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Exposure to veterinary medicines: a particular risk for raptors and avian scavengers

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Because of their feeding behaviour, raptors and avian scavengers may be accidentally exposed to veterinary medicines when they eat the carcasses of ruminants or horses left in the wild.
Anti-inflammatories and barbiturates pose a particular risk to these animals and are subject to specific precautions for use.

Marketing authorisation for a veterinary medicinal product is based on an analysis of whether its benefits outweigh the risks. The assessment considers the safety of the medicinal product for the treated animal, the user, the consumer of any foodstuffs obtained from this animal, and the environment.

With some medicines, a particular risk to wildlife may be identified. In these cases, specific measures are taken, with precautions for use included in the package leaflet in order to limit the exposure of wildlife to the product or its residues. These precautions for use are supplemented as and when data are collected through the veterinary pharmacovigilance scheme.

Birds of prey and scavengers may be particularly exposed to veterinary medicines when the carcasses of treated domestic animals are found in areas where avian scavengers feed or when these carcasses are left in fields because rendering is not possible. This may be the case for certain types of livestock farming practised on vast areas of pasture, or in mountain areas where plots of land are difficult to reach.

In recent years, several alerts have led the European veterinary medicine authorities to take targeted measures to limit the risk of secondary poisoning in wild birds.

DICLOFENAC AND FLUNIXIN: ANTI-INFLAMMATORIES THAT ARE PARTICULARLY TOXIC TO BIRDS

Between 1990 and 2006, an episode of mass mortality in vulture populations led to the virtual disappearance of these birds from several regions of the Indian sub-continent (India, Pakistan and Nepal). This mortality was due to the birds consuming carcasses of animals treated with veterinary medicines containing diclofenac, an anti-inflammatory that is highly toxic to raptors [1]. For this reason, since 2006, the use of this compound in veterinary medicine has been prohibited in these countries.

In Europe, because of major differences in the conditions of use of medicines and the monitoring of do-

mestic animals, diclofenac has continued to be used in certain countries such as Italy, Spain and Estonia, with new precautions for use relating to the potential risks to wildlife being added to the summaries of product characteristics (SPCs) and package leaflets for the medicines concerned. No veterinary medicines containing diclofenac are authorised in France.

In 2014, several vultures in a zoo in Italy died after ingesting meat contaminated with flunixin-meglumine, a non-steroidal anti-inflammatory found in several veterinary medicines authorised in France and Europe. These deaths were recorded in Eudravigilance Veterinary, the European veterinary pharmacovigilance database. Since then, several publications in the international literature have reported cases of wild vultures being poisoned by this active ingredient under the same conditions [2].

This led the European Medicines Agency (EMA) to conduct a new assessment in 2022 of the risk to wildlife from the use of veterinary medicinal products containing flunixin-meglumine. It concluded that it was necessary to add the same statement to the SPCs of all the medicinal products concerned as was previously added for products containing diclofenac: "*Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna*".

The French Agency for Veterinary Medicinal Products (ANMV), which is part of ANSES, has also highlighted the need to consider the potential impact on wildlife before prescribing a medicine containing flunixin-meglumine for an animal [3]. If the treated animal is at high risk of mortality and its remains need to be left in situ, for example in the mountains, the use of flunixin should be avoided. This recommendation has been extended to carprofen and ketoprofen, as some publications also mention the possible toxicity of these active ingredients to vultures. For this reason, the use of anti-inflammatories that are less toxic to wild birds – such as meloxicam – should be preferred [4].

PERSISTENCE OF PENTOBARBITAL IN THE CARCASSES OF DOMESTIC ANIMALS

There have also been reported cases of wild birds poisoned due to the probable consumption of carcasses of animals euthanised with pentobarbital, a barbiturate contained in several veterinary medicines authorised for the euthanasia of domestic animals. This compound can now be administered in small but effective doses, making it easier to use on large animals (cattle, horses) whose carcasses are likely to be left in the wild. Pentobarbital is also a very stable compound and can persist for several months in the tissues of euthanised animals [5].

European pharmacovigilance reports have identified 10 cases of secondary poisoning with pentobarbital in wild birds: one in France, one in Spain and eight in Germany, affecting a total of 23 animals of different species: griffon vultures, red kites, Eurasian goshawks, white storks, marsh harriers, common buzzards and bearded vultures. In most cases, the birds had been found dead and exposure to pentobarbital was demonstrated by toxicological analysis after necropsy. The source of exposure remained undetermined in most cases, except for the collective poisoning of eight griffon vultures that had consumed the carcass of a horse euthanised with pentobarbital. Neurological problems such as excitation, lethargy, drowsiness, muscle tremors and digestive disorders were observed in the exposed vultures. In another case involving a bearded vulture found dead, a necropsy of the animal and toxicological analyses indicated suspected death due to accidental contact with power lines, possibly precipitated by the sedative effect of sub-lethal pentobarbital poisoning, thus highlighting the fact that even non-lethal doses can have serious consequences for these animals [6].

A Spanish study recently showed an increase in the prevalence of barbiturate poisoning in scavenging birds, rising from 0.5% to 3.4% of all poisoning cases in these birds between 2012 and 2020 [5]. Meanwhile, data from the US suggest that pentobarbital was involved in 2.6% and 4.3% of poisoning cases in golden eagles and bald eagles, respectively, between 1975 and 2013 [7].

Wild birds are not the only victims. Several cases of secondary poisoning have been reported in farm dogs that ingested pieces of carcass or blood from euthanised animals, and then experienced neurological symptoms (drowsiness, ataxia) in some cases leading to coma and death.

This risk of secondary poisoning is mentioned in the SPCs for veterinary medicines containing pentobarbital authorised for use in livestock.

