 1107/2009. Regarding prosulfocarb and S-metolachlor, these amendments to the conditions for use were prompted by regulatory quality limits being exceeded in food and water. In the case of terbuthylazine, evidence of a high frequency of quantification in water courses led to tighter conditions for use. In the case of metam-sodium, an episode of mass poisoning accelerated the withdrawal of the MAs, which in any case had been assessed unfavourably *a priori*.

In addition, the PPV scheme produces summaries of the surveillance and vigilance data available for active substances, in particular when their MAs are periodically re-examined and in addition to the *a priori* assessments updated in this context. These summaries can help highlight any specific problematic situations that were not identified through the representative uses predefined at European level for conducting European re-assessments of active substances.

The PPV scheme also funds research in situations where the data collected while analysing and classifying potential signals of adverse effects are not sufficient to reach a conclusion. Unlike other existing funding sources, which are organised on the basis of open calls for projects, the PPV scheme funds projects that meet specific needs that it has identified and for which research teams and bodies are then consulted. Since 2015, around 50 projects have been funded for a total of around €13 million. These projects have achieved the following:

- strengthened the surveillance schemes of phytopharmacovigilance partners;
- funded measurement campaigns to better assess the population's exposure to pesticides and the associated health risks, and to prioritise the substances to be monitored;
- identified signals requiring analysis.

Lastly, taking advantage of both its analysis of signals of adverse effects and the projects it funds, phytopharmacovigilance identifies needs for surveillance data, which it passes on to its partners.

France's PPV scheme is the only one of its kind in Europe. Its extension to the other Member States, with the aim of sharing surveillance data and improving the identification of adverse effect signals at European level, is one of the strategic orientations for phytopharmacovigilance for the period 2024–2028, defined by its interministerial steering committee. These orientations define the general strategic framework for phytopharmacovigilance actions over this period. These actions also aim to strengthen the collection of reports of adverse effects and the development of tools needed to interpret data on environmental contamination and exposure.

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8.2 Legislation and Regulations

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

Act No. 2014-1170 of 13 October 2014 on the future of agriculture, food and forestry

Decree No. 2016-1595 of 24 November 2016 on phytopharmacovigilance and amending various other provisions of the Rural and Maritime Fishing Code relating to plant protection

Ministerial Order of 16 February 2017 on the bodies participating in phytopharmacovigilance, issued in application of Article R.253-46-4 of the Rural and Maritime Fishing Code

Article R.253-46-3 of the Rural and Maritime Fishing Code

Article R.253-46-4 of the Rural and Maritime Fishing Code

Article L.253-8-1 of the Rural and Maritime Fishing Code

8.3 Hearings

Hearing of 25 March 2025, organised jointly by the National Assembly's Commission for Economic Affairs and Commission for Sustainable Development and Land Planning, with Mr Benoit Vallet, Director General of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), on the Agency's situation and work.

ANNEXES

Annex 1: List of studies funded by phytopharmacovigilance

Table 7: List of studies funded by phytopharmacovigilance

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
VIGIPhyto VIGIBiocides: Creation of a secondary hierarchy to greatly simplify case searches in the BNCI (Automation)	Human health	Develop or consolidate schemes, tools or methods	AP-HP and Nancy University Hospital	2015	2017	Finalised
FILATURES: Feasibility study to access the territorial dynamics behind the use of plant protection products in order to control risks: contributions and limitations of current records for commercial exploitation	Other	Develop or consolidate schemes, tools or methods	INRA	2015	2016	Finalised
INTERBEE: The role of virus/pesticide interactions in the decline of bees	Animal health	Generate new knowledge	ANSES's Sophia-Antipolis Laboratory	2015	2018	Finalised
RNV3P: Occupational exposure to pesticides and occupational health problems – Pilot study for the optimisation of data collection by the RNV3P	Human health	Develop or consolidate schemes, tools or methods	Bordeaux University Hospital	2015	2018	Finalised

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
ETAT RESISTANCES: Organisation of PPV for resistance. Overview and case studies	Resistance	Develop or consolidate schemes, tools or methods	ANSES's Lyon Laboratory, INRA, CNRS	2016	2019	Finalised
ANNELIDES: Assessment of changes in earthworm populations exposed to two plant protection products during field trials – recovery and functional consequences	Biodiversity	Generate new knowledge	INRA	2015	2018	Finalised
REPHYBAN II: Reduce exposure of banana plantation operators to plant protection products (control of Sigatoka disease)	Human health	Generate new knowledge	Irstea	2015	2018	Finalised
OPERATEUR SERRE: Estimate exposure of operators in greenhouses	Human health	Generate new knowledge	Eurofins/Staphyt	2015	2017	Finalised
SPH'AIR: Rank pesticides to be monitored in ambient air	Human health	Develop or consolidate schemes, tools or methods	Ineris/LCSQA	2016	2016	Finalised

