anses
French agency for food, environmental and occupational health & safety
Investigate, evaluate, protect

NATIONAL NUTRIVIGILANCE SCHEME

Review in 2018

KEY WORDS

Nutrivigilance, food supplement, novel food, food intended for specific diets, fortified food

CONTENTS

LIST OF FIGURES

ACRONYMS AND ABBREVIATIONS

ANSM: French Health Products Safety Agency

CAP: Poison Control Centre

CRPV: Regional Pharmacovigilance Centre

DGCCRF: Directorate General for Competition, Consumer Affairs and Fraud Control

DGS: Directorate General for Health

FISD: Food intended for specific diets

FS: Food supplement

FSNP: Food to which substances are added for nutritional or physiological purposes («fortified food»)

NF: Novel food

INTRODUCTION

Implementation of the national nutrivigilance scheme was entrusted to ANSES in July 2009 under the French Act on Regional Health Governance (HPST). The purpose of this scheme 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 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, etc.) who identify adverse effects in their patients that they suspect of being related to consumption of these specific foods, as well as companies marketing these products who become aware of such effects, are invited to report them. Individuals can submit their own reports, but should preferably contact a health professional.

Adverse effects can be reported on the Adverse Health Event Reporting Portal of the Ministry of Social Affairs and Health (https://solidarites-sante.gouv.fr/soins-et-maladies/signalement-sante-gouv-fr/) or directly by filling in the online reporting form (https://pro.anses.fr/nutrivigilance/).

ANSES registers the reports while concealing the consumer's identity, and then conducts an initial analysis of the severity of the incident, the product's composition, any concordance with previous reports, etc. For each report, ANSES may contact the reporter again to obtain any missing information. Reports containing sufficient information are then submitted to medical experts, who analyse the likelihood of a link between consumption of a product and occurrence of an adverse effect (causality). The Agency informs the authorities of the cases received and may be required to issue an alert (for example, with a life-threatening case in which causality is strong). Cases are examined by a group of specialised experts. With the help of these experts, the Agency establishes its priorities for risk assessment work to be undertaken based on the effects observed, the number of cases received and the likelihood of them being associated with consumption of the product in question. This work leads to the publication of scientific opinions, along with recommendations intended for healthcare professionals, consumers and manufacturers. These opinions are submitted to the ministries concerned to enable them to implement appropriate management measures.

Between the launch of ANSES's nutrivigilance scheme on 13 November 2009 and 31 December 2018, the Agency received 4312 reports of adverse effects.

The purpose of this report is to review the activity of the nutrivigilance scheme for 2018.

1 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 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 Regulation (EU) No 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods

4 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

REVIEW OF NUTRIVIGILANCE REPORTS RECEIVED BY ANSES IN 2018

Number of reports received

Figure 1 illustrates the change in the annual number of reports since the creation of the nutrivigilance scheme.

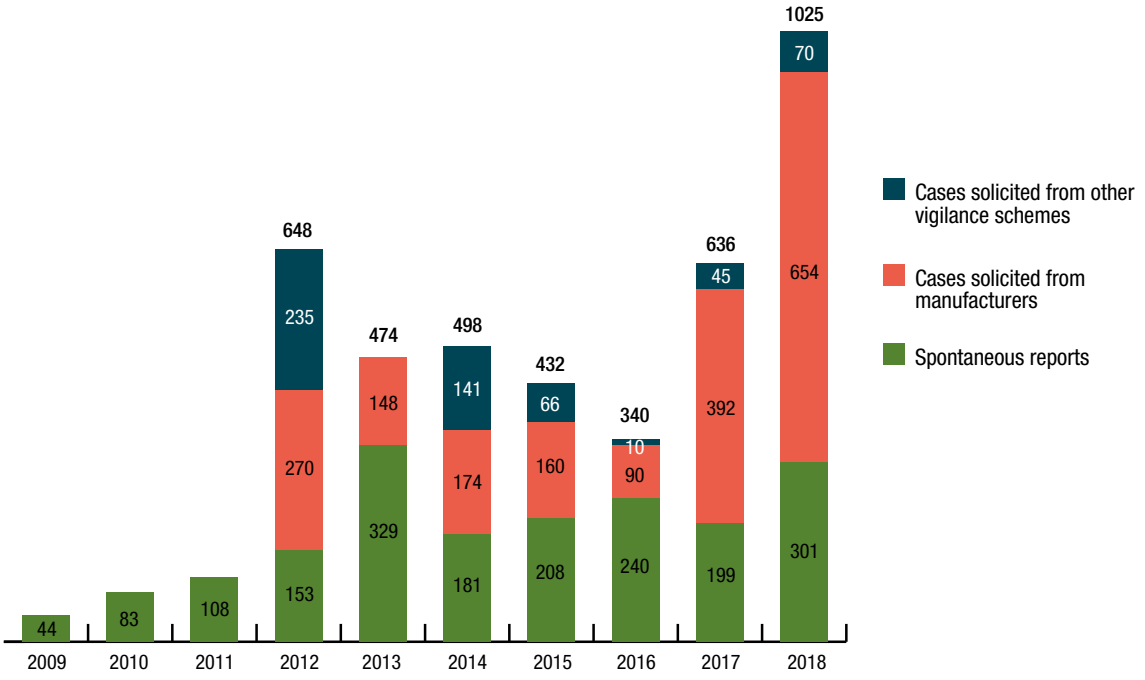

***Figure 1:** Change in number of reports between 2009 and 2018*

Until 2011, cases of nutrivigilance were spontaneously reported by healthcare professionals. In 2012, ANSES initiated a process of proactively seeking out cases from manufacturers and other vigilance schemes (pharmacovigilance, toxicovigilance). Since then, therefore, the spontaneous reports have been joined by "solicited cases" received as a result of these requests.

The sharp increase in the number of spontaneous cases in 2013 can be explained by the decision of certain manufacturers to volunteer other cases brought to their attention, after first being approached about the solicited cases.

The increase in the number of spontaneous reports between 2017 and 2018 was mainly due to the systematic transfer of nutrivigilance cases received by the poison control centres, which was implemented from March 2018. In addition, there was a sharp rise in the number of cases submitted by manufacturers following requests from the Agency (67%), resulting in a 61% increase in the total number of reports compared to 2017.

Admissibility and analysability of cases

Admissible and non-admissible cases

An admissible case is a report that corresponds to the scope of nutrivigilance and for which a product and an adverse effect have been clearly identified. Article R1323-3 of the French Public Health Code defines an adverse effect as "any harmful reaction occurring in humans under normal conditions of use of the food, or resulting from use that does not comply with its purpose, with normal use or with the instructions for use or special precautions for use specified on the labelling".

In 2018, 14% of cases received under the nutrivigilance scheme were considered non-admissible (Figure 2). The main reason for non-admissibility, shown in Figure 3, was the absence of any observed adverse effects. The other causes of non-admissibility concerned problems with the quality of the product consumed (which are the responsibility of the DGCCRF), cases that occurred abroad, foodstuffs not covered by the scope of nutrivigilance, dosage problems, etc. Non-admissible cases that are covered by another vigilance scheme (pharmacovigilance, toxicovigilance, medical device vigilance, etc.) or another authority are systematically redirected to the appropriate contact point. In 2018, 86% of cases were therefore deemed admissible. Not all these admissible cases were able to be analysed.