The SPCs also reiterate that carcasses should not be fed to other animals and should be disposed of in accordance with national legislation. Nevertheless, new pharmacovigilance data recently led the ANMV to issue a specific warning to practising veterinarians and animal breeders and owners about the risks of secondary poisoning when the carcasses of animals euthanised with pentobarbital are not rapidly removed[1].

Jacques Bietrix and Sylviane Laurentie
(French Agency for Veterinary Medicinal Products, within ANSES)

FIND OUT MORE :

To access the SPCs of the medicinal products mentioned in this article: https://www.ircp.anmv.anses.fr

To report an adverse effect in an animal following the use of a veterinary drug:
https://pharmacovigilance-anmv.anses.fr

For the most recent decisions relating to veterinary medicines, as well as the latest ANMV news, subscribe to the ANMV newsletter:
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"CheniPRO": a study of the occupations most exposed to processionary caterpillars

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Because they often work in contact with oak or pine trees, timber and forestry professionals, workers maintaining or developing green spaces, and equestrian professionals are particularly at risk of exposure to the stinging hairs of processionary caterpillars. Timber and forestry professionals such as silviculturists, lumberjacks and logging workers are the most affected by poisoning due to these caterpillars. Raising awareness of the risks and wearing personal protective equipment remain key measures for safeguarding these workers.

PROCESSIONARY CATERPILLARS: HARMFUL TO HUMAN HEALTH

Pine and oak processionary caterpillars are moth larvae that proliferate and then defoliate the trees they colonise. They feed on the leaves after emerging from their nests of silk. Once fully developed, pine processionary caterpillars descend the trunks in single file in order to burrow into the ground, while oak processionary caterpillars remain in the colonised trees.

Both species have been classified as harmful to human health since April 2022, as their hairs can cause potentially serious inflammatory reactions in both humans and animals. These hairs are located on dorsal plates that the caterpillars open when they feel threatened. These microscopic «spears» can become embedded in the skin, eyes or respiratory tract, causing stinging reactions as they release the toxic substances they contain, mainly thaumetopoein.

Since the venom remains active even after the hairs have been shed, people can be exposed via air when handling nests (including when empty), or through contact with clothing, objects, plants or animals that have been exposed.

RISKS DESCRIBED USING DATA FROM POISON CONTROL CENTRES

ANSES and the French poison control centres (PCCs) studied cases of processionary caterpillar poisonings that had been the subject of teleconsultations with the PCCs between January 2012 and July 2019 [1]. A total of 1022 poisonings by these caterpillars were recorded during this period. Almost all the victims reported dermal clinical manifestations (97%), along with ocular (8%) or general signs (fever, fatigue, faintness, etc.) (4%), or ear, nose and throat (3%), respiratory tract (3%) or digestive tract symptoms (2%).

Although only 2% of these poisonings occurred in the course of their work – landscaping, tree pruning, gardening or municipal work – the proportion of serious cases seemed higher among professionals (12%) aged between 16 and 55 years during the study, than among adult members of the public under 60 years of age (4%).

In order to gain a better understanding of these occupational exposures and their impact on health, ANSES conducted a specific study of the occupation types most at risk of exposure to processionary caterpillars.

CHENIPRO, THE FIRST EVER WORKPLACE STUDY

People working in agriculture in France, whether they are employees or self-employed, are affiliated to the Agricultural Mutual Insurance Scheme (MSA). In order to question workers in occupations most at risk of exposure to processionary caterpillars, ANSES referred to the records of the MSA's Central Fund (CCMSA). Since processionary caterpillars are endemic to the Grand-Est region, staff from the Lorraine MSA and the Moselle Accident Insurance Fund were interviewed to identify the occupations thought to be most at risk of repeated exposure, namely those in the timber or forestry sectors, in maintaining and developing green spaces, and in the equestrian field.

In 2023, ANSES sent an electronic questionnaire to 50,000 people drawn at random from the 220,000 professionals working in one of the occupations identified and registered with the CCMSA in 2022.

The responses were analysed in accordance with the rules guaranteeing the security of personal data, after authorisation by an institutional review board.

The questions concerned the affiliate's occupation, factors of exposure to processionary caterpillars, the occurrence of symptoms and their medical treatment, knowledge of the risk and wearing of personal protective equipment (PPE).

A total of 1026 people responded and 900 questionnaires contained enough information to be analysed (2% response rate).

Of these 900 respondents, 66% worked in green spaces, 22% were in timber or forestry occupations and the remaining 12% were equestrian professionals. The breakdown of respondents' occupation types was similar to that of the sampling frame, with 65% of them working in green spaces, 17% in the timber or forestry sectors and 18% in the equestrian field. However, after analysis of the questionnaire the occupation type of certain affiliates was reclassified in a different category. Table I details the occupations held by respondents.

