anses

NUTRIVIGILANCE

2024 Annual report

Investigate, evaluate, protect

CONTENTS

PREAMBLE

Since 2009, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has been responsible for implementing the French nutrivigilance system. Its purpose is to improve consumer safety by rapidly identifying any possible adverse effects related to the consumption of:

- food supplements[1];
- foods or beverages fortified with substances for nutritional or physiological purposes[2] (vitamins, minerals, amino acids, plant extracts, etc.) such as so-called energy drinks;
- novel foods and novel ingredients[3] (phytosterols, guar gum, noni juice, etc.);
- products intended as food for specific categories of the population[4] (infants, patients suffering from metabolic disorders, malnutrition, dysphagia, etc.).

Healthcare professionals (doctors, pharmacists, dieticians, nutritionists, etc.), private individuals and companies marketing the products are invited to report any adverse effects relating to the consumption of these products of which they become aware. This can be done on the adverse health event reporting portal of the Ministry of Labour, Health and Solidarity (https://sante.gouv.fr/soins-et-maladies/signalement-sante-gouv-fr/) or directly by completing the online declaration form (https://www.nutrivigilance-anses.fr).

These reports are recorded by ANSES while preserving the consumer's anonymity. ANSES may contact the reporting party again to obtain any missing information. Sufficiently documented (analysable) cases are then examined by experts to determine the severity of the effect and the likelihood of a link between consumption of a product and occurrence of an adverse effect (i.e. the causality).
To carry out this task, ANSES relies on the Nutrivigilance Working Group (WG) it set up, which reports to the Expert Committee on Human Nutrition.

The Agency informs the authorities of the cases it receives and may, if there is strong causality and high severity, be required to issue an alert. With the help of its experts from the Nutrivigilance WG and according to the effects observed, number of cases reported and causality of the products in question, the Agency then establishes its priorities for risk assessment work to be undertaken. The nutrivigilance experts may also be asked to participate in the work of other working groups, in particular the WG on Plants, which was created by ANSES in May 2016 on the entry into force of the Ministerial Order of 24 June 2014 establishing the list of plants authorised in France in food supplements and the conditions of their use. This work leads to the publication of scientific opinions, along with recommendations for healthcare professionals, consumers and manufacturers. These opinions are submitted to the ministries concerned and published on the ANSES website, to enable each stakeholder to take the appropriate management measures.

Between the launch of the nutrivigilance system on 13 November 2009 and 31 December 2024, the Agency received **9172 reports**.

[1] Governed by Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.
[2] Governed by Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and certain other substances to foods.
[3] Governed by Regulation (EU) No 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods.
[4] Governed by Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control.

KEY FIGURES

478 REPORTS RECORDED IN 2024

- 66% of cases were analysable, compared with 70% in 2023
- 5.6% of the analysable cases were severe[5] (severity levels 3 and 4), compared with 6% in 2023

9 ALERTS IN 2024

- Cases with strong causality[6] and high severity (life-threatening)
- Reports were sent to the Ministries of Health and Agriculture in order to determine suitable management measures

2 OPINIONS PUBLISHED ON SERIOUS CASES WITH STRONG CAUSALITY

- ANSES Opinion on a case of acute kidney injury associated with consumption of the product Matcha Slim®
- ANSES Opinion on a case of hallucinations associated with consumption of the food supplement Novanuit® Triple Action

1 OPINION ON A PLANT-RELATED HEALTH RISK ASSESSMENT

This expert appraisal was based on an analysis of nutrivigilance cases:

- ANSES Opinion on the risks associated with the use of *Withania somnifera* (L.) Dunal preparations in food supplements

[5] The scale of severity in nutrivigilance varies from Level 1 (low severity) to Level 4 (death).
[6] The intrinsic causality score ranges from 10 (excluded) to 14 (very likely).