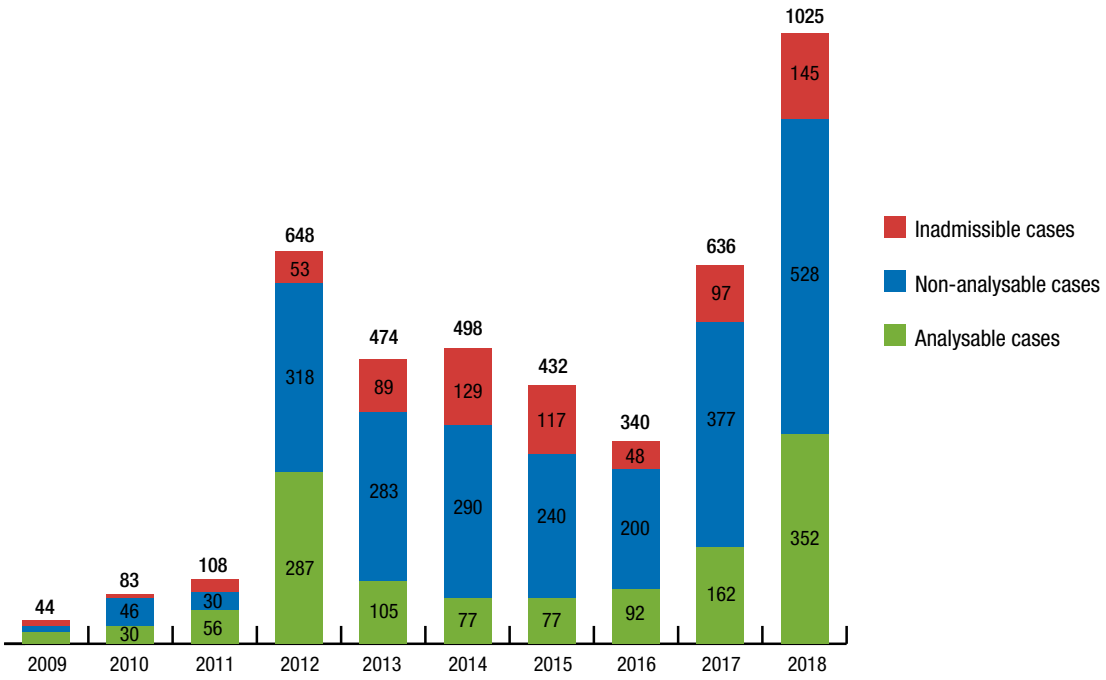

***Figure 2:** Change in the proportion of analysable, non-analysable and non-admissible cases between 2009 and 2018*

Analysable cases

An analysable case is a report that falls within the scope of nutrivigilance (admissible case) and is sufficiently documented to enable a full causality analysis to be conducted.

The proportion of analysable cases in 2018 (34%) increased sharply compared to 2017 (26%) (Figure 2).

Non-analysable cases

If a case is admissible but insufficiently documented (not analysable), ANSES contacts the reporter to ask for additional information.

In 2018, about half of the reported cases (52%) could not be analysed (Figure 3) due to insufficient information being provided, such as unknown consumption dates.

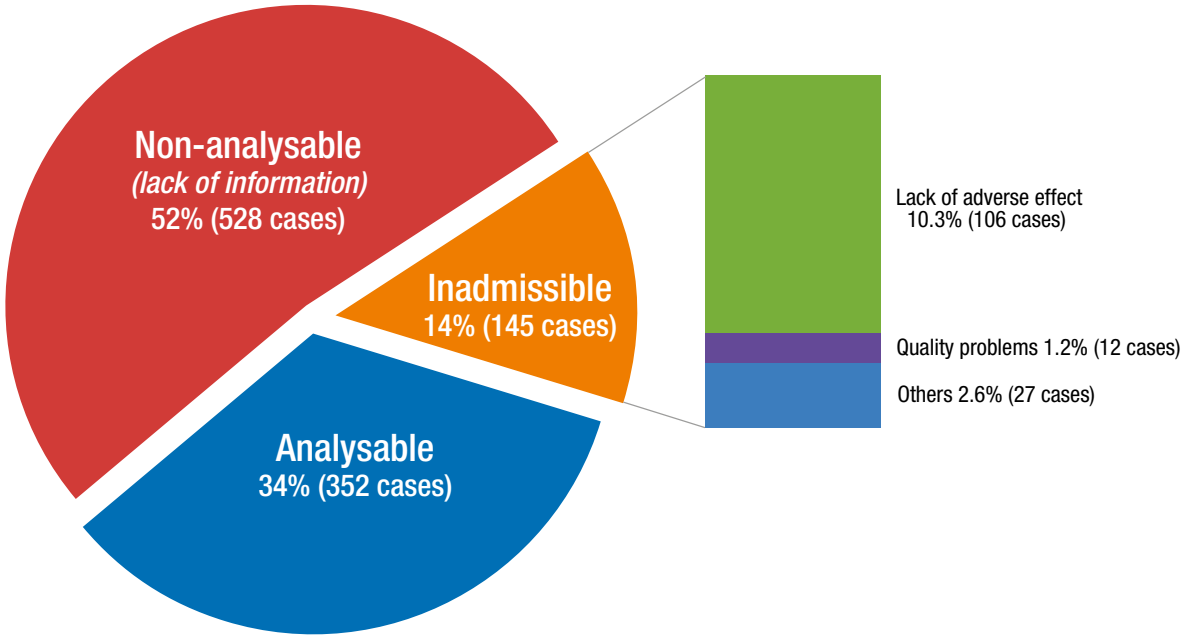

Figure 3: Analysable, non-analysable and non-admissible cases and reasons for non-admissibility in 2018

Identity of the reporters

Accounting for more than 66% of reports submitted, manufacturers were the main nutrivigilance reporters in 2018. Poison control centres (CAPs) reported 15% of cases, regional pharmacovigilance centres (CRPVs) 8%, pharmacies 4% and hospitals 3%. Private practitioners, individuals and other reporters such as nurses and home healthcare providers each reported less than 2% of cases (Figure 4).

