Phytopharmacovigilance: the only vigilance scheme of its kind in Europe

Plant protection products designed to protect plants and crop products against pests can pose risks to human health, ecosystems and living organisms, which need to be identified and monitored in order to better prevent them. With this in mind, the legislator created a scheme, known as phytopharmacovigilance, for detecting and monitoring adverse effects associated with the use of plant protection products available on the market. Implementation of this vigilance scheme, enshrined in the Act on the future of agriculture, food and forestry of 13 October 2014, was entrusted to the French Agency for Food, Environmental and Occupational Health & Safety (ANSES). Phytopharmacovigilance is the latest addition to ANSES's missions on prior assessment of risks associated with plant protection products, as part of the process to issue marketing authorisations.

In this context, ANSES is tasked with collecting all reports of adverse effects related, or potentially related, to the use of plant protection products. This vigilance scheme, set up in 2015 and the only one of its kind in Europe, covers all adverse effects concerning the environment, food, and plant, animal and human health.

It operates on the basis of information produced by existing surveillance or vigilance networks, reports of adverse effects, and the possibility of conducting studies to answer specific questions.

The surveillance and vigilance networks taking part in phytopharmacovigilance were appointed by the Ministerial Order of 16 February 2017. About 15 organisations operating in the many fields covered by phytopharmacovigilance (adverse effects of plant protection products on humans, farmed and wild animals or ecosystems, as well as the appearance of resistance phenomena) provide ANSES with regular reports and data collected under the scheme, and alert the Agency in the event of any serious, immediate or unexpected risk.

Specifically with regard to human health, these organisations are:

- Poison control centres (PCCs), whose toxicovigilance activities are coordinated by ANSES;
- The Phyt'attitude scheme of the Agricultural Mutual Insurance Scheme (MSA);
- The National Network for the Monitoring and Prevention of Occupational Diseases (RNV3P), coordinated by ANSES; *Santé Publique France*;
- The AGRICAN cohort[1] led by the François Baclesse Centre.

Whether it concerns humans, farmed and wild animals, ecosystems, or the appearance of resistance phenomena, reporting the adverse effects of plant protection products is mandatory for certain professional stakeholders such as holders of marketing authorisations and parallel trade permits[2] for plant protection products, manufacturers, importers, distributors or professional users of plant protection products, as well as advisers and trainers of these users. In these cases, reports are transmitted to the body competent to deal with them, which informs ANSES via a notification. Cases can also be sent directly to ANSES via the web page devoted to reporting. However, anyone can report an incident, accident or adverse effect, associated or potentially associated with a plant protection product or an adjuvant.

How should an adverse effect in humans be reported?

Anyone experiencing an adverse effect requiring medical advice or treatment should contact a doctor or a poison control centre.

For other situations, or if some time has passed since their occurrence, if the adverse effects resulting from the use of plant protection products specifically affect the health of farmers and/or people affiliated to the MSA, they must be reported to the MSA's specific Phyt'attitude scheme via the French freephone number: 0 800 887 887.

1. The AGRICAN (AGRIculture and CANcer) cohort study is an epidemiological study launched in 2005 to address the lack of information on occupational risks in the French agricultural population (exposure to plant protection products, fertilisers, UVs, mechanical risks, animal viruses, mould, etc.). Scheduled to continue until 2020, it is based on the follow-up of 180,000 agricultural insurance holders and is now one of the largest studies in the world on health in agriculture.

2. A plant protection product that is authorised in one Member State (Member State of origin) may, subject to the granting of a parallel trade permit, be introduced, placed on the market or used in another Member State (Member State of introduction) if the latter establishes that the plant protection product is identical in composition to a plant protection product already authorised in its country (reference product). The application is submitted to the competent authority of the Member State of introduction.

All other reports (by non-farmers and/or anyone not affiliated to the MSA, healthcare professionals), can be formalised via the Ministry of Health's portal for reporting adverse health events (https://signalement.social-sante.gouv.fr/psig_ihm_utilisateurs/index.html#/accueil). Professionals subject to the reporting obligation have a dedicated area for submitting their reports on this same portal.

The reports registered on the portal are processed and assessed by MSA doctors for reports to Phyt'attitude, or by the regionally competent PCC for other cases. Anonymised data on adverse effects are regularly communicated to ANSES, which will immediately be notified of any reports submitted by a professional subject to the reporting obligation.

The reporting channel for adverse effects occurring in humans following the use of plant protection products is shown in Figure 1.

Depending on the severity of the effect mentioned and the results of the investigations carried out, ANSES and/or the competent authorities can then immediately take all measures necessary to limit the impact (e.g. by amending the product's conditions of use).

How should an adverse effect not related to human health be reported?

Adverse effects of plant protection products on animals, plants, food, environments or ecosystems must be reported using a dedicated form[3] depending on the status of the reporter, and sent to ANSES by post[4] or by email (ppv@anses.fr).

Ad hoc studies are financed under the phytopharmacovigilance scheme when information on adverse effects provided by surveillance and vigilance organisations is deemed to warrant further clarification, or in order to improve the quality and accessibility of information from partner networks for phytopharmacovigilance purposes.