WORK CARRIED OUT

CASE OF ACUTE KIDNEY INJURY ASSOCIATED WITH CONSUMPTION OF THE PRODUCT MATCHA SLIM®

ANSES published a case of acute kidney injury (AKI) due to oxalic nephropathy following consumption of the product Matcha Slim®, whose causality was deemed to be very likely. This product contains matcha green tea leaf powder, vitamin C and taurine. The work served as a reminder that the literature already contains numerous cases of oxalic nephropathy leading to AKI in people with or without risk factors (diabetes, chronic kidney disease, intestinal malabsorption), who have consumed excessive amounts of foods rich in oxalates or vitamin C (an oxalate precursor). AKI may also be caused by excessive taurine intake without any link to oxalate crystal formation. However, there are insufficient data available in the literature for estimating the minimum amount of oxalate provided by the diet that could cause oxalic nephropathy likely to lead to kidney disease. Indeed, there is still some uncertainty regarding the role of dietary oxalate intake in the onset of this disease, since a combination of many other physiological or dietary factors may promote it. Nevertheless, pending the identification of clear mechanisms, analysis of this case led ANSES to recommend that people suffering from kidney failure or diabetes and those with a history of kidney disorders be warned against consuming Matcha Slim® and products with a similar composition.

CASE OF HALLUCINATIONS DUE TO CONSUMPTION OF THE FOOD SUPPLEMENT NOVANUIT® TRIPLE ACTION

ANSES also published a case of hallucinations and confusion involving the food supplement Novanuit® Triple Action, whose causality was deemed to be very likely. Literature searches carried out on this product's ingredients did not identify any ingredient likely to be directly responsible for the adverse effects observed. Two assumptions were put forward to explain the occurrence of these adverse effects: a possible interaction of an ingredient in the food supplement with medicines, or adulteration of the food supplement with a psychotropic substance. The assumption of product adulteration or counterfeiting could not be tested, as no sample was available for analysis. The possibility of an interaction between melatonin or the plant *Eschscholtzia californica* (both of which are found in the product) and certain medicines that can induce psychodysleptic effects cannot be ruled out. A list of medicines that may have caused an interaction, and whose overdose could lead to hallucinations and confusion, was drawn up. Once again, this case stresses the need for caution when consuming food supplements in conjunction with medicines. While such interactions have not been proven, they cannot be excluded.

NUTRIVIGILANCE CASES INVOLVING CONSUMPTION OF FOOD SUPPLEMENTS CONTAINING THE PLANT *WITHANIA SOMNIFERA*

ANSES's WG on "Plants" assessed the risks associated with the use of *Withania somnifera* (L.) Dunal preparations in food supplements. As part of its expert appraisal, nutrivigilance cases involving a product containing a preparation from this plant were extracted. Eight reports were found, six of which were analysed for causality. The most frequently reported adverse effects were mainly digestive (diarrhoea, vomiting), general symptoms (drowsiness) or skin manifestations.
By analysing the available data, this expert appraisal work identified adverse effects on the thyroid, liver, heart, central nervous system, fertility and foetal development. ANSES therefore recommended that people with thyroid, liver or heart disease, or hyperandrogenism, as well as pregnant women and people taking sedatives or medication with a depressant effect on the central nervous system, should refrain from taking food supplements containing *Withania somnifera*. Due to the lack of data on breastfeeding women and children, as a precaution, these vulnerable populations are also advised not to consume such food supplements.
Furthermore, despite disparities in the data on potential interactions, ANSES calls for the utmost caution when taking certain medicines concomitantly.

MAJOR PROJECT

European project on emerging risks associated with food supplements

Launched in 2023, the preparatory and preliminary work for this project culminated on 24 May 2024 in the signing of an agreement between the European Food Safety Authority (EFSA) and ANSES. This enabled work to begin on identifying emerging risks associated with the consumption of food supplements.
This project, led by ANSES, has two main themes:

- analysis of reports from nutrivigilance or other appropriate vigilance systems;
- identification of the presence on the market in Member States of food supplements containing plants identified in the European *Compendium of Botanicals* as potentially having toxic properties (identified by QSAR[7] methods).