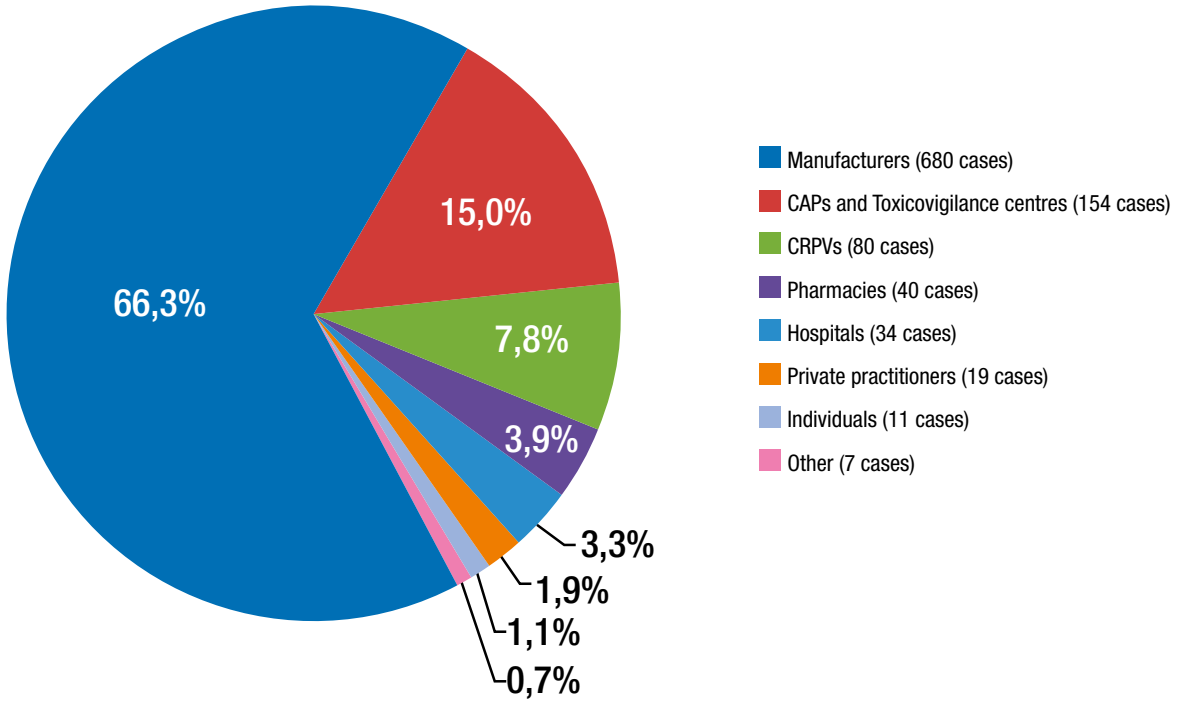

Figure 4: Identity of reporters (all reports combined)

If only analysable cases are considered (Figure 5), reports from manufacturers were still the leading source of reports. The proportion of analysable cases per reporter is shown in Figure 6.

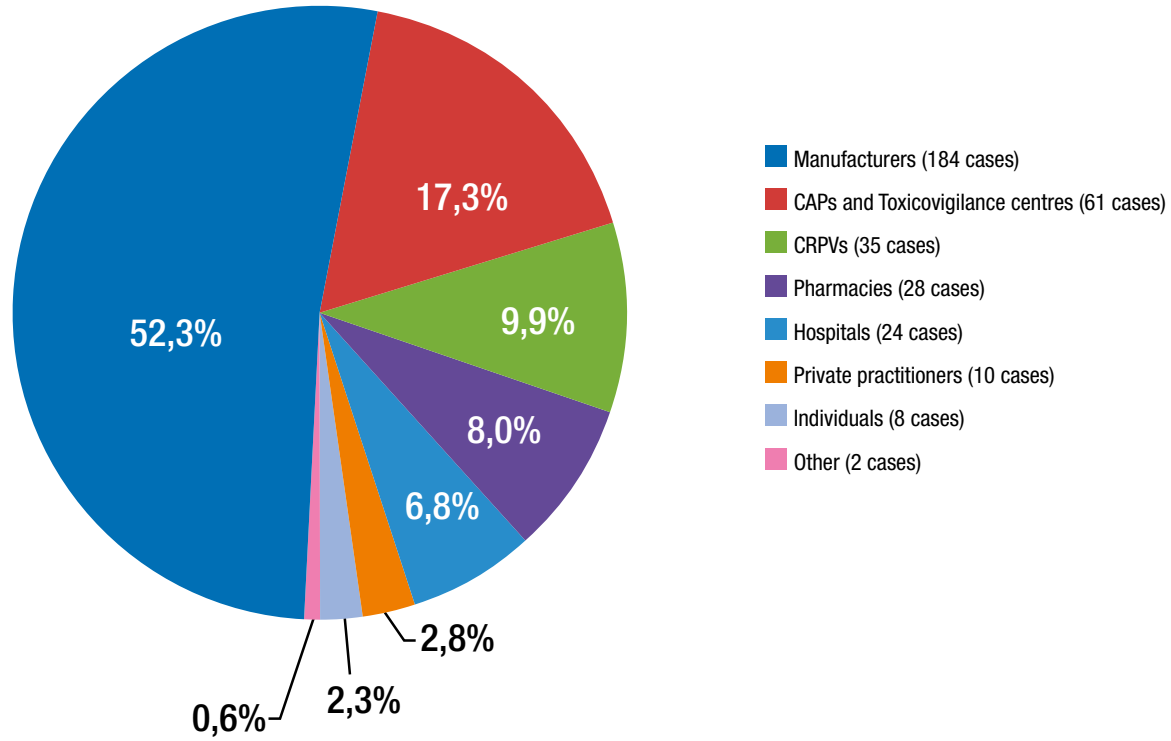

Figure 5: *Identity of the reporters (analysable cases)*

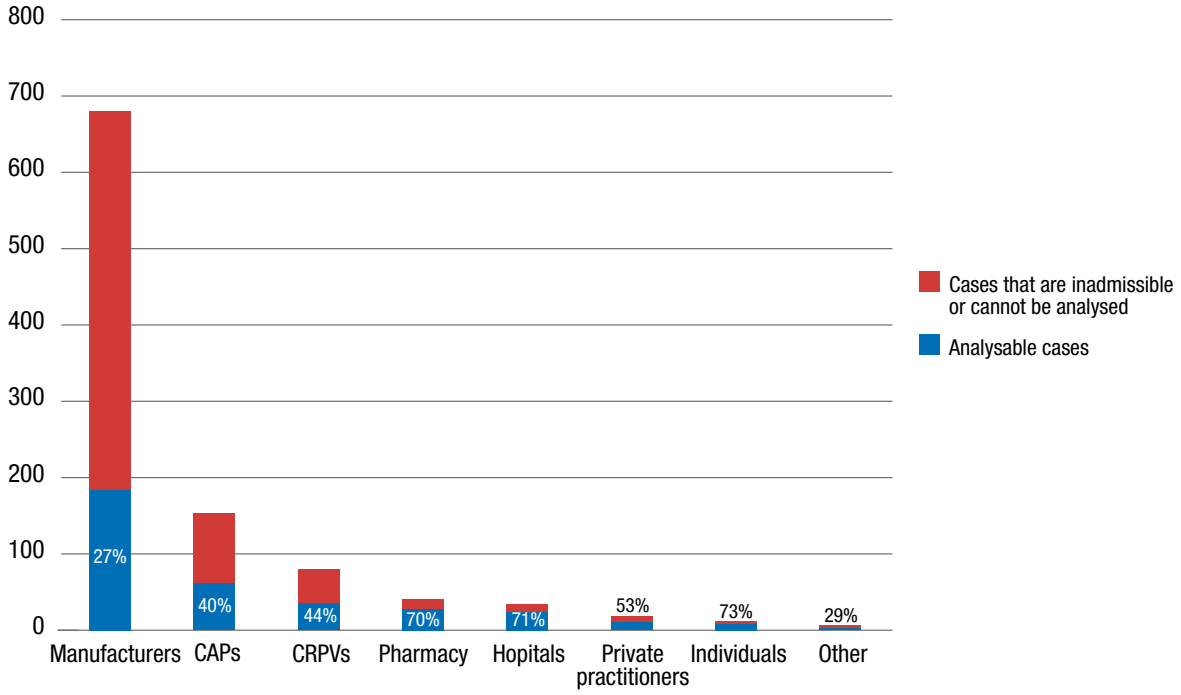

Figure 6: *Analysable cases (%) per reporter*

The remainder of this review only concerns analysable cases, *i.e. admissible reports that fall within the scope of nutrivigilance and are sufficiently documented to enable a complete analysis to be conducted.*
In addition, it is important to stress that no attempt should be made to interpret the variations observed from one year to the next because of the low number of reported cases.

