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Investigate, evaluate, protect

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The arrival of autumn is unfortunately synonymous with **poisonings due to wild mushrooms**. In this Issue 6 of Vigil'Anses, we present the figures for the 2017 season, which was particularly deadly, with two deaths and a high number of serious poisoning cases compared to the previous year. It is an opportunity to remind people of the good practices that ensure safe picking and eating of wild mushrooms.

Slime is still in fashion! This colourful, sticky, elastic putty is prepared by children and then kneaded for hours to help them relax. Unfortunately, most "homemade" recipes involve the misuse of chemicals, a practice that is strongly discouraged because of their toxicity. Even some commercially available kits are non-compliant and have been withdrawn from the market for this reason. An article in this issue describes the risks associated with this practice, based on an analysis of cases reported by three networks of healthcare professionals.

An article previously published in Issue 3 of Vigil'Anses presented the French phyto-pharmacovigilance scheme, the only one of its kind in Europe. This scheme monitors the adverse effects associated with plant protection products (commonly called pesticides). In the current issue, an article presents a specific example of a signal investigated within this scheme: detection of the contamination of crops (in this case apples, watercress and baby salad leaves) by **prosulfocarb**, a plant protection substance that is not authorised for these crops.

Applying ear drops to a dog can be risky if the dog shakes its head and the product gets into the eye of the owner, the vet or the dog itself. More than a dozen cases of eye injury in dogs and people have been reported, mainly in the United States, when using **Osurnia® ear drops for dogs**. An article reviews these accidents and reiterates the precautions to be taken.

Lastly, in the news section, you can read or re-read the opinion published by ANSES in May 2018 on cases of serious allergies that occurred after consumption **of food supplements containing pollen or hive products** (such as royal jelly).

Juliette Bloch, Editor-in-Chief of Vigil'Anses

Twice as many poisonings and serious cases due to mushrooms in 2017 as in 2016

Every year since 2010, poisonings due to wild mushrooms in France have been monitored nationally from July to December (weeks 27 to 52). This is due to the seasonal nature of these cases, since mushroom growth is dependent on temperature and humidity. This surveillance enables national and local media to disseminate prevention messages each year during the mushroom picking season.

ANSES has been in charge of this surveillance since 2016, and had provided an earlier assessment in its second issue of Vigil'Anses **[1]**. The particularly high number of poisonings and serious cases of poisoning in 2017 meant that a new review was now called for.

Mushroom poisoning cases occurring between 4 July 2017 and 31 December 2017 were extracted from the National Database of Poisoning Cases (BNCI) of the Poison Control Centres' Information System (SICAP).

A case was defined as a person who had consumed one or more of the higher fungi[1] (macromycetes) and had presented at least one clinical sign following this ingestion, for which the advice of a poison control centre was sought.

Only cases of poisoning for which the overall causality was coded as non-zero were retained. Cases where causality was zero[2], i.e. where the link between clinical signs and mushroom consumption was excluded, were not included in this analysis, nor were cases of symptomless ingestion, or intentional ingestion of inedible mushrooms for recreational purposes or as part of a suicide attempt.

While 2016 only saw a few symptomatic poisoning cases (N = 603), in 2017, 1,386 cases of mushroom poisoning were recorded by the network of poison control centres (PCCs) during the surveillance period.

These poisonings occurred mainly in September (35.6%) and October (38% of cases), with respective peaks of 291 cases in week 39 and 215 cases in week 40.

During these weeks, the weather conditions combining heavy rainfall, little sunlight and cool temperatures favoured wild mushroom growth and therefore picking, which was responsible for the increase in poisonings.

Almost all cases of poisoning showed digestive signs (92%), which were mainly vomiting (62.8%), diarrhoea (45.7%), nausea (22.7%) or abdominal pain (40.8%).

More worryingly, 2017 also saw a high number of serious cases. While around 20 serious cases are expected every year on average, 41 cases of high severity[3], including three deaths, were recorded by PCCs in 2017, with 33 cases occurring between weeks 39 and 42.