Table 1 – Main occupations held by survey respondents, by type

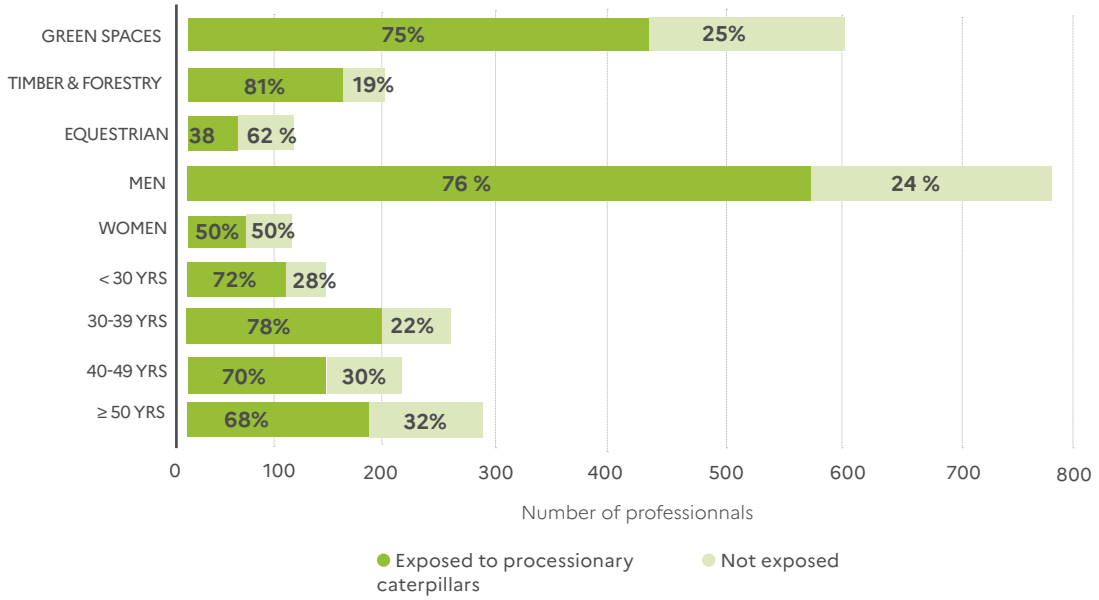
GREEN SPACES	TIMBER & FORESTRY	EQUESTRIAN
Tree surgeons Tree-climbing arborists Reforestation workers Gardeners Freight drivers Workers maintaining green spaces Gamekeepers, fishing or forestry rangers Winegrowers Farmers...	Skidder operators Silviculturists Lumberjacks Forest firefighters Forest managers Logging workers Sawmill workers Forestry equipment operators Logging truck drivers...	Breeders Trainers Teachers, riding instructors Riders, jockeys Equine veterinarians Facility directors, managers & employees Farriers...

AN INCREASED RISK OF EXPOSURE AMONG PROFESSIONALS WORKING WITH WOOD AND IN GREEN SPACES

Of the 900 respondents, 72% (n=647) reported that they had been exposed to processionary caterpillars in the course of their work. While exposure concerned 81% of timber or forestry professionals and 75% working in green spaces, by contrast only 38% of equestrian professionals were exposed (see Figure 1).

Men, who accounted for the majority of survey respondents (85%), reported being exposed more often than women (75% versus 50%). Lastly, professionals aged between 30 and 39 were more often exposed than those over 50 years of age (78% and 68%, respectively).

Figure 1 – Numbers and percentages of professionals exposed to processionary caterpillars in the course of their work, by occupation type, sex and age



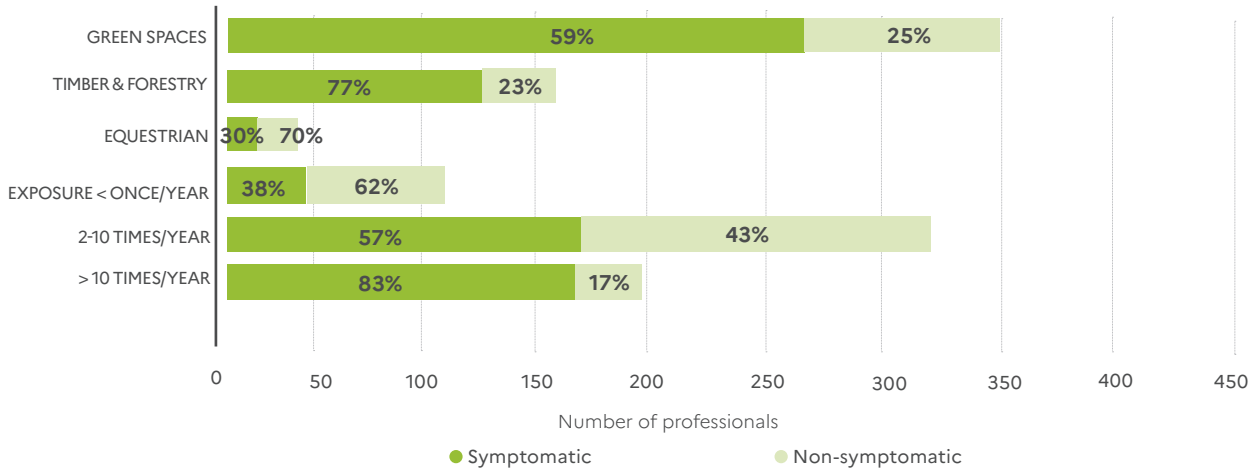
TIMBER OR FORESTRY PROFESSIONALS AT GREATER RISK OF POISONING

As many as 62% of professionals exposed to processionary caterpillars (399 out of 647) said they had experienced symptoms at least once in the course of their work.

Timber or forestry professionals were more likely to suffer symptoms than those working in green spaces or in the equestrian field (77%, 59% and 30% respectively) (Figure 2).

The risk of symptoms increased in line with the frequency of exposure: 83% of workers exposed more than 10 times a year reported symptoms, compared with 38% of those exposed less than once a year.

Figure 2 – Numbers and percentages of professionals experiencing symptoms after exposure to processionary caterpillars, by type of occupation, type of contact and frequency of exposure