Products reported

Although nutrivigilance concerns four categories of food products – food supplements (FS), food intended for specific diets (FISD), fortified foods (FSNP), and novel foods (NF) – the vast majority of the cases it collects involve food supplements, which accounted for 94.3% of the cases deemed analysable.

This predominance of food supplements is seen year after year (Figure 7).

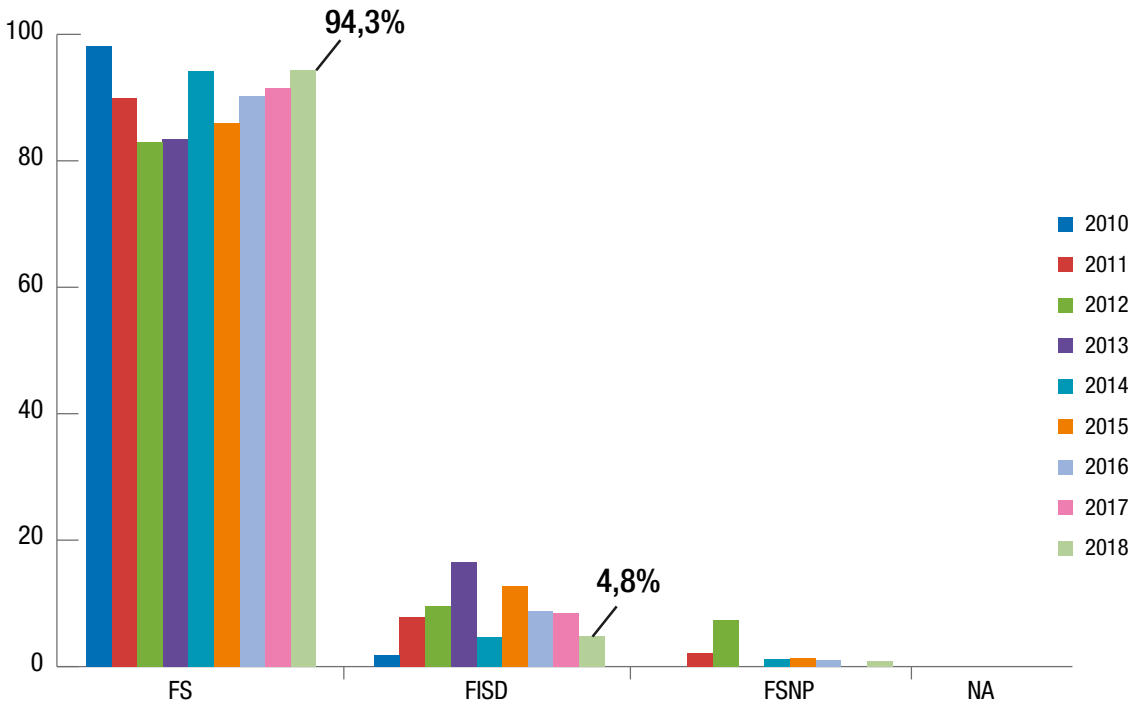

Figure 7: *Types of products reported in nutrivigilance (analysable cases)*

Types of food supplements reported

Among the 352 analysable cases in 2018, 333 involved at least one food supplement.

The types of food supplements reported vary greatly from one year to the next, due to the predominance of cases sought from manufacturers. This is because the initial request from the Agency may then prompt a manufacturer to periodically submit numerous cases concerning a specific product. These are often older cases registered by the manufacturer since the product was first placed on the market. This explains the variability of the most commonly reported types of food supplements from one year to the next, since each year, the cases submitted in this context involve different products. For example, the most commonly reported food supplements in 2018 (Figure 8) were products for aiding "sleep" (147 cases), far ahead of those for "vitality" (35 cases) and "suncare" (27 cases). On the other hand, in 2017, supplements to boost "natural defences" were at the top of the list.

This breakdown does not therefore reflect the food supplement market and does not rank food supplements according to the risks they pose to health.

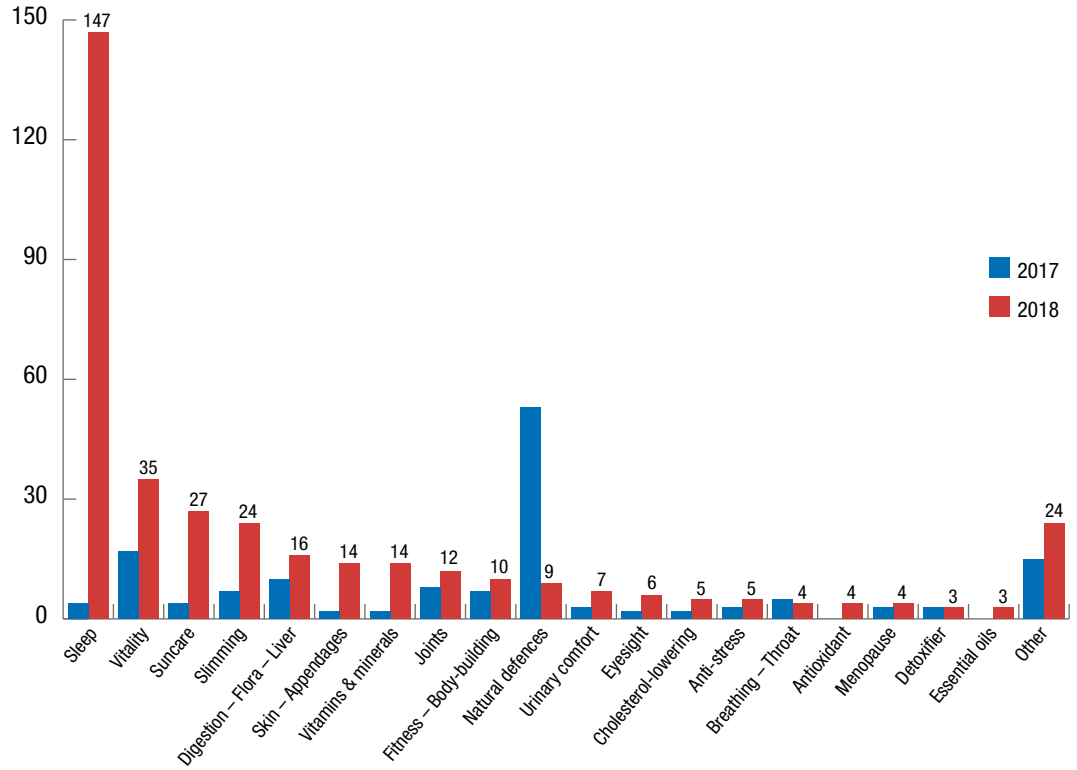

Figure 8: Breakdown of the types of food supplements implicated in the nutrivigilance reports in 2017 and 2018 (analysable cases)

Types of adverse effects

The main types of adverse effects reported in 2018 were digestive (132 cases), general, i.e. non-specific effects such as headache, nausea, asthenia, etc. (111 cases) and cardiovascular (39 cases) (Figure 9).