Of these 41 cases of high severity, more than two thirds (25 cases) corresponded to poisonings caused by wild mushrooms containing amanitin toxins (amatoxin poisonings). This is characterised by digestive signs (nausea, vomiting, abdominal pain and profuse diarrhea) occurring on average 8 to 12 hours after consumption, and can lead to serious or even fatal liver damage. This syndrome can be caused by death cap (*Amanita phalloides*), European destroying angel (*Amanita virosa*), etc.), small *Lepiota* or *Galerina*.

1.Mould was not included in this study.

2.Causality is the link between exposure to the agent and the patient's symptom. This causality is calculated according to version 7.6 of the method for determining causality in toxicovigilance (the method and a calculator are available at tv.toxalert.fr). When this causality is zero, it means that the symptoms presented by the exposed individual are not related to the agent, which explains why these individuals are excluded from studies.

3.Causality is rated from I0 to I4: excluded, unlikely, plausible, likely, very likely.

Severity assessed based on the Poisoning Severity Score (Persson HE, Sjöberg GK, Haines JA, Pronczuk de Garbino, J. J Clin Toxicol. 1998;36 (3):205-13).

The 25 patients with amatoxin poisoning ranged in age from 14 to 90 years (median 62 years). All the victims were poisoned during a meal. In five collective cases (representing 10 cases of poisoning), the meal had been shared by at least two diners who all suffered from high-severity amatoxin poisoning. Where information was available in the PCC files, most cases concerned fungi mistakenly assumed to be parasol mushrooms (*Macrolepiota procera*), boletus (*Boletus spp.)*, sheathed woodtuft (*Kuehneromyces mutabilis or Pholiota mutabilis*), saffron milk cap (*Lactarius deliciosus*), puffballs (*Calvatia spp. or Lycoperdon spp.*) or field mushrooms (*Agaricus campestris*). In four cases, death cap (*Amanita phalloides)* and *Amanita submembranacea* were formally identified through photos; in the other cases the patients had not taken any photos of the mushrooms they had picked.

All 25 cases of high-severity *Amatoxin* poisoning caused liver damage, including 14 that were serious.

Of these, three cases required liver transplantation and two patients died before transplantation.

ANSES and the Directorate General for Health (DGS) issued an initial joint press release on 29 September 2017 (week 39) following the first peak in the number of poisoning cases, in order to remind the general public of the recommendations for good mushroom picking and consumption.

Due to an unusually large number of prescriptions in French hospitals for the antidote (Legalon®) used in the treatment of amatoxin poisoning, identified by the French Health Products Safety Agency (ANSM), ANSES issued a second press release on 20 October 2017 to reiterate the dangers related to mushroom consumption.

Apart from the large number of cases and the high frequency of severe cases, 2017 was comparable to 2016 in terms of the other characteristics of the poisoning victims. There were as many men as women and all age groups were involved, ranging from 9 months to 92 years (median age 48).

While all regions were represented, the geographical distribution was uneven, with a high proportion of cases in Nouvelle Aquitaine (14%) and Pays-de-la-Loire (12.7%) followed by the Grand-Est and Ile-de-France regions (around 11% of cases).

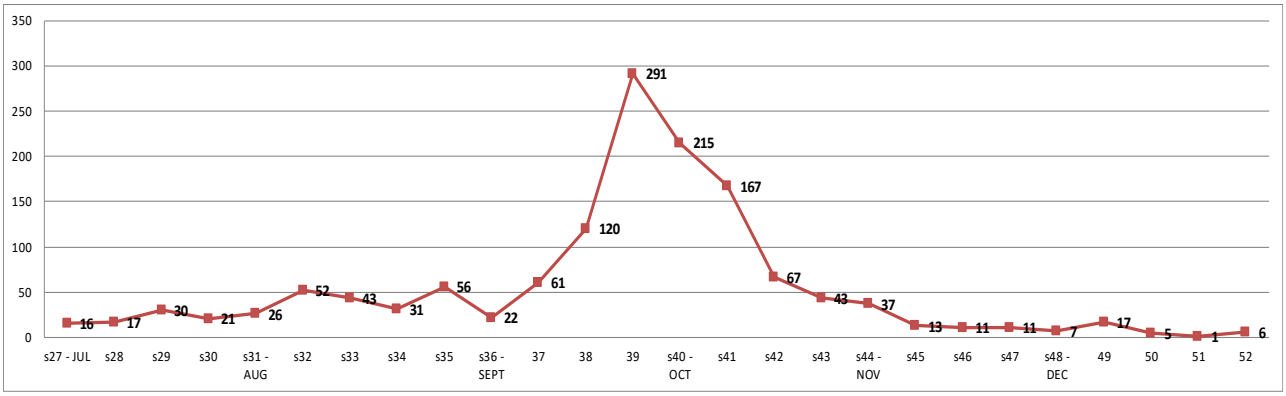

Figure 1: Weekly distribution of mushroom poisoning cases observed in SICAP between weeks 27 and 52.