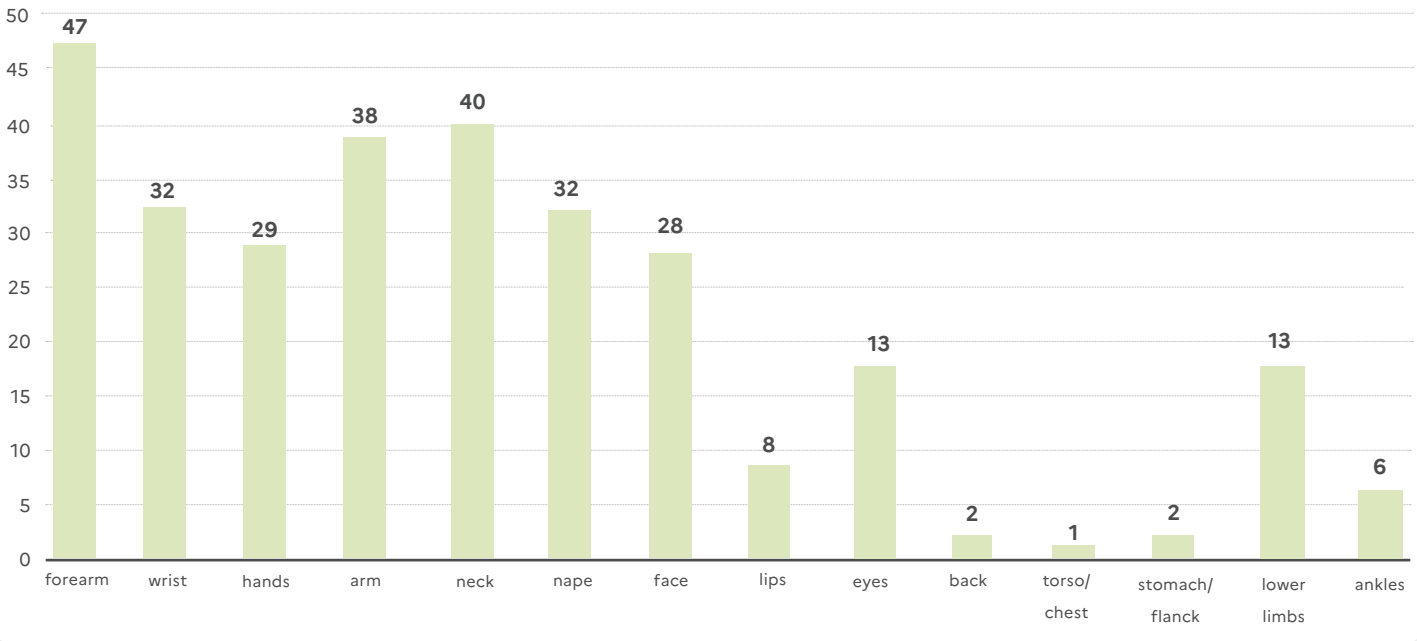


EYES AFFECTED AS WELL AS SKIN

While the symptoms reported were mainly dermal (98%), ocular symptoms were also reported by 28% of people, followed by respiratory (18%) and general (4%) signs.

The parts of the body affected by the stinging hairs were mainly exposed areas such as the forearms (47%), neck (40%) and arms (38%) (Figure 3), which could all be better protected.

Figure 3 – Percentage of professionals with symptoms according to the area of the body affected (several answers possible)



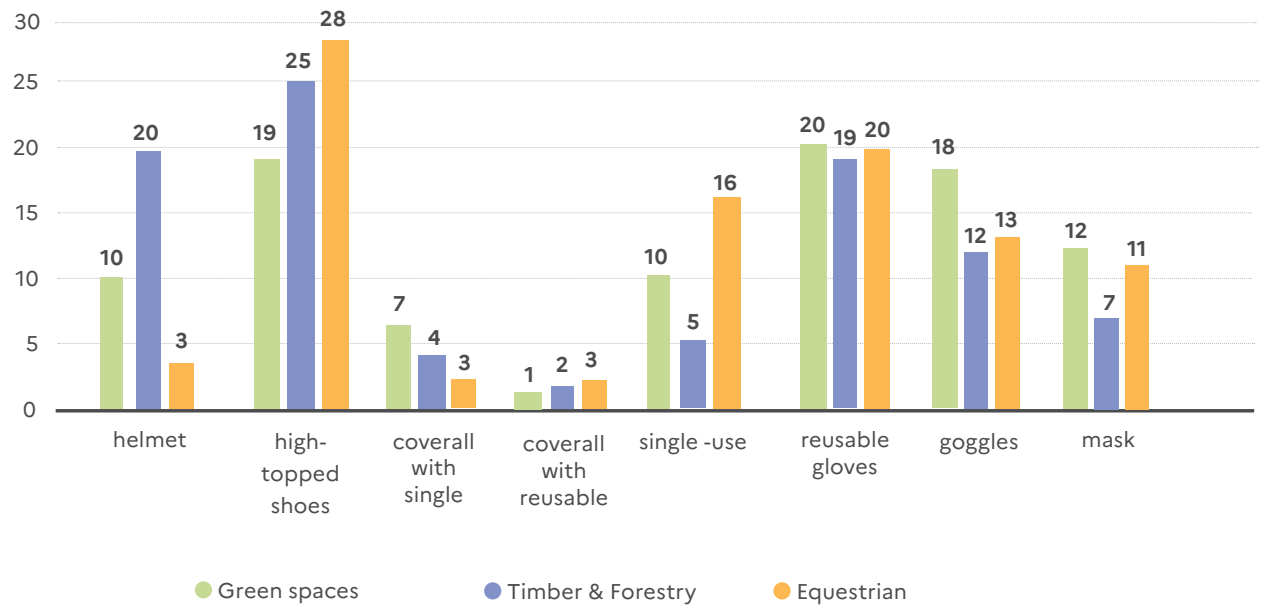
Lastly, 37% of professionals suffering poisoning had consulted a pharmacist, 25% a general practitioner and 5% an emergency service. Only 3% had consulted their occupational physician.

HOW IS PERSONAL PROTECTIVE EQUIPMENT USED?

Seventy-nine per cent of exposed individuals said they had worn one or more items of PPE to protect themselves from stinging caterpillars. Professionals working in green spaces were the most likely to wear it (85%), followed by timber and forestry professionals (77%) and equestrian professionals (61%).

However, the survey question concerned equipment worn as protection from caterpillars with stinging hairs, and people may have responded by listing any PPE worn for their job, regardless of the risk of exposure to caterpillars (e.g. helmets to protect them from impacts). The equipment used varied according to the occupation: helmets were preferred by timber and forestry professionals (20%), high-topped shoes by equestrian professionals (28%) and goggles by those working in green spaces (18%) (Figure 4).