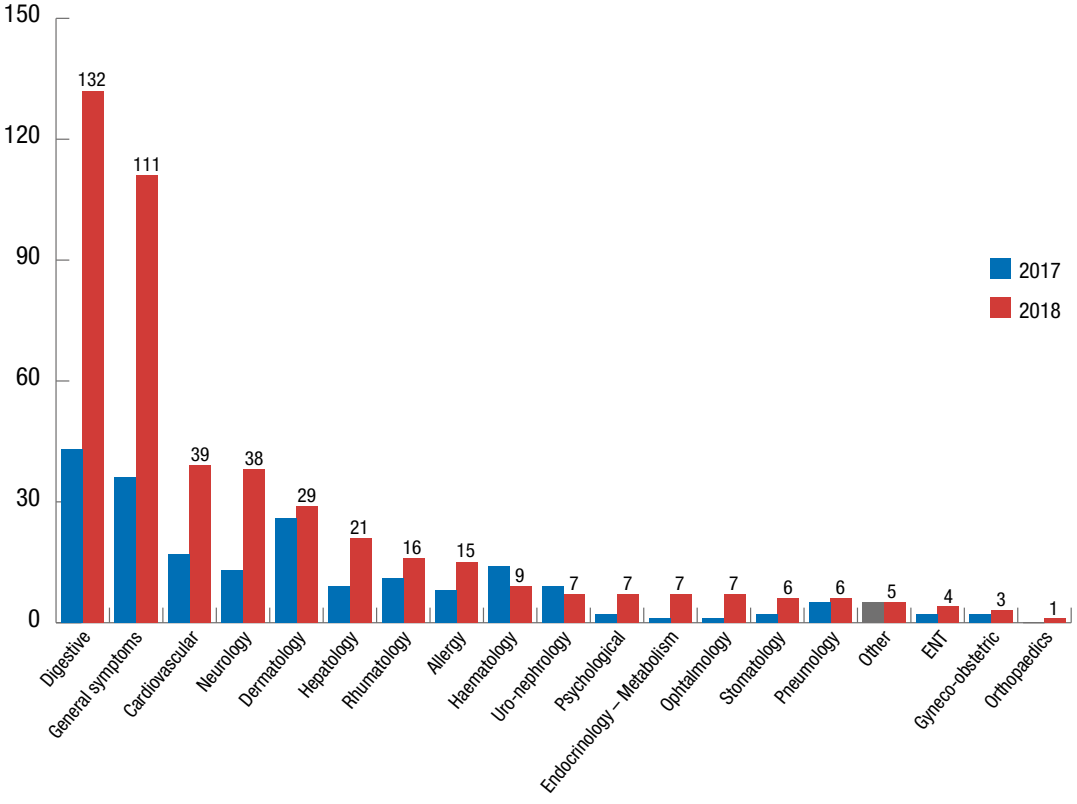

Figure 9: Breakdown of adverse effects reported in 2017 and 2018 (analysable cases)

Intrinsic causality

For each sufficiently documented report received by the nutrivigilance scheme, the causality is determined, i.e. the likelihood that the adverse effect reported is related to consumption of the product. The assessment method was defined in ANSES's opinion No. 2010-SA-0195 of 11 May 2011 on the development of a method for determining causality in reports of adverse reactions in nutrivigilance. This opinion is available on the ANSES website. Causality may be: excluded (I0), unlikely (I1), possible (I2), likely (I3) or very likely (I4).

Of the 352 analysable cases in 2018, causality was excluded (I0) in 13 cases (4%), was unlikely (I1) in 43 cases (12%), possible (I2) in 147 cases (42%), likely (I3) in 138 cases (39%) and very likely (I4) in 11 cases (3%). This breakdown showed a higher proportion of cases with "possible" causality than the previous year (Figure 10).

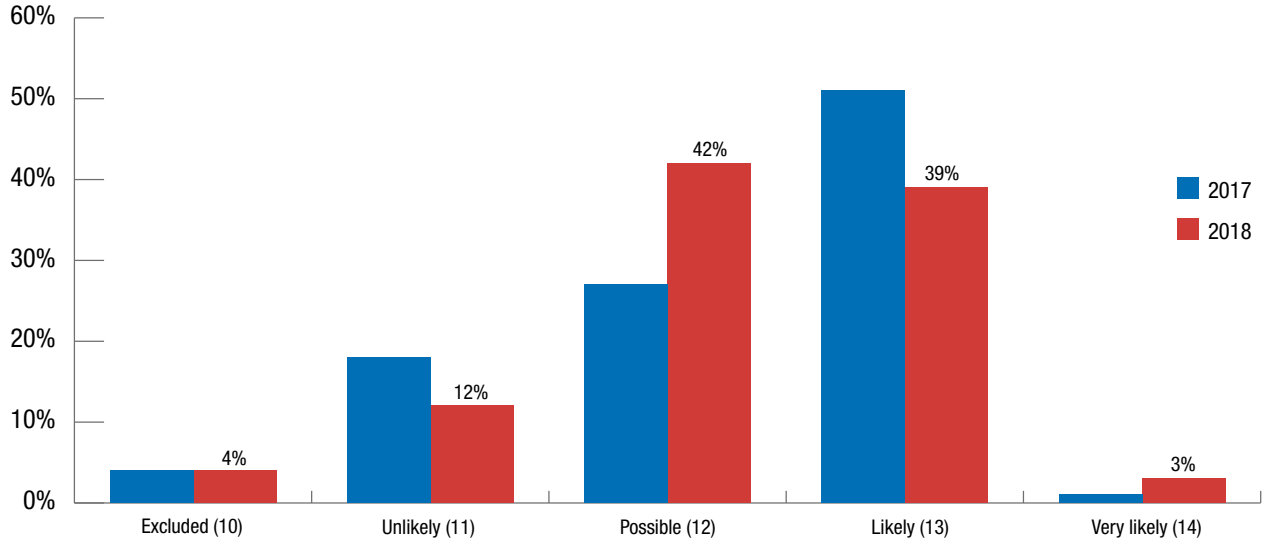

Figure 10: *Causality of cases received in 2017 and 2018 (analysable cases)*

Figure 11 shows causality by type of effect. The sum of the cases presented in this diagram is greater than the number of analysable cases (352) because several types of adverse effects can be reported in a single case.

