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

Press Kit

# Nutrivigilance, a scheme devoted to consumer safety

*8 October 2014*

**Press liaison: Elena Seité – +33 (0)1 49 77 27 80 - elena.seite@anses.fr**
**All our press releases and kits on www.anses.fr**
**@Anses_fr**

# Contents

**After more than three years of operation, ANSES takes stock of its nutrivigilance scheme.**

**Press release**

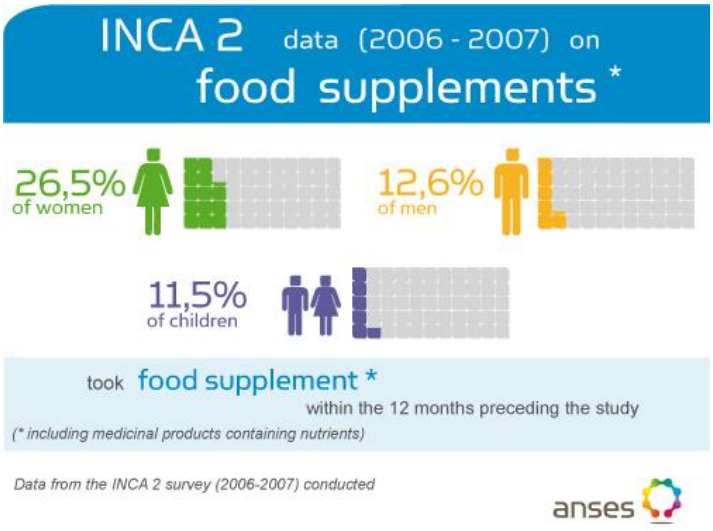
## Nutrivigilance, a scheme devoted to consumer safety

**The consumption and availability of food supplements as well as of certain special food items such as energy drinks, are in constant progression. Meanwhile, distribution channels are diversifying, especially with regard to the Internet. However, these new products, often perceived by consumers as without danger, can under certain conditions expose them to risks. Because of this, ANSES has been tasked since 2010 with a nutrivigilance mission whose objective is to identify the adverse effects of consuming these foods. The nutrivigilance scheme contributes to consumer safety. One of its achievements has been the issuing of recommendations on nine different products, including energy drinks, red yeast rice-based food supplements and *p*-synephrine. Today, after over three years in operation, ANSES provides a preliminary overview of its nutrivigilance scheme, while also reminding physicians of their essential role in its success.**

Over the last few decades the range of available foods has greatly expanded, with **new products** characterised by innovative and novel technology, ingredients and formats, including food supplements and fortified foods and beverages (energy drinks, etc.). The food supplement market in particular has grown exponentially, with turnover of over 1.3 billion euros in 2013. Moreover, **products have become increasingly based on technology**, while their **distribution channels have diversified** and **consumer habits have evolved**. While food safety is highly regulated and monitored, these new products, often perceived as safe by the consumer, can under certain conditions **expose them to risks** that we need to be able to identify. This is the goal of ANSES's nutrivigilance scheme, which is now an integral part of the monitoring schemes set up by the health authorities to protect the health of consumers.

### Food supplements: primary source of incident reports

In France, according to the INCA 2 survey conducted by ANSES, **one out of every five adults** and **one out of every ten children** take food supplements or vitamins and minerals in a medical form at least occasionally. Furthermore, among these consumers, **23% of adults and 12% of children take these products all year round or most of the year.**




Since ANSES's nutrivigilance scheme was initiated, it has received **over 1500 reports** of adverse effects. Among these, **76%** were due to consumption of **food supplements** and 24% to fortified foods or foods for special dietary uses. With regard to food supplements, over one-third of the valid declarations received on food supplements involved **weight-loss**, **hair health** or **cholesterol-lowering** products. In addition, the main adverse effects reported involved the **liver, digestive system** and **allergies**.

## Incident reports are central to ANSES's work

An analysis of the reports received led the Agency to issue an internal request in order to conduct **nine health risk assessments** on the risks of consuming certain substances found in food supplements (lutein, zeaxanthin, *p*-synephrine, red yeast rice, *etc.*). The Agency has also studied other types of products, and has evaluated in particular the risks linked to so-called "energy drinks" as well as feeding infants under one year of age beverages other than mother's milk or its substitutes.