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
IODATOX: Design of IT tools to standardise data entry practices, and pool and exploit data on bees	Animal health	Develop or consolidate schemes, tools or methods	ITSAP – Bee Institute	2016	2018	Finalised
ESTEBAN: Contribution to the InVS's national biomonitoring programme	Human health	Generate new knowledge	*Santé publique France*	2016	2021	Finalised
BDD MSA: Data mining in the MSA's medico-administrative databases for vigilance purposes	Human health	Develop or consolidate schemes, tools or methods	CNRS's TIMC Laboratory + Joseph Fourier University, Grenoble	2016	2018	Finalised
AGRICAN: Describe exposure to plant protection products of subjects in the AGRICAN cohort (agricultural environment)	Human health	Generate new knowledge	François Baclesse Centre	2016	2019	Finalised
Modernisation of the Nancy CAPTV's BNPC database	Human health	Develop or consolidate schemes, tools or methods	InVS and Nancy University Hospital – French eHealth Agency (ASIP)	2016	2019	Finalised

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
NN NECTAR & POLLEN: Measure the potential level of exposure of bees and other pollinators on attractive crops following a non-attractive crop treated with a substance from the neonicotinoid class	Animal health	Generate new knowledge	ITSAP – Bee Institute, INRAE, CNRS, Terres Inovia, Interprofessional Technical Centre for Fruit and Vegetables (CTIFL)	2017	2017	Finalised
EXPOBEE: Assess the exposure of colonies of bees and pollinators for epidemiological surveillance purposes: review of knowledge and practices.	Animal health	Generate new knowledge	ANSES's Lyon Laboratory	2016	2016	Finalised
PESTIRIV (feasibility study): Exposure of residents in agricultural areas to PPPs – indoor air feasibility study	Human health	Generate new knowledge	CSTB	2018	2021	Finalised
PESTIRIV (feasibility study): Exposure of residents in agricultural areas to PPPs – ambient air feasibility study	Human health	Generate new knowledge	Ineris	2018	2021	Finalised
POPEI (plant protection products in the indoor environment): Analytical feasibility study in preparation for the OQAI campaigns	Human health	Develop or consolidate schemes, tools or methods	CSTB/OQAI	2017	2020	Finalised

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
GEOCAP-Agri: Clusters of paediatric cancers in the vicinity of agricultural areas	Human health	Reporting	Inserm	2017	2021	Finalised
Bt TIAC: Risk of consumption associated with *Bacillus thuringiensis*, analysis of samples from foodborne illness outbreaks to determine whether Bt is responsible for certain poisonings	Food	Reporting	ANSES's Laboratory for Food Safety, SCL, GAMER mission, sequencing service provider	2017	2019	Finalised
Study of the exposure of bystanders and residents to plant protection products during vineyard application in accordance with good laboratory practice and the OECD's "Guidance document for the conduct of studies of occupational exposure to pesticides during agricultural application"	Human health	Generate new knowledge	Call for tenders	2017	2018	Finalised
Network of reference hives: Feasibility study for the creation of a network of regional reference apiaries	Animal health	Develop or consolidate schemes, tools or methods	INRAE	2017	2018	Finalised

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
CNEP: Surveillance of PPPs in ambient air/exploratory campaign	Human health	Generate new knowledge	AASQAs, LCSQA	2017	2020	Finalised
Identify research teams that can be mobilised by the PPV scheme in human health: surveillance of impacts and exposure	Human health	Develop or consolidate schemes, tools or methods	Opus Line	2018	2018	Finalised
PHYTOSOL: Review of the contamination of French soil by plant protection active substances during the second RMQS campaign	Environmental media	Generate new knowledge	INRAE	2018	2022	Finalised
MELANGES AGRI: Describe exposure to plant protection substances of subjects in the AGRICAN cohort and the associated substance mixtures	Human health	Generate new knowledge	François Baclesse Centre	2019	2023	Finalised
DRAGON: Diagnosis of resistance in ragweed: Generation of tools using new sequencing techniques	Resistance	Develop or consolidate schemes, tools or methods	INRAE	2018	2021	Finalised

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
BIG-DATA: Feasibility study: PPV data mining: creation of a tool for generating emerging phenomena for PPV-BIG-DATA	Other	Develop or consolidate schemes, tools or methods	Paris Sorbonne University	2018	2022	Finalised
SULFOXAFLOR: Analytical development of a method for sulfoxaflor/bee matrices	Animal health	Develop or consolidate schemes, tools or methods	ANSES's Sophia-Antipolis Laboratory	2018	2019	Finalised
Bt TIAC 2: Study of the pathogenicity of *Bacillus thuringiensis* and development of surveillance tools for food – Phase II	Food	Reporting	ANSES's Laboratory for Food Safety, SCL, ANSES's Fougères Laboratory, CNRS, INRAE, Sophia Agrobiotech Institute	2019	2022	Finalised
TOXPOLLEN: Toxicological analysis of trap pollen samples and the effect of contamination on the health of honeybee colonies	Animal health	Generate new knowledge	INRAE, ITSAP – Bee Institute, CNRS	2018	2022	Finalised