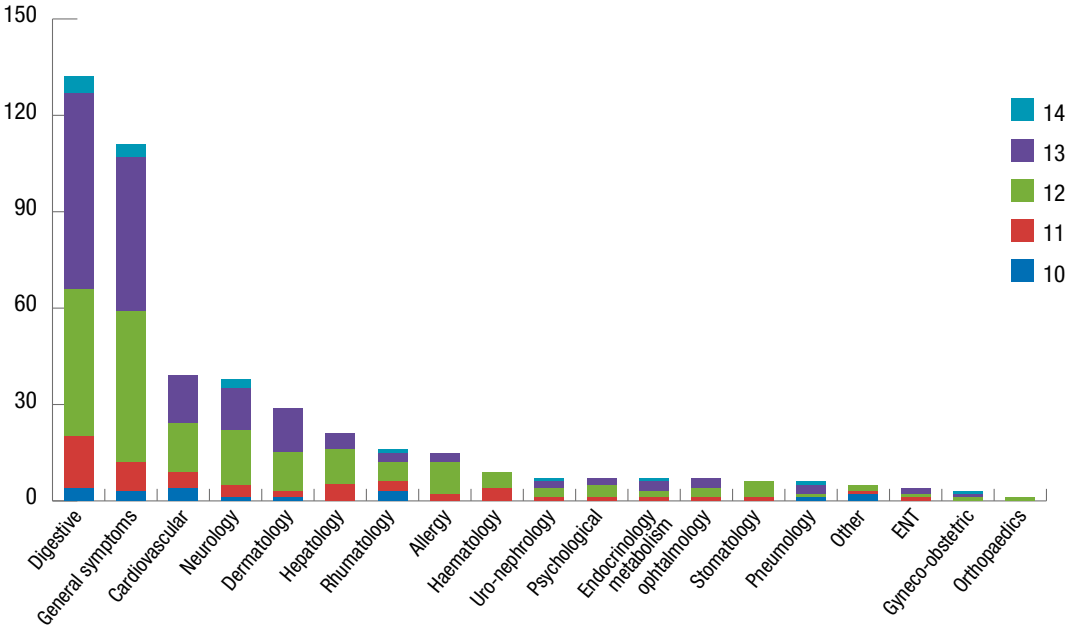

Figure 11: *Causality according to the type of effect (analysable cases)*

Severity of the cases

The scale of severity in nutrivigilance ranges from Level 1 (low severity) to Level 4 (death). Within Level 3, a specific category concerns cases with life-threatening prognosis (LTP). In 2018, while the majority of analysable effects were of Level 1 severity (76%), 6% of cases had high severity (Level 3, Level 3 with life-threatening prognosis, or Level 4) (Figure 12).

Figure 13 shows the breakdown of case causality according to severity.

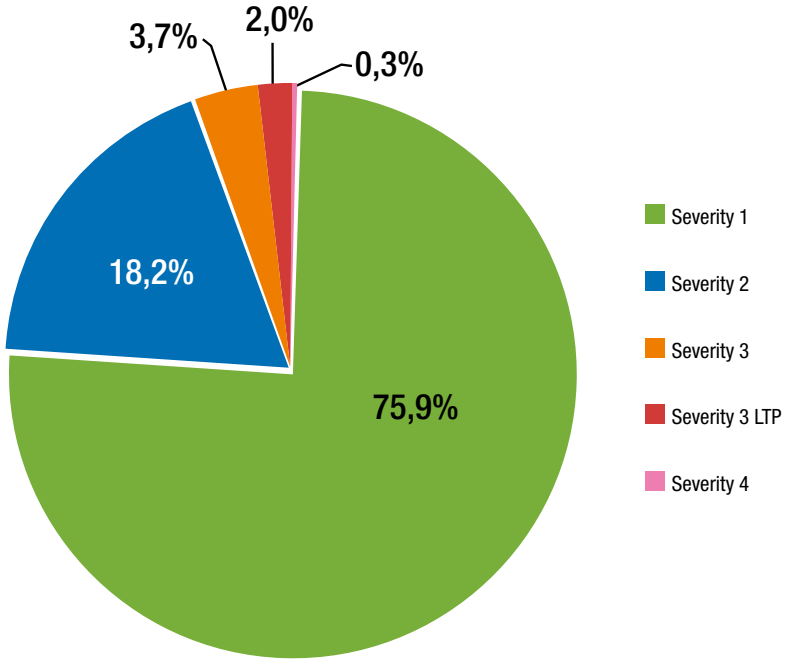

Figure 12: Severity of adverse effects reported (analysable cases)

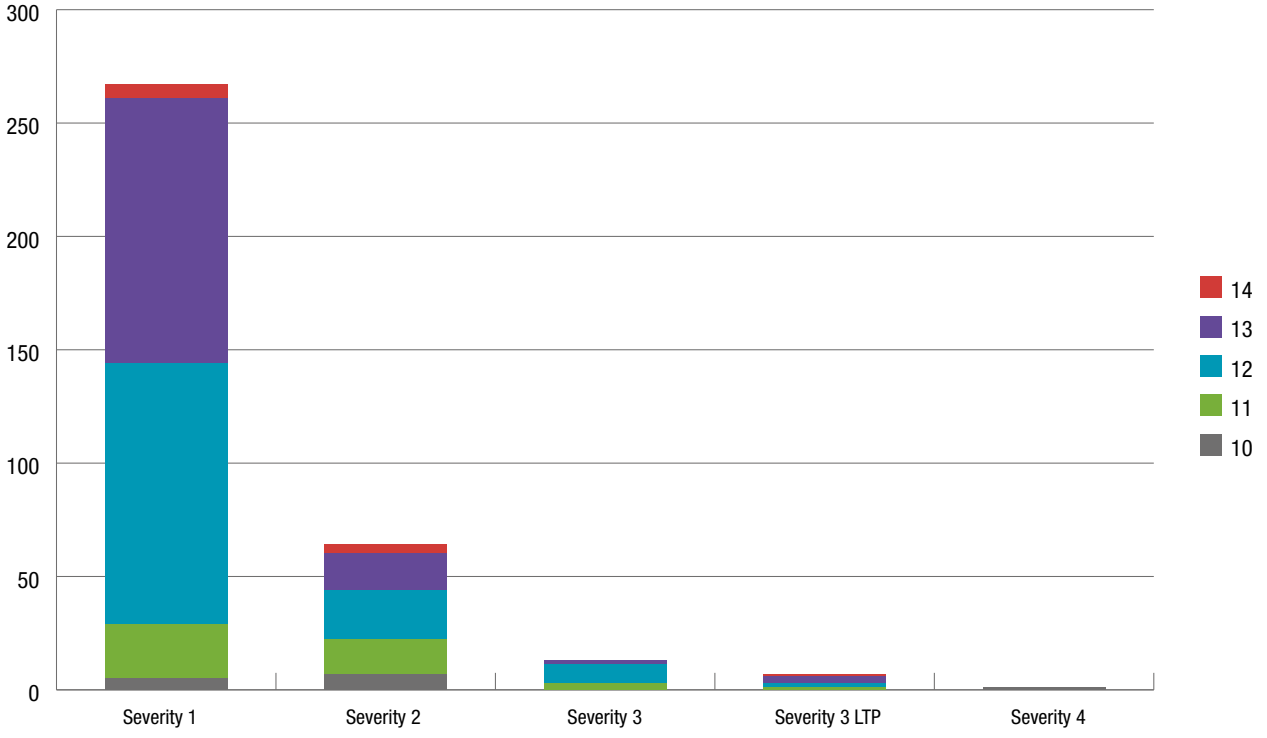

Figure 13: Causality according to severity (analysable cases)

Cases leading to an alert

In the event of a case with Level 4 severity or Level 3 with life-threatening prognosis and where causality is at least possible (I2), the report is forwarded to the alert offices of the Directorate General for Health (DGS) and the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF). This procedure does not apply in the event of an allergy to an ingredient known to be allergenic. In 2018, seven cases met these criteria.