Moreover, the Agency is currently conducting an assessment of the risks of consuming **food supplements made especially for pregnant women or athletes**. The results of this assessment are due to be published in the first half of 2015.

## Healthcare professionals, key players in the scheme

Today ANSES wishes to stress that, after three years in operation, the nutrivigilance scheme's effectiveness depends upon the abundance and precision of the data reported. This is why we wish to remind healthcare professionals that **their involvement is crucial** if the scheme is to remain active and efficient.

We therefore are asking healthcare professionals to continue contributing, and recommend that during medical consultations they ask patients about their use of food supplements and other special dietary foods. We encourage them to remain vigilant, and to declare **all the adverse effects they observe**, especially with regard to the two requests currently being examined, on food supplements for pregnant women and for athletes.

Last, ANSES wishes to remind consumers that food supplements are not without danger. They should not be used as a substitute for a well-balanced, varied diet, and the advice of a healthcare professional should always be sought when taking them. We also recommend strict compliance with the instructions for use on the label. Extreme caution should also be taken with products promoted as "miracle" cures, or those sold through alternative channels, in particular through the Internet.

## What is the nutrivigilance scheme?

**In the last few decades, significant progress has been made in food safety through the efforts of all the stakeholders in the food production chain. However, the range of available foods has greatly expanded, with new products characterised by innovative and novel technology, ingredients and formats, including food supplements, fortified foods and beverages, products sold outside traditional channels, in particular on the Internet, that can expose consumers to new risks that we need to be able to identify. This is the goal of ANSES's nutrivigilance scheme.**

The Agency was asked to set the scheme up in July 2009. The aim of this health surveillance system is to improve consumer safety by rapidly identifying any adverse effects associated with the consumption of food supplements, as well as foods or beverages fortified with substances added for nutritional or physiological purposes (vitamins, minerals, amino acids, plant extracts, etc.), novel foods and ingredients, and products intended for people on specific diets (infants, athletes, patients with food intolerances, etc.).

***An adverse effect is a harmful reaction occurring under normal conditions of use or resulting from misuse, that may lead to the appearance of symptoms of varying severity (for example digestive, allergic, cardiovascular, etc.).***

## Which products are covered by the nutrivigilance scheme?

- **Food supplements**

Food supplements are defined[1] as "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination [...]". They have different purposes: anti-fatigue, hair-care, cholesterol-lowering, boosting the immune system, eyesight, etc.

- **Fortified foods**

These are foods or beverages which have been fortified by substances for nutritional or physiological purposes, such as vitamins, minerals, amino acids, plant extracts, etc. They include so-called energy drinks and products fortified with phytosterols.

- **Novel foods[2]**

Novel foods are foods or ingredients which were not consumed in the Member States of the European Union before 15 May 1997.
These foods include Magnolia bark extract, Guar gum, Noni juice and also dried fruit pulp from Baobab trees.

- **Foods intended for specific diets**

These foods are intended for certain population groups such as infants, gluten-intolerant people, the elderly, etc. who have specific nutritional needs.

[1] According to Directive 2002/46/EC of the European Parliament, transposed by the Decree of 20 March 2006
[2] To find out more, read our article Novel foods and food ingredients

## Regulatory situation

Before they can be placed on the market, **novel foods** must undergo a risk assessment by the health authorities of the Member States and be authorised at EU level after an opinion has been issued by the European Food Safety Authority (EFSA). For other ingredients or foods, i.e. those that can justify a history of their use on the European market before 1997, the scheme is more flexible and does not require prior assessment, but includes provisions that are specific to each category of food.

**Fortified foods** are governed by Regulation (EC) No 1925/2006, whose aim is to regulate the addition of vitamins, minerals and certain other substances to foods, at European level. It establishes the list of these substances and the form under which they may be added.

**Foods intended for specific diets** are regulated by Decree No 91-827 of 29 August 1991. It establishes the list and conditions of use of substances (such as vitamins, minerals, amino acids) that can be incorporated into foods intended for specific diets, as well as the labelling rules for these products.