The first few months of the project were devoted to creating a knowledge community, bringing together seven active member countries (Belgium, Denmark, France, Ireland, Italy, the Netherlands and Portugal) and fifteen observer member countries (Germany, Croatia, Spain, Estonia, Greece, Hungary, Latvia, Lithuania, Malta, Czech Republic, Romania, Serbia, Slovenia, Sweden and Switzerland).
The initial interim report was submitted to EFSA in November 2024. It presents the member countries of this community, along with the systems in place to watch out for the adverse effects of food supplements and notify the marketing of these products.

[7] QSAR: Quantitative structure-activity relationship is a modelling method based on the quantitative and qualitative relationships between chemical structure and biological activity.

KEY EVENTS

Reform of food safety

On 1 January 2024, the Ministry of Agriculture and Food Sovereignty became the body with sole competence for all regulations and controls relating to food and feed safety. The Directorate General for Food (DGAL) is now responsible for monitoring and enforcing regulations concerning the placing on the market of food supplements and fortified foodstuffs, missions that were previously fulfilled by the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF). The Bureau for Establishments and Products in Specialised Food Industries (BEPIAS) has therefore taken over the task of monitoring the declarations that need to be made before food supplements can be placed on the market. Since September 2024, these declarations have had to be submitted using a new online reporting tool, Compl'alim (which replaces Téléicare).
The DGCCRF remains responsible for ensuring the fairness of information and labelling on food products, for example by monitoring the use of improper claims.

Publication of the fundamental principles underlying ANSES's vigilance systems

ANSES coordinates and operates seven vigilance systems: veterinary pharmacovigilance, the National Network for Monitoring and Prevention of Occupational and Environmental Diseases (RNV3PE), phytopharmacovigilance, toxicovigilance, cosmetovigilance, tatoovigilance and nutrivigilance. In January 2024, it published the fundamental principles underlying its vigilance systems[8], guaranteeing the same standards in the analysis of reports; these principles also ensure consistency between the methods used in the systems for characterising signals and health alerts, following up reports and publishing analyses.

Continued updating of the nutrivigilance database

In 2024, work continued on improving the features of the nutrivigilance database.
To comply with the requirements of the General Data Protection Regulation (GDPR), reporters' personal data are automatically anonymised in the database on a monthly basis if they have not made any new declarations in the past 10 years.
In addition, changes have been made to enable prompt identification of duplicate declarations in the database.
Lastly, new concatenated variables have been created, simplifying exports and making it easier to use and analyse the data.

[8] https://www.anses.fr/fr/system/files/Principes-fondamentaux-des-vigilances.pdf

Outlook

The following expert appraisal in connection with the nutrivigilance system was initiated in 2024:

- Updating of the ANSES Opinion on the risks associated with the consumption of products for athletes seeking to develop muscle or reduce body fat.

Communication measures to publicise the system

In 2024, ANSES continued its training activities to raise awareness about the nutrivigilance system. More than 10 courses were offered to students in pharmacy (third and fourth years, masters and DU university diplomas), sports science (degrees, masters and DU), public health (masters) and nutrition (masters and DU) from different universities in France.

In addition, two oral presentations were given at the Francophone Forum for Nutrition (JFN). Their aim was to explain how the nutrivigilance system works and how the data obtained from adverse effect reporting are used, illustrated with the examples of slimming or weight-loss products and cases of bezoar associated with the consumption of enteral nutrition products.

To coincide with the organisation of the Olympic Games in Paris, *Cahiers de Nutrition et de Diététique* published a special issue on sports nutrition in August 2024. An article entitled "Nutrition: About vigilance for products targeting athletes" was written to provide an overview of cases of adverse effects reported to nutrivigilance and involving the consumption of products intended for athletes.

Lastly, 22 interviews were given to the mainstream media. In addition to content published in the scientific and mainstream press (estimated at nearly 640 articles), nutrivigilance work provided input for two articles in the bulletin for all ANSES's vigilance systems (Vigil'Anses)[9].

[9] https://vigilanses.anses.fr/

MAIN PUBLICATIONS

ANSES. 2024. Opinion of the French Agency for Food, Environmental and Occupational Health & Safety on a case of acute kidney injury associated with consumption of the product Matcha Slim® (2023-VIG-0159). ANSES (Maisons-Alfort).
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