Figure 4 – Percentage of professionals using PPE, by occupation type. Respondents may have reported wearing more than one item of equipment



To avoid any contact with stinging hairs when working on trees or in infested areas, it is important to remind these workers that they should wear PPE that protects the skin, eyes and respiratory tract, just like for the professionals working on control of processionary caterpillars (see box).

In conclusion, the results of the CheniPRO study suggest that the risk of poisoning by processionary caterpillars is greater among professionals working in timber/forestry sectors and green spaces than among those working with horses. However, these results are based on a low response rate to the survey and should be interpreted with caution. Personal protective equipment tailored to the job, worn correctly and then decontaminated after use, is essential for safeguarding workers from contact with stinging hairs.

Sandra Sinno-Tellier (ANSES)
Maryline Deryene (ANSES)
Emeline Hily (ANSES)

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RECOMMENDATIONS ON PERSONAL PROTECTIVE EQUIPMENT FOR PROFESSIONALS INVOLVED IN CONTROL OF PROCESSIONARY CATERPILLARS

Source: National Research and Safety Institute (INRS)

- disposable coveralls;
- high-topped shoes;
- impervious gloves (latex not cloth) with gauntlets, and disposable under-gloves (latex or vinyl) worn under the work gloves, enabling soiled clothing and equipment to be removed without contaminating hands;
- helmet with cape and powered respirator, or coveralls with hood, safety helmet and full-face mask with powered respirator, or coveralls with hood, and over-hood with powered respirator.

ANSES would like to thank the Central Fund for the Agricultural Mutual Insurance Scheme (CCMSA) for randomly selecting the survey participants from the CCMSA database in accordance with the established

Cosmetics and tattoo products: two new vigilance schemes for ANSES

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Since 1 January 2024, ANSES has been responsible for vigilance and expert appraisal relating to cosmetics and tattoo products. These new missions, which were formerly the responsibility of the ANSM[1], increase the number of everyday products for which the Agency deploys specific skills in terms of vigilance and risk assessment relating to chemicals.
Reporting their adverse effects to ANSES can reveal as yet unidentified risks, enabling the regulations to be amended, if necessary, to prevent them.

WHAT ARE COSMETICS AND TATTOO PRODUCTS?

Although skin creams and make-up immediately spring to mind, in reality, cosmetic products are defined in the European regulations as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours."

These products are not intended for healing. Toothpastes, shampoos and soaps, sunscreen, nail varnishes, perfumes, deodorants, depilatory creams and hair dyes are all cosmetic products. On the other hand, creams, ointments or gels for therapeutic use (antibiotics, anti-inflammatories, for example) are medicines, not cosmetics.

According to the French Public Health Code, a tattoo product is defined as "any colouring substance or preparation that penetrates the skin in order to create a mark on the superficial parts of the human body...". Temporary tattoos are cosmetic products.

EUROPEAN AND FRENCH REGULATIONS ON COSMETICS

Unlike medicines, cosmetics are not subject to marketing authorisation, but since 11 July 2013 they have been governed by European Regulation (EC) No 1223/2009 on cosmetic products. According to Article 3 of this regulation, any cosmetic product placed on the market must be "*safe for human health when used under normal or reasonably foreseeable conditions of use*".

The regulatory provisions lay down certain marketing obligations: designation of a responsible person[2] for any cosmetic product placed on the market in Europe, assessment of the product's safety, and notification on

[1] National Agency for Medicines and Health Products Safety

the European Cosmetic Products Notification Portal (CPNP), to which ANSES and the poison control centres have access. This notification involves transmitting all the information on the product: category, product name, name and address of the responsible person, country of origin, presence of substances in the form of nanomaterials, etc.

The regulation also lists prohibited substances, substances that are restricted in terms of concentration or use, for example, as well as substances authorised only as colorants, preservatives and UV filters.

In addition, a cosmetic product must be labelled with the name and address of the person responsible for placing it on the market, the country of origin, the weight or volume of the product, the date of minimum durability, precautions for use, the batch number and the complete list of ingredients, in descending order of their concentration in the product.

In the event of serious adverse effects after the product has been placed on the market, the responsible person and distributors must without delay notify the competent authority of the Member State where the adverse effect was observed, providing all information enabling the cosmetic product to be identified and the corrective measures taken. Within the meaning of this regulation, an effect is said to be serious if it results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death.

In France, ANSES is the competent authority for receiving and processing reports. The Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) is responsible for market surveillance and enforcement of health measures, i.e. action to be taken in the event of non-compliance with the regulations. The French Public Health Code stipulates that healthcare professionals must report serious adverse effects from cosmetic products to ANSES without delay. Consumers and professional users can also use this same channel to report any adverse effects, even those resulting from misuse.

In addition, the Public Health Code entrusts ANSES with the task of carrying out research into the safety of these products.

EUROPEAN REGULATIONS ON TATTOOS

The inks used by tattoo and permanent make-up artists are governed by Regulation (EU) No 2020/2081 of 14 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals as regards substances in tattoo inks or permanent make-up. There are also restrictions applicable to these substances under the REACH Regulation on chemicals.

In addition, establishments and practices must comply with Articles L.513-10-1 to 10 of the French Public Health Code and Act No 2014-201 of 24 February 2014, which adapt European Union law in the area of health to their case.