Regarding **food supplements**, if they do not use novel ingredients, they do not require authorisation before they are placed on the market, based on the assessment of an industrial application dossier by an expert appraisal body. Manufacturers are responsible for ensuring that their products comply with current standards in force to ensure consumer safety and prevent fraudulent claims, before marketing them.

However, food supplements are subject to a reporting requirement, specifying their composition, which must be filed with the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF).

Regarding vitamins and minerals used in food supplements, European regulations provide a strict framework for the authorised substances and formats. As for the maximum amounts that can be incorporated into food supplements, these are set by national regulations.

For other substances (caffeine, coenzyme Q10, creatine, carnitine, etc.), especially given the wide diversity of uses in the Member States and the number of substances considered, the European regulations provide for a general obligation of safety on the part of the operators, without establishing a list of substances, chemical forms or amounts authorised. Plants used in food supplements have up to now been governed by a regulatory framework at national level, specifying the plants authorised and the associated conditions of use.

Lastly, **the nutritional claims that can be used to promote these products** are covered by a harmonised framework at European level (Regulation (EC) No 1924/2006). The authorised claims are listed in the Annex to the Regulation. Since 2007 and the entry into force of this Regulation, the European Food Safety Authority (EFSA) has been responsible for assessing health claims before a product can be marketed, while the European Commission keeps the register of authorised claims.

**To find out more about the regulations governing these products, visit the DGCCRF's website: http://www.economie.gouv.fr/dgccrf**

## How the nutrivigilance scheme works

- **Who submits the reports?**

Healthcare professionals (doctors, pharmacists, dieticians, etc.) are invited to report these specific foods when they identify adverse effects in their patients that they suspect of being related to consumption of these foods. It is preferable for individuals who wish to submit a report on their own behalf to contact a healthcare professional.

- **How are reports submitted?**

Reports are made on the ANSES website by filling out an on-line form. On-line reporting is a quick way of informing the authorities of a nutrivigilance problem. Alternatively, the report form can also be downloaded, completed and sent to ANSES by e-mail, fax or post.

- **What happens to the reports?**

The reports are recorded by ANSES, without identifying the consumer, and are then initially analysed by the Agency (to determine the severity of the incident, the product's composition, the concordance with previous reports, etc). For each report, ANSES may contact the reporter to obtain any missing information, if necessary.

Reports containing sufficient information are then submitted to medical experts who analyse the likelihood of a link between consumption of a product and an adverse effect (causality).

The Agency informs the authorities of the cases received and may also initiate an alert procedure (life-threatening cases in which causality is strong).

- **Follow up in terms of health risk assessment**

Cases are examined by a group of specialised experts. Depending on the effects observed, the number of cases received and the likelihood of their being linked to consumption of the product in question, the Agency, with the help of the experts, establishes its priorities with regard to the risk assessment work to be undertaken.

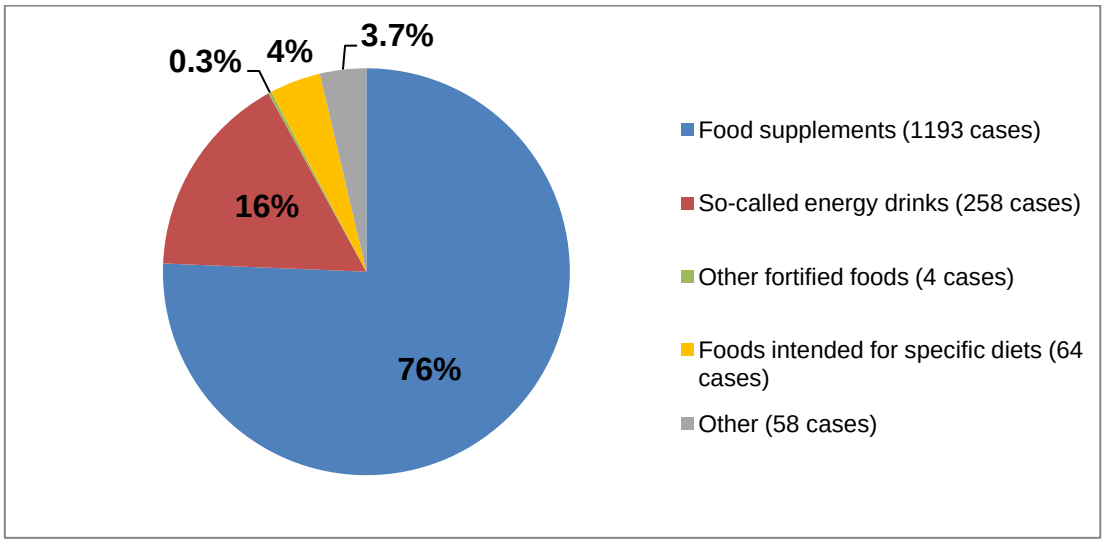
This work leads to the publication of scientific opinions and recommendations intended for healthcare professionals and consumers. These opinions are submitted to the ministries concerned to enable them to implement appropriate management measures.