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
CARTO USAGES NN: Relative risks and benefits of alternatives to plant protection products containing neonicotinoids. Volume 3 – Scientific and technical support report on the agricultural impact	Animal health	Generate new knowledge	INRAE	2018	2018	Finalised
RECOTOX: Produce an overview of the data available within the ECOTOX network, useful for PPV	Biodiversity	Develop or consolidate schemes, tools or methods	INRAE	2018	2019	Finalised
PHYTO-GRAVES: Analysis of CAPTV data	Human health	Generate new knowledge	AP-HP, Nancy University Hospital	2018	2020	Finalised
BDD MSA 2: Data mining in the MSA's medico-administrative databases for vigilance purposes – Phase II	Human health	Generate new knowledge	CNRS's TIMC Laboratory + Joseph Fourier University, Grenoble	2018	2020	Finalised

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
PHYTO CUISSON: Characterise the impact on plant protection substance residues of frying food and cooking in ovens or microwaves	Food	Develop or consolidate schemes, tools or methods	ICPME (CNRS-UPEC), Ineris	2020	2023	Finalised
PPBIODIV: Provide new information for the PPV scheme on the adverse effects of plant protection products on biodiversity (particularly birds, bats and terrestrial invertebrates), through the programmes of the MNHN's Vigie-Nature platform	Biodiversity	Generate new knowledge	MNHN	2019	2022	Finalised
PESTIDUST: Obtain analytical methods for determining the concentrations of plant protection substances in settled dust in French homes and schools – Feasibility study	Human health	Generate new knowledge	EHESP	2019	2021	Finalised

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
PGL-EXPO: Impact of environmental exposure on tumour risk in subjects at risk of hereditary SDH-related paraganglioma PGL-EXPO-1.1&2: Pilot study (50 cases/50 controls)	Human health	Reporting	AP-HP, Inserm, *Centre Léon Bérard*	2019	2023	Finalised
PESTILOGE (CNL2): Measurement of pesticides in the Second National Housing Campaign (CNL2) of the Indoor Air Quality Observatory (OQAI) – PESTILOGE	Human health	Generate new knowledge	CSTB	2020	2024	Finalised
SMaRT: Molecular surveillance of resistance in the regions	Resistance	Generate new knowledge	INRAE	2020	2024	Finalised
MELASSES: Taking better advantage of groundwater surveillance	Environmental media	Generate new knowledge	BRGM	2020	2021	Finalised
PROMIA 2: Agricultural environment programme – 2	Human health	Develop or consolidate schemes, tools or methods	François Baclesse Centre	2020	2025	In progress
PESTIRIV:	Human health	Generate new knowledge	*Santé publique France* + environmental partners	2021	2025	In progress

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
Study to gain a better understanding of the exposure to pesticides of people living in wine-growing and non-wine-growing areas						
GEOCAP-Pest: Exposure to agricultural pesticides and paediatric cancers	Human health	Reporting	Inserm	2023	2027	In progress
MELASSES II: Taking better advantage of groundwater surveillance II	Environmental media	Generate new knowledge	BRGM	2023	2025	In progress
PPBIODIV 2: Identify the potential effects of plant protection products on bird and bat populations	Biodiversity	Generate new knowledge	MNHN	2023	2025	In progress
PGL.EXPO-2.1 Impact of environmental exposure on tumour risk in subjects at risk of hereditary SDH-related paraganglioma. National case-control study. First phase: technical and regulatory authorisations, establishment of the study and recruitment of the first 250 subjects. PGL-EXPO	Human health	Reporting	AP-HP, Inserm, *Centre Léon Bérard*	2023	2025	In progress

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
PGL.EXPO-2.2 Impact of environmental exposure on tumour risk in subjects at risk of hereditary SDH-related paraganglioma. National case-control study. First phase: technical and regulatory authorisations, establishment of the study and recruitment of the first 250 subjects. PGL-EXPO	Human health	Reporting	AP-HP, Inserm, *Centre Léon Bérard*	2024	2029	In progress
AGRICAN-DICAMBA Study of the effects of agricultural occupational exposure to dicamba on the incidence of cancer within the AGRICAN cohort	Human health	Investigate a report	François Baclesse Centre	2024	2027	In progress
PESTEXPOVAP Pesticides: Exposure 20 years later	Human health	Generate new knowledge	François Baclesse Centre	2024	2028	In progress
PHYTOVET Consolidation and use of CAPAE-Ouest data	Animal health	Develop or consolidate schemes, tools or methods	CAPAE-Ouest	2024	2026	In progress

Project title	Topic	Need	Sponsor	Project start year	Project completion year	Status
PHYTOCOL Field effects of plant protection products on soil mesofauna: springtails and mites	Environmental media	Generate new knowledge. Consolidate tools for surveillance, vigilance and risk assessment	INRAE	2024	2026	In progress

Notes

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