These texts set out various obligations:

- declaration: the opening and operation of an establishment manufacturing, packaging or importing tattoo products is subject to a declaration to the administrative authority responsible for competition and consumer affairs (in France, this is the DGCCRF). This declaration must be made by the person responsible for placing the tattoo products on the market. Depending on the case, this may be the manufacturer or its representative, the person on whose behalf the tattoo products are manufactured, or the person placing the imported tattoo products on the market;

- safety assessment: the product must undergo an assessment of its safety for human health, carried out by a qualified person in accordance with good laboratory practice;

- declaration to poison control centres: before tattoo products can be placed on the market, information on the substances they contain must be provided to the PCCs;

- product composition: prohibited substances and substances subject to concentration limits are listed in the annex to the regulation;

- labelling: the batch number, complete list of ingredients, name and address of the responsible person, warnings and safety notices must all be mentioned;

- hygiene rules: the Decree of 19 February 2008 and the Ministerial Order of 11 March 2009 lay down the hygiene and health conditions for the use of permanent tattoo techniques;

- communication of serious adverse effects: the responsible person is required to participate in the national tattoovigilance scheme by reporting any serious adverse effects without delay to the competent authority of the Member State where the adverse effect was observed. In France, this is ANSES.

[2] This person must guarantee compliance with the provisions laid down in this regulation. They may be the manufacturer, importer, distributor or any other person established in the European Union.

HOW SHOULD ADVERSE EFFECTS BE REPORTED?

Since January 2024, ANSES has been responsible for monitoring adverse effects associated with the use of cosmetics and tattoo products. Cosmetovigilance and tattoovigilance rely on spontaneous reports from individuals, and from healthcare and beauty professionals.

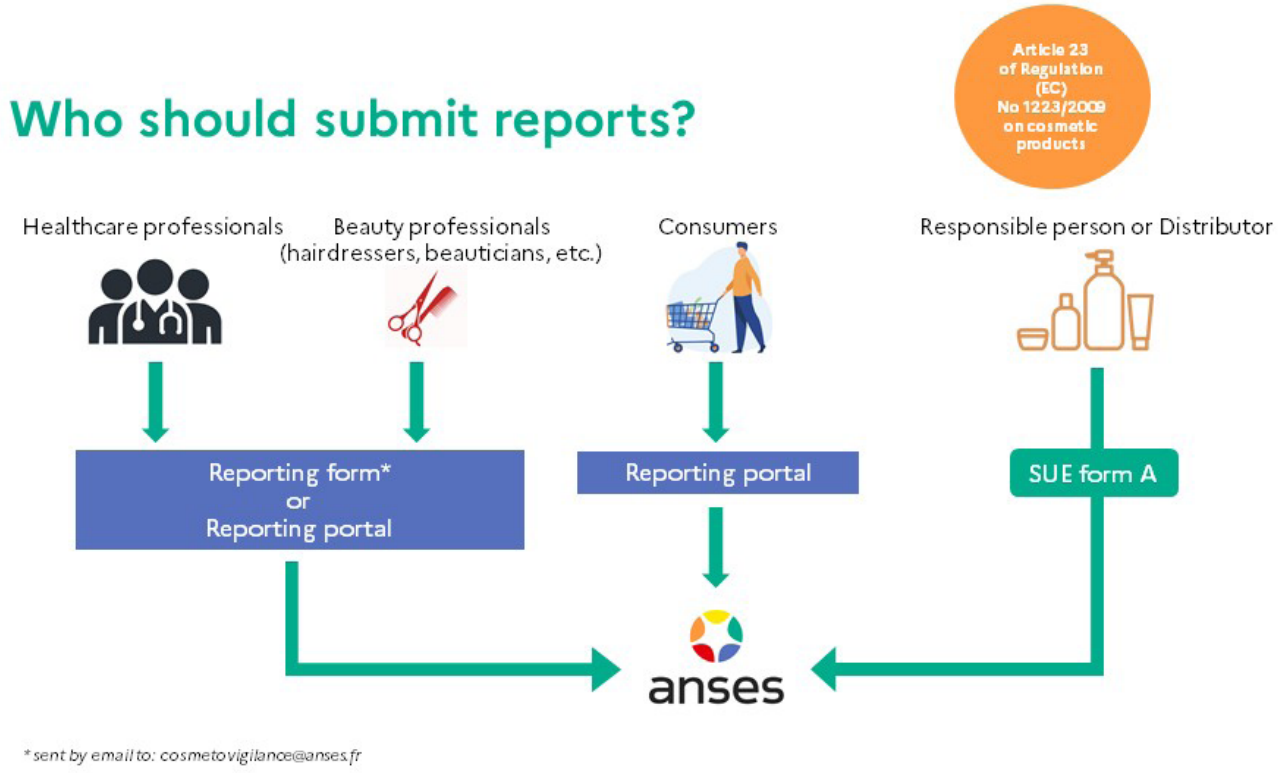
Anyone experiencing an adverse effect after using a cosmetic product can report it to the person responsible for placing it on the market, whose contact details are provided on the product packaging.

This responsible person then enters all the information needed to assess the case in terms of severity and causality (likelihood of a link between what has been observed and the product used) on a reporting form. Healthcare professionals can use the same process to report any serious cases observed among their patients.

Another reporting channel is the Ministry of Health's portal for reporting adverse health events[3], which is not specific to cosmetovigilance. It collects reports of adverse effects, whether serious or not, from users or healthcare professionals. These are then sent to ANSES.

Concerning tattoovigilance, there is no European reporting system. Tattoo artists, manufacturers and healthcare professionals must report any serious adverse effects of which they become aware using a standard form to be sent to ANSES[4]. Consumers and healthcare professionals can also report any adverse effects associated with tattoo products on the Ministry of Health's reporting portal.

Figure 1 : Channels for reporting undesirable effects of cosmetic products



[3] https://signalement.social-sante.gouv.fr
[4] https://www.anses.fr/fr/content/cosmetovigilance-et-tatouvigilance

WHAT SHOULD BE REPORTED?

To enable ANSES to understand what has happened and determine severity and causality, certain types of information are crucial when reporting.