# Results from the scheme

## Number and source of reports received

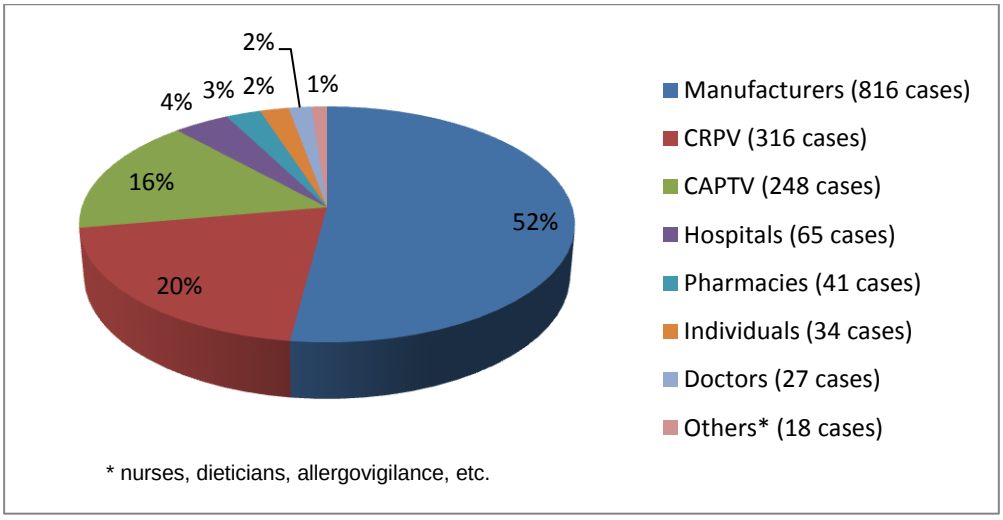
Since 2010, the nutrivigilance scheme has been notified of 1565 cases of adverse effects. The majority of cases received (76%) relate to the consumption of food supplements.

**Products implicated in the reports of adverse effects[3]**




Among all the reported cases, 709 came from healthcare professionals (45%), mainly via the regional pharmacovigilance centres (CRPV, 20%), anti-poison and toxicant monitoring centres (CAPTV, 16%), hospitals (4%), pharmacies (3%) and general practitioners (2%). Fifty-two per cent came from manufacturers, primarily following a request by ANSES after it received a report of an initial case.

**Identity of reporters for the 1565 cases notified**




For each report, ANSES contacts the reporter again to obtain any missing information if necessary. When this process has been completed, 33% of reports are found to contain sufficient information to be analysed in greater depth.