The phytopharmacovigilance scheme pools the information derived from the surveillance or vigilance schemes, conducts *ad hoc* studies and collects spontaneous reports to meet its three objectives:

- enable the marketing authorisation conditions of products currently on the market to be adapted, if necessary (for example, by reducing doses, adapting the conditions of application or withdrawing a marketing authorisation);
- define cross-cutting management measures, for example for protecting people in the vicinity of treated areas;
- contribute to enforcing compliance with bans on the use of products, especially those whose active substances are no longer approved at European level.

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TO FIND OUT MORE, VISIT:

ANSES page:
https://www.anses.fr/fr/content/signalement-deffets-ind%C3%A9sirables-li%C3%A9s-%C3%A0-lutilisation-de-produits-phytopharmaceutiques

Act No. 2014-1170 of 13 October 2014 on the future of agriculture, food and forestry: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000029573022&categorieLien=id

Decree 2016-1595 of 24 November 2016 on phytopharmacovigilance: https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000033478559

3. The reporting forms are available on the ANSES website from the following page: https://www.anses.fr/fr/content/signaler-un-effet-indésirable-ne-portant-pas-sur-la-santé-humaine-lié-à-lutilisation-de

4. ANSES, Direction de l'évaluation des risques, Unité phytopharmacovigilance et observatoire des résidus de pesticides, 14 rue Pierre et Marie Curie, 94 701 Maisons-Alfort Cedex, France

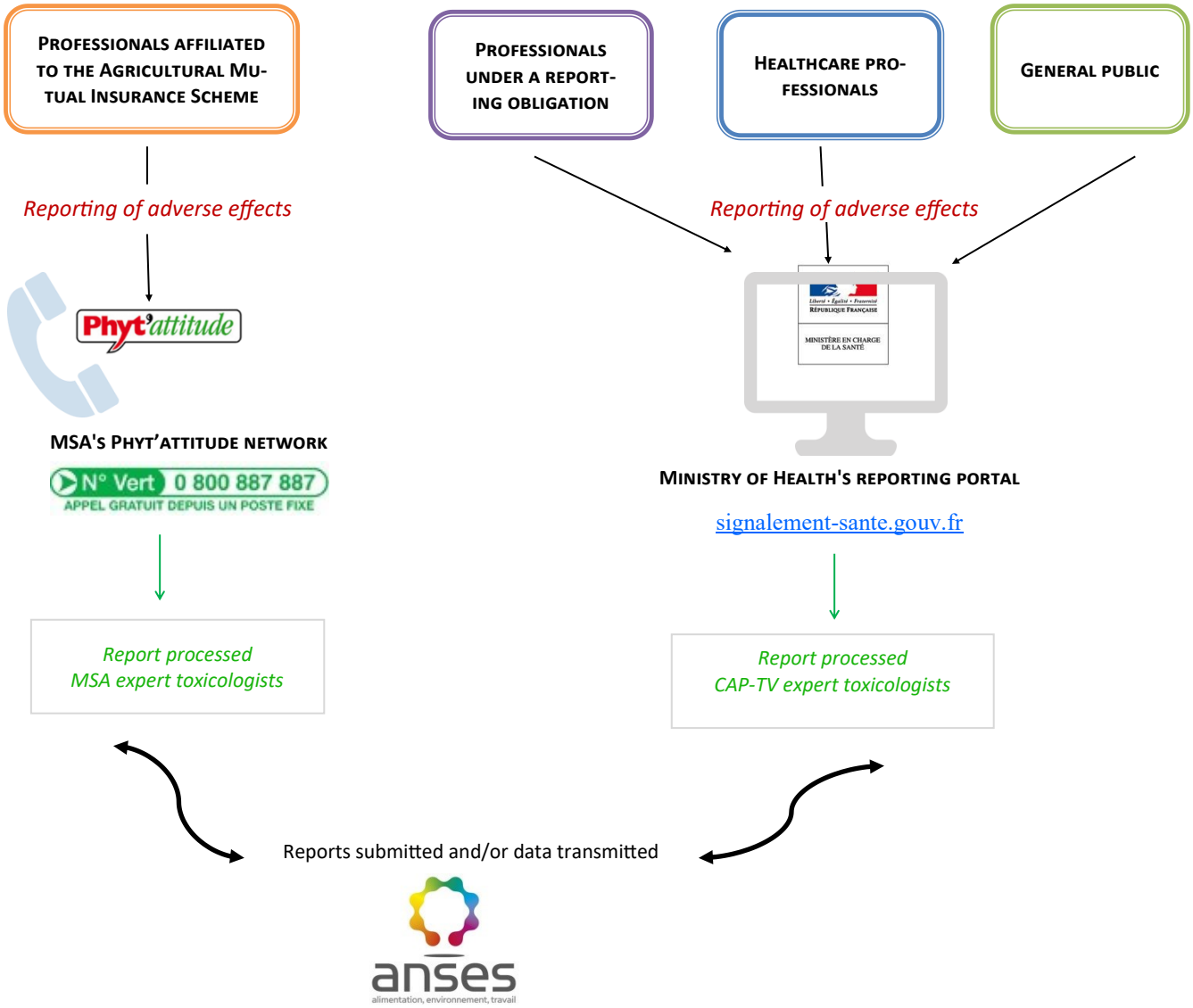

Figure 1: The phytopharmacovigilance scheme: channels for reporting adverse effects in humans