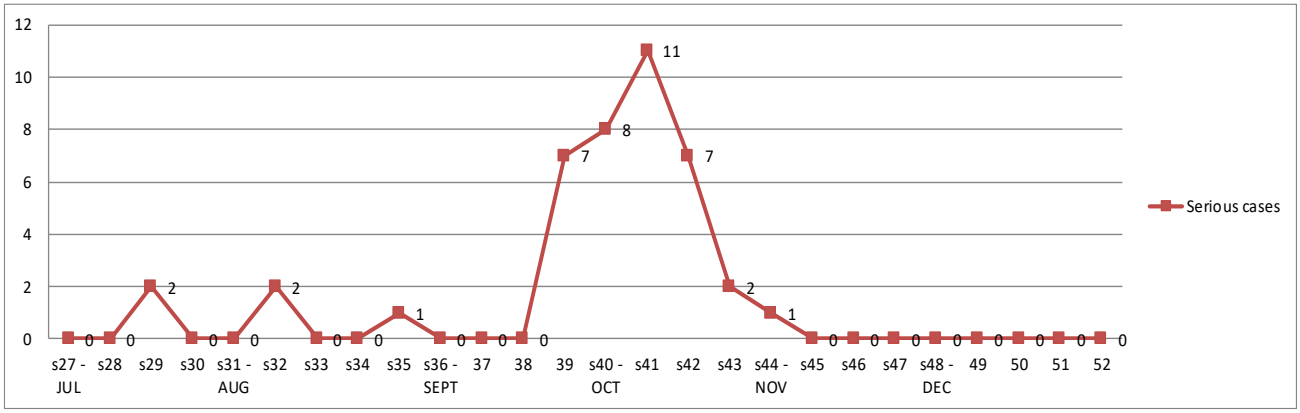

Figure 2: Weekly distribution of severe mushroom poisoning cases observed in SICAP between weeks 27 and 52.

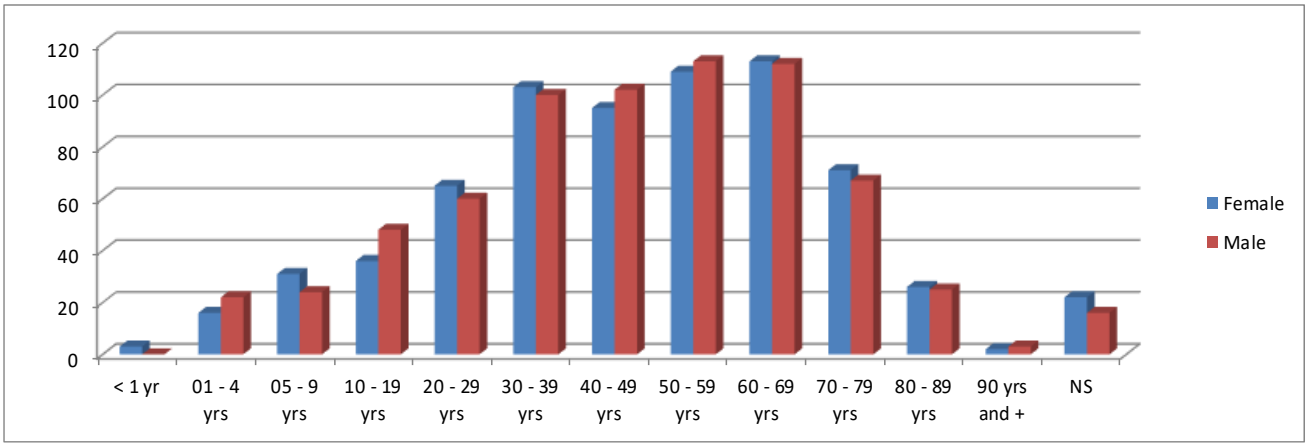

Figure 3: Age and gender distribution of the number of cases of mushroom poisoning between weeks 27 and 52. (Source: SI-CAP).