For cosmetics:
- the product name (as precise as possible, particularly when it belongs to a range), its brand and batch number;
- the conditions under which it was used (dates of first and last use, frequency of use, use in accordance with recommendations, simultaneous use of other products, etc.);
- the time between first use and onset of symptoms;
- a detailed description of the signs, without hesitating to include photos of the affected areas (these will not be sent to the portal but will remain at ANSES on a secure server);
- the medical consequences, in particular any absence from work or hospitalisation, which will be used to classify the severity;
- the diagnosis made by a doctor, the results of tests and treatments prescribed;
- development, particularly if the effects reappeared when the product was used again.

Specific information for tattoos relates to the inks used, the date the tattoo was applied and the date the symptoms appeared.

However, tattoo infections due to a lack of hygiene on the part of the tattoo artist are not a matter for tattoovigilance but for the DGCCRF. They can be reported on the Signal-Conso[5] portal. The professional may then be investigated, particularly if several cases have been reported. A cosmetic result that does not correspond to what was expected does not fall within the scope of tattoovigilance either.

WHY SHOULD ADVERSE EFFECTS BE REPORTED?

A cosmetic product contains many chemicals and its safety must therefore have been demonstrated by the company that placed it on the European market. The most toxic substances are banned, while others must not exceed a certain concentration or are reserved for particular uses or populations.

Although the vast majority of adverse effects concern allergic reactions, even when all the ingredients in the product comply with the regulations, there are several reasons why consumers and healthcare or beauty professionals should report any adverse effects observed:

Firstly, some products on sale are not compliant in terms of composition or labelling. A product batch may also be affected by microbiological contamination. In both these situations, the DGCCRF will contact the responsible person and order the appropriate action – withdrawal, recall, consumer information – pending corrective measures. As an example, some batches of tattoo ink bottles were withdrawn from the market because they did not comply with sterility requirements[6].

The occurrence of several cases of adverse effects with the same product will lead ANSES to examine how it is used and the precautions for use mentioned on the packaging. For instance, in 2018, faced with many cases of skin burns following use of depilatory waxes heated in the microwave, Sofibel, on the recommendation of the ANSM (at the time responsible for cosmetovigilance), reminded consumers of the precautions to take when heating «NAIR CIRE DIVINE» depilatory waxes in order to prevent the risk of burns[7]. Another more recent example is NUUD® deodorant. In 2023, many users reported the appearance of painful cysts in their armpits, sometimes requiring antibiotic treatment, which healed when they stopped using the product. The ANSM conducted an investigation and concluded that the dosage form, a predominantly oily cream, promoted the clogging of pores. To protect consumers, therefore, the manufacturer, in conjunction with the ANSM, decided to withdraw all batches from the market at the various points of sale and from the distributor(s)8.

Lastly, some substances may cause adverse effects that have not yet been described. Only reporting by users and healthcare or beauty professionals enable these to be identified and investigated in order to understand the mechanisms as well as, if necessary, amend the European regulations to exclude the incriminated substance or limit its concentration in cosmetic products.

Reporting is therefore a genuine public health action, which benefits everyone.

HOW MANY REPORTS ARE RECEIVED?

Between 1 January 2024 and 31 May 2024, 189 reports were received by the cosmetovigilance scheme, including 123 from the Ministry of Health's reporting portal (103 from users and 20 from healthcare professionals). Of the reports received directly by ANSES, 39 came from responsible persons and 27 from healthcare professionals or professional users.

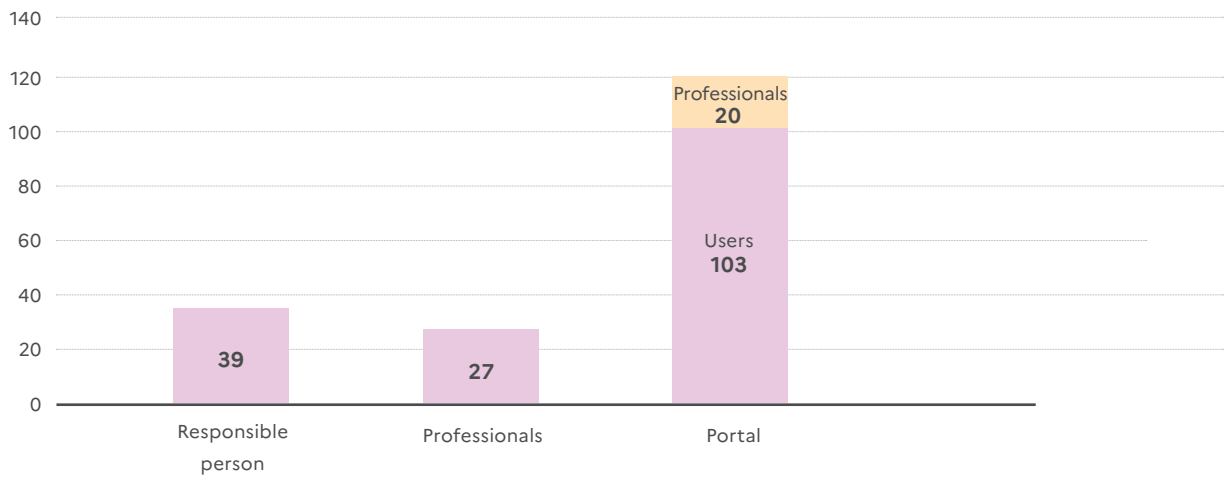
[5] https://signal.conso.gouv.fr/fr
[6] https://rappel.conso.gouv.fr/fiche-rappel/14286/Interne
[7] https://ansm.sante.fr/informations-de-securite/nair-cire-divine-rappel-des-precautions-demploi-a-lattention-des-utilisateurs
[8] https://ansm.sante.fr/actualites/deodorant-nuud-retrait-du-marche-par-le-fabricant-de-lensemble-des-lots-de-ce-deodorant

After assessment, 62 cases (i.e. one third) were classified as serious, according to the criteria described above;.

Twenty of these cases came from the reporting portal.