Case 2018-448 concerned a 56-year-old woman who had **severe hypokalaemia** following consumption of the food supplement Rhubarbe (Juvamine), as a result of misuse. Causality was deemed to be very likely. This case was published in an opinion (see Section 2.3).

Case 2018-112 concerned a 62-year-old man treated with Brilique (a platelet aggregation inhibitor), who developed **acute coronary syndrome** following consumption of XtraSlim 700 (Forté Pharma). Causality was deemed to be likely.

Case 2018-208 concerned a 28-year-old man who developed **cerebral venous thrombosis** following consumption of Multi PRZ (Prozis) in combination with other unidentified food supplements. Causality was deemed to be likely.

Case 2018-056 concerned **intrauterine growth retardation and neonatal hypothyroidism** in a newborn whose mother had consumed the Plasma Marin (Quinton) food supplement throughout her pregnancy. Causality was deemed to be likely.

Case 2018-074 concerned a 62-year-old woman who had **reversible cerebral vasoconstriction syndrome** following consumption of three food supplements from the Modere brand: Green Qi, Mineral Solutions and Protozymes. Causality was deemed to be possible.

Case 2018-022 concerned a 63-year-old woman who presented with **DRESS syndrome** following consumption of the Liporedux (Forté Pharma) food supplement. Causality was deemed to be likely.

Case 2018-017 concerned a 79-year-old woman who presented with **severe thrombocytopaenic purpura** following consumption of the Extra Artichaut (Milical) food supplement. Causality was deemed to be possible.

REVIEW OF THE OPINIONS PUBLISHED BY ANSES

The analysis of reports received by its nutrivigilance scheme enables ANSES, with the help of the experts, to establish its priorities for risk assessment.

Since 2009, therefore, ANSES has published around a dozen opinions on a wide range of products monitored by nutrivigilance, including on the risks associated with the consumption of certain substances found in food supplements (spirulina, lutein, zeaxanthin, synephrin, red yeast rice, etc.), food supplements for athletes, food supplements for pregnant women, so-called energy drinks, and beverages other than breast milk and its substitutes in the diet of infants under one year of age.

Risk assessment opinions

Food supplements containing melatonin

On 23 February 2018, ANSES issued an opinion on the risks associated with the consumption of food supplements containing melatonin. The Agency conducted an analysis of the 90 reports of adverse effects likely to be associated with the consumption of food supplements containing melatonin, received between the creation of the nutrivigilance scheme in 2009 and May 2017. This analysis was supplemented by the study of bibliographic data, enabling ANSES to identify the risks associated with their use.

The expert appraisal highlighted the existence of populations and situations at risk. In particular, these include breastfed children whose mothers may have consumed food supplements containing melatonin, children and adolescents, people suffering from inflammatory or autoimmune diseases, people carrying out any activity requiring sustained vigilance where drowsiness could pose a safety problem, and people with epilepsy, asthma, or suffering from mood, behaviour or personality disorders.

Because of the many possible pharmacokinetic and pharmacodynamic interactions between melatonin and certain drugs, ANSES recommended, in the event of drug therapy, avoiding the use of food supplements containing melatonin without first seeking the advice of a doctor. The Agency also recommended favouring simple formulations that do not combine melatonin with other ingredients and avoiding the concomitant use of several food supplements, in order to limit the risks of interactions.

Lastly, ANSES believed it necessary for a harmonised regulatory framework to be defined at European level.

The opinion can be consulted via the following link: https://www.anses.fr/fr/system/files/NUT2016SA0209EN.pdf

Food supplements containing glucosamine and/or chondroitin sulphate

On 4 January 2019, ANSES issued an opinion on the risks associated with the consumption of food supplements containing glucosamine and/or chondroitin sulphate. ANSES conducted an analysis of the 74 reports of adverse effects likely to be associated with the consumption of these food supplements received between the creation of the nutrivigilance scheme in 2009 and February 2018. This analysis was supplemented by the study of bibliographic data, enabling ANSES to identify the risks associated with their use.

The expert appraisal revealed the existence of specific populations for whom the consumption of food supplements containing glucosamine or chondroitin sulphate presents a risk. The consumption of these food supplements is therefore not recommended for people with diabetes or pre-diabetic conditions, asthmatics, people treated with vitamin K antagonists, with a food allergy to crustaceans or insects, or whose diets are controlled for sodium, potassium or calcium. In addition, in the absence of sufficient safety data, ANSES advised against the consumption of these food supplements by pregnant or breastfeeding women, and children. The Agency considered that manufacturers should take the necessary measures with regard to consumers in this respect.

Lastly, ANSES believes that the maximum daily doses

of glucosamine and chondroitin sulphate authorised in food supplements should be harmonised at European level on the basis of safety data from robust safety studies – currently lacking – for glucosamine and chondroitin sulphate.

The opinion can be consulted via the following link: https://www.anses.fr/fr/system/files/NUT2015SA0069EN.pdf

Methodological opinion

Updating the method for determining causality in reports of adverse effects in nutrivigilance

The causal relationship between a product covered by the national nutrivigilance scheme and the reported adverse effect must be analysed using an appropriate and objective analytical method. This method, referred to as the «method for determining causality in nutrivigilance», is applied as part of a standardised approach designed to resolve any differences in opinion that may exist between observers.

Given the significant differences compared with drugs (no demonstrated benefit or safety study), ANSES issued an internal request on 25 August 2010 to develop a method of determining causality specific to reports of adverse effects likely to be associated with the consumption of products concerned by the national nutrivigilance scheme. This first method of determining causality was published on 11 May 2011 (https://www.anses.fr/en/system/files/NUT2010sa0195.pdf).

Since 2011, this method has been supplemented and clarified throughout its application by the «Nutrivigilance» Working Group. These details are recorded in a «manual of decisions», which is not published.

In 2018, ANSES issued an internal request to update the method for determining causality in reports of adverse effects in nutrivigilance. This update takes account of the changes submitted by the «Nutrivigilance» Working Group and also of the remarks made following a test to establish concordance between assessors.

This updated method was published on 18 April 2019. It provides the basis for a more discriminatory assessment of the relationship between the consumption of a product falling within the scope of nutrivigilance, and the occurrence of an adverse effect. It details each component in the method in order to improve repeatability. Lastly, it underlines the need to take account of the risk of interactions with other substances consumed, particularly drugs.