Most of the mushrooms consumed were picked (72% of cases), whereas a small proportion (5.5%) were bought at a market or in a shop.

In addition, in almost 92% of cases, people were poisoned during a meal. However, in 5% of cases, ingestion of a piece of inedible mushroom concerned young children or, to a lesser extent, adults with neuropsychiatric disorders: they consumed a mushroom found by chance in the garden, without the knowledge of those around them.

Mushroom poisoning most often results from confusion with edible species. However, in some cases people are completely unaware of the existence of poisonous fungi; they then pick poisonous species and fail to seek specialist advice before eating them.

If you pick mushrooms, therefore, **it is worth getting into the habit of asking a mycologist to identify them and taking photos of them before cooking! In the event of poisoning, the photo will help the practitioner at the PCC decide on suitable treatment.**

In the event of one or more symptoms occurring (especially diarrhea, vomiting, nausea, tremors, dizziness, vision problems, etc.) following the consumption of picked wild mushrooms, **immediately dial "15" or call the poison control centre in your region, and explain that you have eaten wild mushrooms.**

Chloé GREILLET (Anses)

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[1] https://vigilanses.anses.fr/fr/issue/2%20DE%20VIGIL'ANSES

Avoid "homemade" slime!

Slime, a sticky, elastic putty for kneading, is currently very popular with children and adolescents who find it entertaining and relaxing. This trend, which began in late 2016, has become a social phenomenon in France. Children knead slime for hours on end, both as a game and to relieve stress. There are many tutorials on the Internet on how to make your own. Numerous recipes are available that show how to vary the appearance and texture (by adding colour, glitter, etc.). There are also ready-to-use forms of slime, or "noise putty", on the market that have the same consistency, as well as slime preparation kits for children over 6 years of age that are sold in toy stores.

The principle of making slime is simple: it involves a cross-linking reaction of polyvinyl alcohol or starch with a cross-linking agent (hardener), usually boric acid or borax (sodium tetraborate decahydrate). Based on this principle, the online tutorials and recipes recommend the use of the following products, in very approximate proportions:

- As polymers: aqueous solutions of polyvinyl alcohol found in adhesives, mainly paper glues available to the general public. Transparent or white, they can be sold in large bottles (up to 5 kg). Starch is also suggested as a polymer for homemade slime;
- As a hardener: boron, in the form of boric acid or borax, incorporated directly as a powder or found in eyewash, contact lens solutions or laundry detergents;
- As dyes: coloured solutions or glitter gels from stationery stores, food colourings, textile dyes etc.;
- As a "bulking" agent: shaving foam, added to give the slime a lighter, more airy appearance (fluffy slime).

Slime preparation is therefore based on the misuse of chemicals and medicines. These products contain substances that are toxic to health, starting with boric acid. It is classified as a Category 1B reprotoxic substance under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Effects on fertility, as well as on embryo-foetal development, have been observed for this substance after oral exposure in experimental studies.

Contact dermatitis due to handling slime (Source: Dr Schreiber)

Regarding the glues and dyes used in slime preparation, these products may contain preservatives whose normal use complies with Regulation (EU) No 528/2012 on biocidal products. These are mainly isothiazolinones, responsible for skin allergies.
Lastly, in the particular case of shaving foam, according to Regulation (EC) No 1223/2009 on cosmetics, it is defined as a rinse-off product. It is not intended to stay in prolonged contact with the skin (as opposed to a leave-on product, such as cream).

Alerted to children and adolescents using boron in this context, in June 2017 the Directorate General of Health asked ANSES to analyse the toxicovigilance data associated with exposure to slime. The poison control centres (PCCs), the dermato-allergology vigilance network (Revidal-Gerda[1]) and the Allergos network[2] all worked to identify cases and characterise their symptoms.
The PCCs searched the National Database of Poisoning Cases (BNCI) for symptomatic or non-symptomatic cases recorded between 1 January 2014 and 15 May 2018 associated with "slime" or commercial slime products (slime preparation kits, ready-to-use slime or "noise putty") contained in the National Database on Products and Compositions (BNPC).

