# Elucidating the causes of an adverse phenomenon through phytopharmacovigilance: the example of prosulfocarb on apples

Plant protection products (PPPs) include pesticides used in agriculture to protect plants and fruit from pests. However, they can have adverse effects on human and animal health and the environment, and can lead to the development of resistance in pests. For this reason, these products can only be marketed and used after a marketing authorisation (MA) has been issued by ANSES, following analysis of a complete dossier, containing all the scientific knowledge acquired on the product and specifying the authorised conditions of use (crop, quantity, application conditions, etc.).

The active substance(s) contained in the product must have been previously authorised at European level. However, it is still possible for an adverse effect to occur. This led ANSES in 2015 to set up a scheme called phytopharmacovigilance (PPV), the only one of its kind in Europe, as one of the measures of the Act of 13 October 2014 on the future of agriculture, food and forestry (see the presentation in Issue 3 of Vigil'Anses **[1]**). Its objective is to collect and analyse any signal or alert concerning a possible adverse phenomenon/effect associated with these products, based on spontaneous reports, scientific studies subsequent to those analysed for the MA, or data collected on a routine basis.

Signals can come from a variety of sources, including the companies holding the MAs. An example of this is shown below.

**The signal**

In 2016, an MA holder of products containing the active substance prosulfocarb informed ANSES via the PPV scheme that systematic checks on late-harvested apples had revealed that the authorised maximum residue level (MRL) of prosulfocarb was regularly being exceeded, making the fruit unfit for marketing. Prosulfocarb is not authorised for use on apples. It is a herbicidal substance, moderately volatile, not readily biodegradable in water and readily adsorbed to soil **[2]**. Four commercial products were involved at the time of the signal.

**Confirmation of the signal**

The first step in the process was to verify whether or not the signal posed a threat to human health. An acute health risk to consumers was ruled out, as an adult would have to consume 75 kg of apples and a child 12.5 kg in one day to reach the toxicity threshold.

The second step was to substantiate the signal with data from other sources. Through its pesticide residue surveillance plans, the Directorate General for Food (DGAL) confirmed the presence of prosulfocarb on crops for which its use is not authorised; not only on late-harvested apples but also on watercress, spinach and leek crops.

**Investigation and hypotheses**

In June 2017, ANSES was asked to investigate the reasons for these MRLs being exceeded and recommend corrective measures. The aim was to understand why this substance – which was authorised and used on other crops – was found on crops for which it was not authorised, and determine how to avoid it.

To do this, ANSES first examined the possible vectors of contamination and the factors that could influence them, in order to draw up a list of possible contamination hypotheses. Numerous data were analysed by ANSES with the help of five experts. These data came from the PPV scheme and other sources, including:

- Data on environmental contamination (ambient air, surface water, groundwater).
- Data from the surveillance and control plans carried out systematically by the DGAL and the DGCCRF for foodstuffs, at the production and distribution stages;
- Data on quality monitoring of drinking water;
- Sales data from the French national database of sales of plant protection products by distributors (BNVD).

To supplement these data, particularly on the contamination of fruit and vegetables, ANSES also contacted the professional federations concerned, the main purchasing centres and the three agricultural technical institutes mainly concerned.

It interviewed these institutes to obtain information on the problems linked to prosulfocarb for their respective sectors, and on the actions and experiments they were conducting or wished to conduct in order to limit environmental contamination.

Lastly, ANSES reviewed the literature on this issue.

**ANSES's conclusions and recommendations**

The conclusions of the work were published in November 2017 and can be viewed on the ANSES website **[3]**.

Spray application of a plant protection product can lead to its dispersion in the environment and in particular:

- in the air, due to direct losses from drift during application (i.e. a fraction of the spray, at the time of application, does not reach the plant or the soil and ends up elsewhere) and indirect losses after application by volatilisation from the soil or treated area;
- in water, due to runoff or infiltration in the soil;
- in soil.

Once released into one of these environments or compartments (air, water or soil) and according to the compartment in question, PPPs can be transported varying distances from the source, depending on weather conditions but also on their physical state and persistence in the environment. Thus, untreated crops may be contaminated by dry or wet deposition (if PPPs are in the air), during irrigation (if PPPs are in the water used) or by root nutrition, depending on their physical state and persistence in the environment.

The factors positively or negatively influencing spray drift during application and the phenomenon of vaporisation after application were studied in particular (details of these are given in the ANSES report **[3]**).

Then, each situation in which MRLs were exceeded was analysed with regard to these different factors and hypotheses, to try and understand the mechanism (drift or vaporisation) and develop recommendations.

For apple contamination, two hypotheses – drift and volatilisation – were possible, perhaps even in combination.

For watercress, contamination from the water supplying the growing beds was ruled out and spray drift was implausible. Only the hypothesis of product volatilisation and then direct deposition by contact or after precipitation could not be ruled out.

For young rocket shoots, the particularity of this crop was that in three of the cases where the exceeded limits were reported, it was grown under shelter and required spray irrigation, mainly with rainwater collected from the shelters. Despite this, contamination by volatilisation or drift was possible because the shelters were opened at certain times for ventilation, enabling outside air to circulate in them. In addition, prosulfocarb may have been in the rainwater collected for spray irrigation.

For all three crops, soil contamination appeared to be ruled out.

All the work highlighted the need to improve knowledge of the mechanisms of contamination and to monitor it in order to assess the impact of the management measures taken.

**Immediate consequence: amendment to the MA for PPPs containing prosulfocarb**

The first assumptions made about the origin of the contamination were that the prosulfocarb product "drifted" from its target when sprayed on crops and reached other, non-target plots. Therefore, without waiting for the work to be completed, ANSES amended the conditions of use of products containing prosulfocarb. Since 16 October 2017, the MA has mentioned the requirement to use an approved device to limit spray drift of products **[4-7]**.

Work on this issue is continuing, in particular to take greater account of other hypotheses, such as aerosolisation of the PPP.

In October 2018, in view of the continuing contamination, ANSES reinforced the measures to protect neighbouring crops, in particular by prohibiting use of the product within 500 metres of a crop not targeted by the treatment, such as apples, until they have been harvested.

This example shows how, if a professional notifies the authorities of an adverse phenomenon, protective measures can be taken and work initiated to better understand the reasons.

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**References**:

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