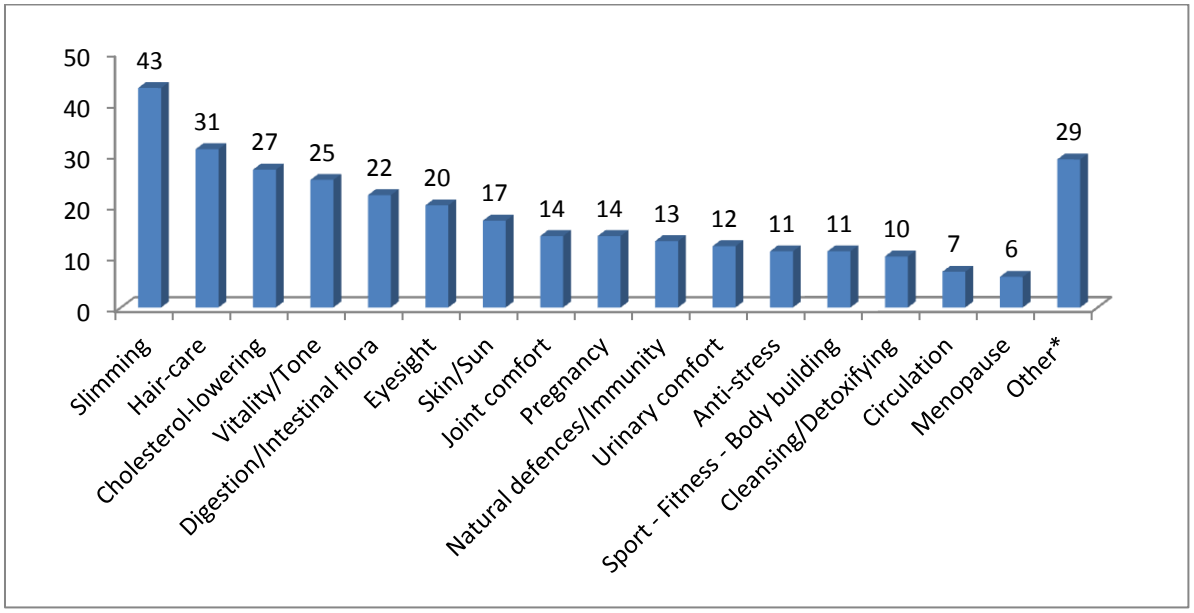
[3] The combined number of cases is greater than 1565 because a reported case may involve several types of foods.

## Food supplements: main source of incident reports

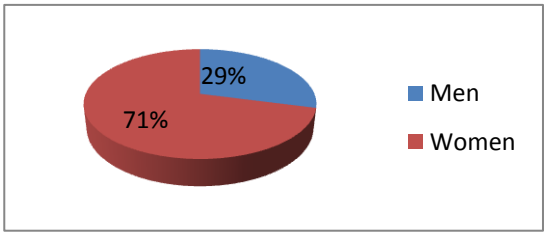
Since the nutrivigilance scheme was set up, of all admissible cases, food supplements have been the category of products most frequently reported, accounting for 76% of reported cases. **It was therefore decided to focus on food supplements in this report.**

Slimming supplements are involved in 15% of admissible cases implicating at least one food supplement. They are followed by hair-care supplements (11%) and cholesterol-lowering supplements (10%).

**Number of reports by type of food supplement among the 282 admissible cases implicating at least one food supplement[4]**




The male/female distribution of reported cases is generally consistent with that of consumption (2/3 of women for 1/3 men). Of the 282 admissible cases implicating at least one food supplement, 71% concern women and 29% men.