1.Dermato-allergology vigilance network (Revidal) and Dermato-allergology study and research group
2.Allergos is an association that has set up a network for sharing information on complex cases in allergology

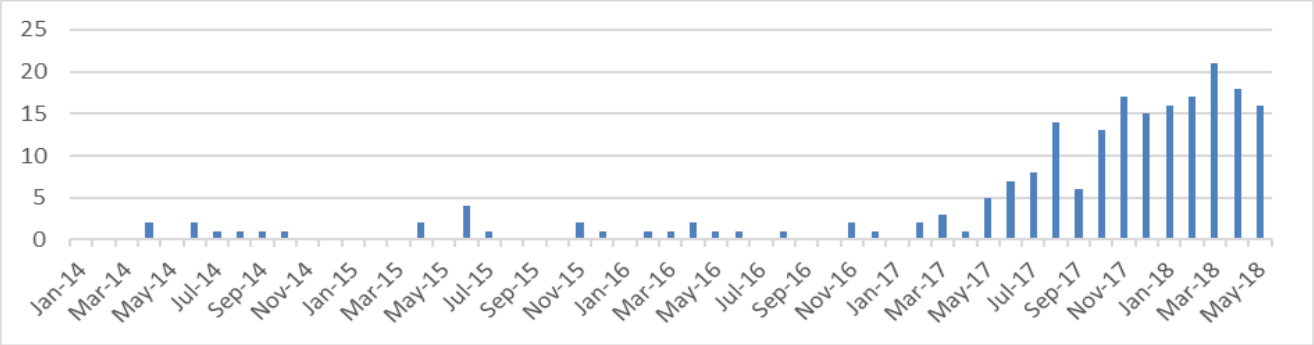

Figure 1: Number of cases meeting the "slime" selection criteria registered in the PCC information system from 1 January 2014 to 15 May 2018

Two hundred and five cases were extracted for the study period, including 91 in 2017 and 87 from 1 January to 15 May 2018, corresponding mainly to girls with an average age of 8 years. These figures confirm that this is a new phenomenon, as PCC teleconsultations following slime exposure began gaining momentum in 2017, and then increased significantly in early 2018 (**Figure 1**).

Regarding the agents involved in this exposure, in 61 cases the victims had used commercially available slime preparation kits. For "homemade" preparations, in most cases it was very difficult to obtain recipes at the time of the teleconsultations, despite the parents being asked by the PCCs. This is because children often make their own slime, without adult supervision, mixing recipes found on the Internet. However, for the best documented cases, the most frequently reported products used were liquid laundry detergents and glues.

With children up to 15 years of age, exposure to slime was due to handling or was accidental (accidental mouthing in the case of toddlers, eye splashes). Two children were victims of malicious acts (cruel "jokes" at school). The use of gloves during preparation was noted in only one case, which is not surprising. Children handle the product without gloves because they are specifically seeking contact of their hands with the slime.

Most cases reported to PCCs involved oral/buccal exposure (163 cases), which was mainly asymptomatic (114 cases). As reported by patients during teleconsultations, the amounts ingested were low.

For the dermal route, 78% of the cases identified by PCCs were symptomatic (21 cases out of 27) and reported local lesions such as skin burns, redness and itching. In one case, lesions on the scalp and ears in addition to the hands were indicative of slime toxicity probably transferred by the hands.

Lastly, it should be noted that due to the volatility of many chemicals in the products used by children, inhalation exposure is also possible, causing headaches and nausea.

Data from Revidal-Gerda and the Allergos network confirm the recent increase in dermato-allergology consultations following the preparation or the handling of slime. The majority of patients were girls over 10 years of age. Patch tests performed on these patients often revealed an allergy to isothiazolinones, preservatives found in many of the ingredients used to make slime. Positive patch tests for lanolin were also observed: this allergenic substance is found in shaving foam, for example.

In light of these toxicovigilance data and the observed misuse of chemicals and medicines, ANSES, together with the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF), is alerting consumers to the dangers of "homemade" preparations and repeated and prolonged handling of slime.