The opinion can be consulted via the following link: https://www.anses.fr/fr/system/files/NUT2018SA0026.pdf

Severe cases with high causality

In addition to its risk assessment opinions, ANSES publishes cases deemed to have high causality (very likely) and high severity (Level 3, Level 3 with life-threatening prognosis, or Level 4).

Three opinions have been published in this context.

Allergies to food supplements containing pollen or hive products

On 23 May 2018, ANSES issued an opinion on three cases of Level 3 severity involving allergy to food supplements containing pollen or hive products. The causality of these food supplements in the occurrence of the adverse effects was considered likely or very likely. The Agency pointed out that pollen allergy is a risk factor for allergy to hive products (royal jelly, propolis, honey) and stressed that food supplements, like normal foods, may contain allergens as ingredients or contaminants.

The opinion can be consulted via the following link: https://www.anses.fr/en/system/files/NUT2017SA0215EN.pdf

Allergy to a food supplement containing flax

On 23 May 2018, ANSES issued an opinion on a case of Level 3 severity involving allergy to the food supplement Nutrilin. The causality of this food supplement in the occurrence of the adverse event was considered very likely. The Agency reiterated that food supplements, like normal foods, may contain allergens as ingredients or contaminants. People with a known allergy to a particular ingredient need to be vigilant regarding the composition

of any food supplements that may contain it.

The opinion can be consulted via the following link: https://www.anses.fr/fr/system/files/NUT2018SA0013.pdf

Hypokalaemia following misuse of a food supplement containing liquorice and rhubarb

On 16 January 2019, ANSES issued an opinion on a case of hypokalaemia of Level 3 severity with life-threatening prognosis involving an evident overdose through misuse of the food supplement Rhubarbe®, which contains liquorice and rhubarb. The causality of this food supplement in the occurrence of the adverse effect was considered likely. Cases of hypokalaemia have been reported in the literature following the consumption of liquorice. Due to its laxative properties, rhubarb can also indirectly lead to hypokalaemia. The severity of the adverse effect observed in this report can be attributed to the combination of these two plants, consumed in excess.

The opinion is available via the following link: https://www.anses.fr/en/system/files/NUT2018SA0209EN.pdf

REVIEW OF INFORMATION AND COMMUNICATION ACTIVITIES

European exchanges

Despite the existence of European Directive 2002/46/EC defining food supplements, regulation of these products varies considerably from one country to another. For example, with regard to their placing on the market, some countries do not impose any pre-marketing obligations, in accordance with the European Directive, while other countries have set up notification or authorisation systems. The composition of food supplements can also differ widely depending on the country. An ingredient authorised in one European country may be prohibited in another. Despite this, these products may be available throughout Europe due to the free movement of goods. Regarding the monitoring of adverse effects, there is the same disparity since few European countries have developed a dedicated vigilance system. Nevertheless, besides France's nutrivigilance initiative, several other countries are investigating or have already started setting up a similar scheme (such as Italy, the Czech Republic, Slovenia, Ireland and Sweden).

To unify these schemes and raise awareness among other Member States, ANSES held a kick-off meeting for a nutrivigilance information exchange network in Maisons-Alfort on 12 June 2014, which was attended by 13 Member States.

Since then, the initial network has expanded and now involves 28 countries: Austria, Belgium, Brazil, the Czech Republic, Croatia, Cyprus, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, Malta, the Netherlands, Norway, Portugal, Serbia, Slovakia, Slovenia, Sweden, Switzerland, the United Kingdom.

This network enables the sharing of information on cases, literature and the concerns of Member States. This pooling of knowledge of product composition and the cases reported in other European countries is essential in the context of the free movement of goods.

Training activities organised

As part of efforts to promote nutrivigilance among healthcare professionals, in 2018 ANSES continued its training actions among students of pharmacy (3rd and 4th years, Master and DU degree), medicine (3rd year and Master) and sport science (Master and DU) at different faculties in France. It also offered training to other students in the framework of Master or specialised DU courses in nutrition.

Other actions

The nutrivigilance scheme was presented at the Francophone Forum for Hepato-Gastroenterology and Digestive Oncology (JFHOD), and the Pharmagora Plus trade show for pharmacists and members of Synadiet (the French Food Supplements Association).

Lastly, nutrivigilance was presented in poster form at the Francophone Forum for Nutrition (JFN 2018).

CONCLUSIONS

Between the launch of ANSES's nutrivigilance scheme and 31 December 2018, the Agency received 4312 reports of adverse effects. In 2018, the number of reported cases increased sharply compared to 2017 (+61%), mainly due to the many cases submitted by manufacturers after being approached by the Agency. The quality of reports has also improved, with the proportion of analysable cases increasing from 26% in 2017 to 34% in 2018. Seven of the cases received in 2018 led to an alert, enabling the rapid implementation of health and safety measures by the competent health authorities where necessary.

The analysis of reports also enables ANSES to identify, in conjunction with its experts, the topics requiring a specific expert appraisal for risk assessment. These expert appraisals lead ANSES to formulate recommendations to guarantee the safety of products placed on the market, by identifying vulnerable populations, risk situations and interactions. These recommendations are intended for health professionals, consumers, manufacturers and public authorities. They enable the authorities in charge of risk management to take measures to ensure the safety of these products. In 2018, ANSES issued two risk assessment opinions, one on food supplements containing melatonin and the other on food supplements containing glucosamine and/or chondroitin sulphate.

The Agency has also changed the way it analyses reports, and has published an update of its method for determining causality. This update details each component with the aim of improving its repeatability.

To ensure optimal performance of this scheme, the Agency wishes to remind healthcare professionals and companies marketing products of the importance of their involvement as reporters. All cases of adverse effects that may be linked to the consumption of food supplements should be reported to ANSES. The Agency also invites healthcare professionals to question their patients during medical consultations about their use of food supplements and other special dietary foods such as fortified beverages, and to notify the nutrivigilance scheme of any adverse effects they are made aware of.

In general, ANSES reiterates that deficiencies in nutrients are very rare in the general population, and mainly concern a few specific substances such as vitamin D, or particular population groups (pregnant women, the elderly, economically vulnerable populations, etc.). In these specific population groups, additional intakes of vitamins, minerals and other nutrients through food supplements may be of benefit, but on medical advice. For a large majority of the population, a balanced diet provides most of the nutrients required to meet nutritional needs. ANSES stresses that food supplements are not without danger and sometimes have significant pharmacological activity. They should not be used as a substitute for a varied diet, and the advice of a healthcare professional should always be sought when taking them. Pregnant and breastfeeding women, children, and people taking medication should systematically seek advice from their general practitioner before consuming food supplements.

Lastly, the Agency advises consumers to:

- comply with the conditions of use specified by the manufacturer;
- notify a healthcare professional of any adverse effect occurring after consumption of a food supplement;
- avoid taking food supplements on a prolonged, repeated or multiple basis throughout the year without having sought the advice of a healthcare professional;
- exercise extreme caution with products promoted as "miracle" cures and/or those sold through alternative channels, in particular through the Internet.

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