If these figures are extrapolated to a full year, around 450 reports, 150 of them serious, can be expected each year.

Figure 2 – Breakdown of reports received by source and person



Regarding tattoovigilance, activity is much lower: around 15 reports were received in five months, but many concerned a lack of hygiene on the part of the tattoo artist, while others did not mention the name or brand of ink used, making it impossible to investigate further. However, thanks to one report from a tattoo artist, batches of non-sterile inks responsible for tattoo infections were withdrawn from the market.

WHAT HAPPENS AFTER THE REPORT HAS BEEN SUBMITTED?

When the ANSES team receives a report relating to a cosmetic product, regardless of how it was submitted, it verifies that the incriminated product is registered in the European CPNP database, as required by the regulations (see above). This enables them to determine the product's composition and the precautions for use that must appear on the packaging.

ANSES assesses causality on the basis of the information provided, determining it on the basis of the symptoms, the time taken for them to appear, the results of tests (e.g. to screen for an allergy to the product), the absence of any other diagnosis and the reappearance of signs if the product is used again. Causality has five classes: excluded, unlikely, possible, likely and very likely. For its assessment, ANSES may seek the opinion of its «Vigilance for chemical products» expert group, which includes toxicologists from the poison control centres. Regardless of the causality, ANSES reports all serious cases on the European Information and Communication System for Market Surveillance (ICSMS) portal, ensuring that all the European authorities responsible for cosmetovigilance are informed.

The Agency verifies whether there are any adverse effects associated with the same product listed in the archives. It can also search the PCC database for any calls seeking medical advice about the product. When a product is responsible for several cases, particularly if they are serious, ANSES will contact the manufacturer and ask them to provide any reports they may have received, along with the precise composition of the product, its current packaging[9] , advice on use and sales volumes. Any breaches of the regulations are reported to the DGCCRF.

[9] Packaging refers to the different layers enveloping the product, including the one that will be in direct contact with it.

If a substance is suspected of causing the adverse effects, even though it is not subject to regulatory prohibitions or restrictions on use, ANSES can initiate an expert appraisal in order to assess the risks.

RISK ASSESSMENT OF COSMETICS AND TATTOO PRODUCTS

ANSES's Risk Assessment Department conducts three types of expert appraisal:

- Assessing the hazards and risks of substances, under the European Cosmetics Regulation.
The expert appraisal work that ANSES already carried out on chemicals has been extended to include cosmetic substances and products, and tattoos.
At European level, the Scientific Committee on Consumer Safety (SCCS) is responsible for assessing the safety of cosmetic ingredients, on behalf of the European Commission. As part of the regulatory process, the SCCS's preliminary opinions are submitted for public consultation. In this context, ANSES may prepare comments to be taken into consideration by the SCCS when finalising its opinion. To date, ANSES has already submitted comments on several substances assessed by the SCCS, including hexyl salicylate, titanium dioxide and silver. ANSES also provides scientific support to its supervisory ministries in defining French positions to be presented at European level in meetings of the Standing Committee on Cosmetic Products (SCCP).

- Expert appraisals to support the DGCCRF with market surveillance and enforcement of health measures for these products. ANSES can therefore be called upon by the DGCCRF to provide support with its inspections, decisions on enforcement of health measures or investigations, if concerns are raised about the safety of cosmetics and tattoo products.

- Leading studies into exposure to these products and the substances they contain.
This new activity, which is in addition to the tasks transferred from the ANSM, may lead ANSES, on the basis of a review of existing data, to recommend that new studies be carried out or even to finance them.

HOW TO PROPOSE AN AMENDMENT TO THE EUROPEAN REGULATION

If an ingredient used in a cosmetic product gives rise to safety concerns, a Member State may ask the European Commission to give the SCCS a mandate to assess or reassess its safety of use. On this basis, the European Commission will amend the annexes to the Cosmetics Regulation, in particular Annex II on prohibited substances and Annex III on substances with restrictions on use.

FIND OUT MORE ABOUT THE REGULATIONS:

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance), 342 OJ L § (2009). http://data.europa.eu/eli/reg/2009/1223/oj/fra

Commission Regulation (EU) 2020/2081 of 14 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up (Text with EEA relevance), 423 OJ L § (2020). http://data.europa.eu/eli/reg/2020/2081/oj/fra

Ministerial Order of 31 May 2016 establishing the list of information to be sent to poison control centres on substances contained in tattoo products (n.d.). Accessed on 3 June 2024.

French Public Health Code "Chapter X: Tattoo products (Articles L513-10-1 to L513-10-10) – Légifrance". Accessed on 3 June 2024. https://www.legifrance.gouv.fr/codes/id/LEGISCTA000006171384

Juliette Bloch (ANSES)
Sandrine Charles (ANSES)
Sarah Aouad (ANSES)
Élodie Lontsi (ANSES)

Editorial board

ANSES, which is responsible for several health vigilance schemes (pharmacovigilance of veterinary medicinal products, nutrivigilance, phytopharmacovigilance , toxicovigilance and vigilance for occupational diseases), reports on its vigilance activities through a dedicated newsletter: Vigil'Anses.

Reflecting the latest news from each of the vigilance schemes, this four-monthly newsletter presents the main results of the Agency's work as part of its vigilance missions, in conjunction with its partners, professional networks and expert groups, along with the actions undertaken. The articles, which are deliberately short, are aimed at all environmental and occupational health players: public authorities, health agencies, ANSES's expert appraisal partner organisations and institutes, managers of prevention policies, the scientific community, professionals, associations and users. They encourage the interested reader to read the publications, opinions or reports available on the Internet for further information.

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AGENCE NATIONALE DE SÉCURITÉ SANITAIRE
de l'alimentation, de l'environnement et du travail
14 rue Pierre et Marie Curie
94701 Maisons-Alfort Cedex

www.anses.fr – @Anses_fr

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