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.

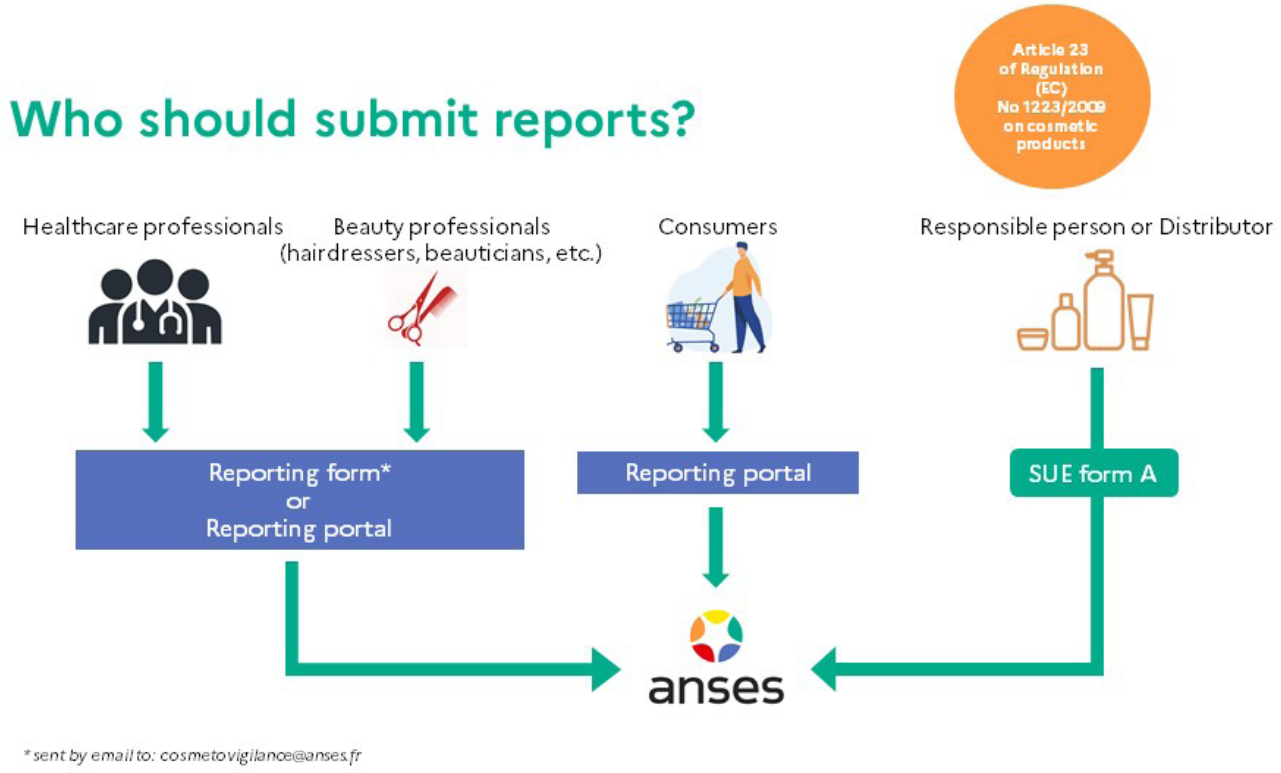
Anyone experiencing an adverse effect after using a cosmetic product can report it to the person responsible for placing it on the market, whose contact details are provided on the product packaging.

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.

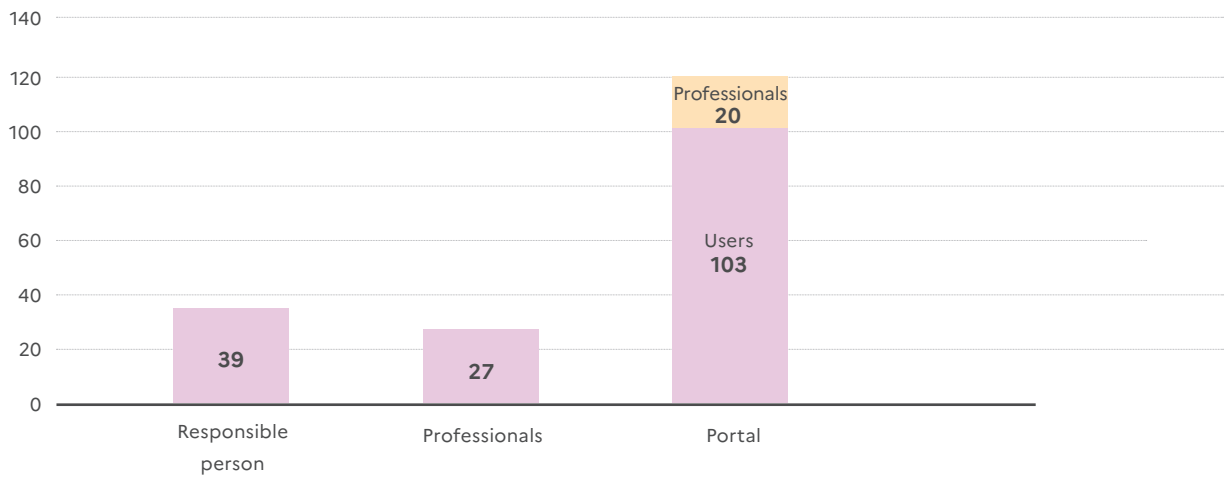
[5] https://signal.conso.gouv.fr/fr
[6] https://rappel.conso.gouv.fr/fiche-rappel/14286/Interne
[7] https://ansm.sante.fr/informations-de-securite/nair-cire-divine-rappel-des-precautions-demploi-a-lattention-des-utilisateurs
[8] https://ansm.sante.fr/actualites/deodorant-nuud-retrait-du-marche-par-le-fabricant-de-lensemble-des-lots-de-ce-deodorant

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

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