ANSES points out that regardless of the products containing them, boric acid and its derivatives must not be handled repeatedly by children. These compounds are toxic to fertility and embryo-foetal development, and must not be used for any purpose other than that for which they are marketed. This is particularly important since the amounts of boron used when preparing slime may be greater than in the recommended uses, and the recreational handling of slime is regular over long periods. In 2016, Health Canada recommended following boric acid-free slime recipes to minimise exposure to boron, which occurs naturally in food and water.

The repeated and prolonged handling of laundry detergent or glues can also lead to severe contact dermatitis, because all these products contain preservatives that are allergenic or irritant to the skin. They are not designed for prolonged, intense and repeated dermal contact.

Furthermore, the use of large containers of glue exposes consumers, especially children, to solvents, some of which can cause irritation of the eyes and airways, and are toxic to the central nervous system.

Lastly, not all the dyes used to prepare "homemade" slime are food grade or intended to come into contact with the skin.

ANSES also warns about certain ways in which slime is mishandled, such as the formation of giant slime bubbles with a straw, or "slime baths" in which slime is made in a bathtub: this practice exponentially increases the quantities of products used for its preparation and therefore the health risks.

Commercially available slime kits must comply with the Toy Safety Directive 2009/48/EC, which refers to specific testing standards. Thus, the NF EN 71-4 standard on experimental chemistry sets must be complied with. For this type of toy, ANSES and the DGCCRF remind users to follow the precautions for use: spatulas or devices for mixing the ingredients, included in these sets, enable skin contact with the chemicals to be limited.

Regarding retail sales of ready-made slime or "noise putty", these items must also comply with Directive 2009/48/EC and the NF EN 71-3 standard on the migration of certain elements. This standard ensures a boron migration limit in Category II toys (which include slime and "noise putty") of 300 mg/kg. In 2018, this regulatory framework led the DGCCRF to conduct an investigation to ensure the compliance of slime, "noise putty" and slime preparation kits sold in French stores. Six out of the 15 samples analysed had a boron content above the authorised limit and were withdrawn from the market. Given the popularity of slime among children and adolescents, the DGCCRF is continuing its inspections and market surveillance activities.

For recreational purposes, it is definitely preferable to use preparation kits or ready-to-use forms of slime or "noise putty", which avoid the misuse of chemicals and medicines. However, repeated and prolonged handling of this putty is not without health risks.

Cécilia SOLAL (Anses)

TO FIND OUT MORE, VISIT:

ANSES. 2018. Exposition au Slime : données des centres antipoison et remontée d'alertes du Revidal-Gerda et du réseau Allergos [Slime exposure: data from poison control centres and reports of alerts from Revidal-Gerda and the Allergos network]
https://www.anses.fr/fr/system/files/Toxicovigilance2018SA0262Ra.pdf

Directive 2009/48/EC on the safety of toys. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:170:0001:0037:EN:PDF

Standard NF EN 71-3. 2018. Toy safety. Part 3: Migration of certain elements.

Health Canada. 2016. Recalls and safety alerts. Health Canada advises Canadians to avoid homemade craft and pesticide recipes using boric acid https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/59514a-eng.php

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.

Juliette BLOCH (Anses)

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Osurnia®: how a dog's ear infection treatment can injure the owner's eye

Osurnia® is an ear gel "indicated in dogs for the treatment of otitis externa and acute manifestations of recurrent otitis externa associated with strains of bacteria *Staphylococcus pseudintermedius* and fungi *Malassezia pachydermatis*", from the pharmaceutical company Elanco Europe. It has had a European marketing authorisation since July 2014 and is subject to veterinary prescription.

This veterinary medicine is a combination of three active substances: terbinafine (antifungal), florfenicol (antibiotic) and betamethasone acetate (corticoid). One tube of gel per infected ear is applied in a single dose and repeated after seven days.

The European Medicines Agency's Committee for Veterinary Medicinal Products (CVMP) and ANSES (ANMV) alerted veterinarians to cases of eye injury in pets and humans after exposure to Osurnia® and reminded them of the precautions to be taken when using this veterinary medicine.

Since it was first placed on the market, 16 cases of adverse effects in humans have been reported, mostly in the United States. In 14 cases, the victim was the person administering the product, but in two cases it was another person nearby.

Fourteen cases involved accidental eye exposure due to splashing of the product. One case involved dermal exposure (around the lips). Lastly, in one case, nausea was reported following Osurnia® administration. The accidents generally occurred when the treated dog shook its head during or immediately after application. Four of the people involved were the animals' owners, but accidents were also observed when the medicinal product was administered by veterinary assistants (4 cases) or the veterinarians themselves (2 cases).

The first eye symptoms appeared immediately after contact. These were mainly eye irritation, conjunctivitis, redness, burning and itching. Despite prompt rinsing of the affected eye with clean water, these signs sometimes persisted or even worsened. For example, two cases of corneal ulcers were reported.

In France, no cases of human exposure following the use of this veterinary medicinal product on an animal have been notified to ANSES to date.

Eye injuries have also been reported in dogs when using this ear product, although contact with the eye was not always confirmed. Symptoms observed in the dogs included corneal ulcers, blinking, decreased visual acuity, conjunctivitis, redness and swelling around the eyes.

Every precaution (such as restraining the dog or wearing safety glasses) should be taken to avoid contact of Osurnia® with the eyes of dogs and people around them. In the event of accidental contact, the affected eyes should be rinsed immediately with plenty of clean water and medical advice should be sought.

The European Medicines Agency, in conjunction with national authorities, is continuing to monitor the adverse effects of this veterinary medicine and will take any regulatory action deemed necessary.

Sylviane LAURENTIE (Anses-ANMV)

TO FIND OUT MORE, VISIT:

The SPC and package leaflet for Osurnia can be found on the EMA website:
https://www.ema.europa.eu/en/documents/product-information/osurnia-epar-product-information_fr.pdf

Allergies to pollen and food supplements: ANSES reminds consumers of the precautions to be taken

Cases of allergies associated with the consumption of food supplements are regularly reported to ANSES under its nutrivigilance scheme. Recently, severe allergic reactions following the consumption of food supplements containing hive products and pollen have been reported. ANSES reminds consumers that people who are allergic to pollen can be at risk from allergies when consuming foods and food supplements containing hive products.

In fact, pollen can be found in hive products such as royal jelly, propolis or honey, even when this is not explicitly stated. People who are allergic to pollen, as well as anyone predisposed to allergies or asthma, are therefore advised to avoid consuming food supplements containing these products.

In general, the Agency stresses that food supplements, just like normal foods, can contain all types of allergens. People with an allergy to a particular ingredient need to be vigilant regarding the composition of any food supplements that may contain it.

The Agency therefore advises consumers to:

- notify a healthcare professional of any adverse effect occurring after consumption of a food supplement;
- comply with the conditions of use specified by the manufacturer;
- avoid taking food supplements on a multiple, prolonged or repeated basis throughout the year without having sought the advice of a healthcare professional;
- be vigilant with regard to products presenting unjustified claims, or products marketed outside regulated channels, particularly on the Internet.

ANSES also reminds healthcare professionals of the importance of reporting to its nutrivigilance scheme any cases of adverse effects suspected of being associated with the consumption of food supplements.

Gwenn VO VAN REGNAULT (Anses)

TO FIND OUT MORE, VISIT:

https://www.anses.fr/en/system/files/NUT2017SA0215EN.pdf

Editorial board

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ANSES is in charge of several health vigilance systems: pharmacovigilance for veterinary medicinal products, nutrivigilance, phytopharmacovigilance, toxicovigilance and vigilance for occupational diseases. Our vigilance activities make little noise and are therefore poorly known to public health actors, health professionals, marketers and users in general. And so, in order to make our work more visible we have decided to create a dedicated newsletter entitled Vigil'Anses.

As news on each of our vigilance topics crops up, this quarterly newsletter presents the main results of the work carried out by ANSES within the framework of its vigilance missions, in conjunction with its partners, professional networks and expert groups, as well as the actions we have undertaken.
The articles are deliberately short, and are intended for all those involved in the occupational and environmental health and safety field: public authorities, health agencies, institutes and expert bodies that are partners of ANSES, prevention policy managers, the scientific community, professionals, associations and users. Vigil'Anses also invites the interested reader to delve deeper and discover publications, opinions and reports available online that will further their knowledge.

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