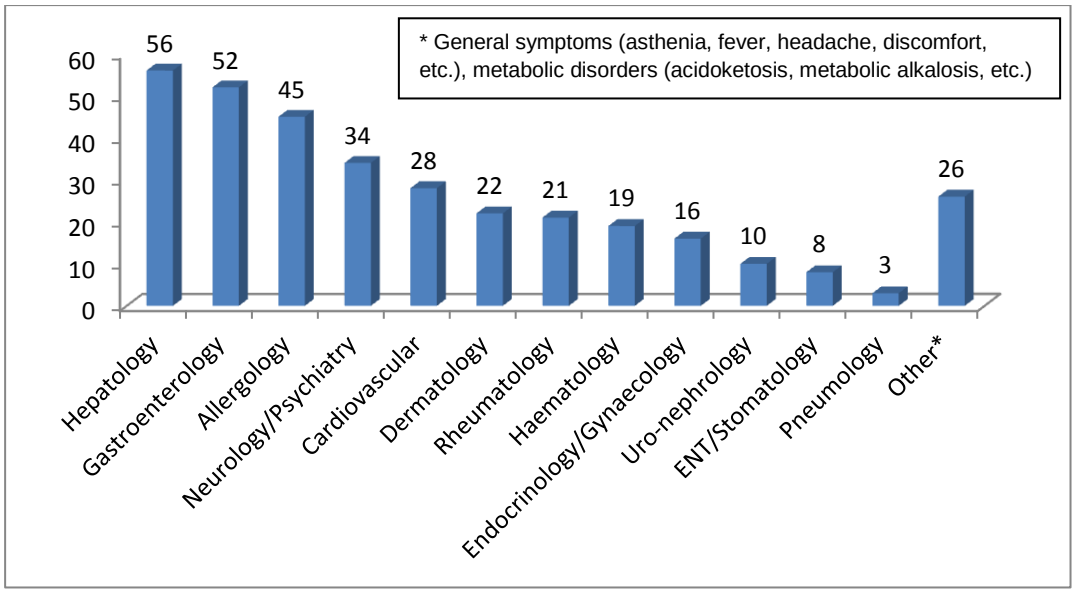



[4] The combined total of percentages is greater than 100% (111%) because certain cases concern several different types of food supplements

## Adverse effects reported

Regarding the adverse effects reported to the nutrivigilance scheme relating to food supplements, most involved liver disorders (19.9%), the digestive system (18.4%) and allergies (16%).

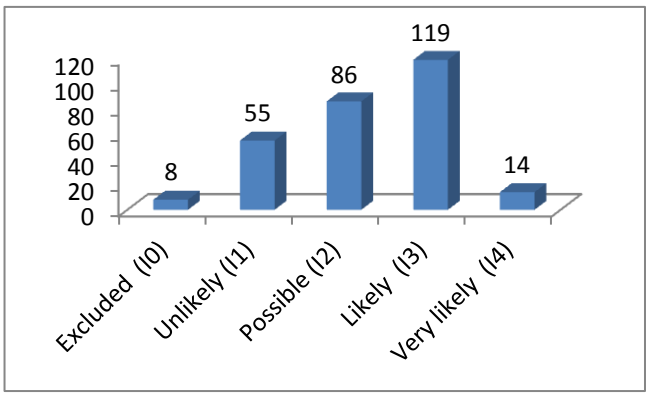
**Types of adverse effects reported**
**(of the 282 admissible "food supplements" cases)[5]**




## Appearance of adverse effects related to the consumption of food supplements: determination of causality

For each 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. Causality may be:

- excluded (I.0),
- unlikely (I.1),
- possible (I.2),
- likely (I.3),
- very likely (I.4).

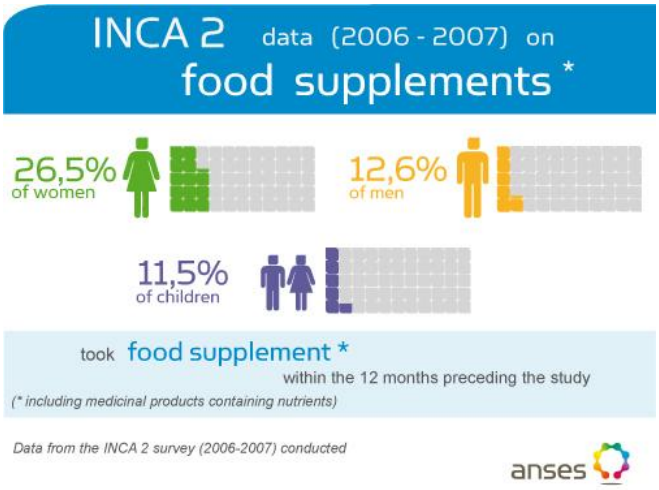



Of the 282 admissible cases implicating at least one food supplement, 53% had weak causality (I.0 to I.2) and 47% had strong causality (I.3 and I.4).

## Consumption of food supplements in France

[5] The combined total of percentages is greater than 100% (120.6%) because a case may concern several different types of effects

## Who are the consumers?




Every seven years, ANSES conducts a national study of individual food consumption (INCA). The INCA studies provide, at a precise moment in time, a snapshot of the food consumption habits of the population of mainland France.

The INCA 2 study, conducted from late 2005 to 2007, collected information on the consumption of food supplements by adults and children aged three years and over. Nearly one adult in five had consumed food supplements at least once in the year. Similarly, one child in ten had consumed a food supplement or vitamins and minerals in drug form. Consumption of these products is positively correlated with the level of education.

In adults, twice as many women as men take food supplements. In children on the other hand, consumption in girls is similar to that in boys.

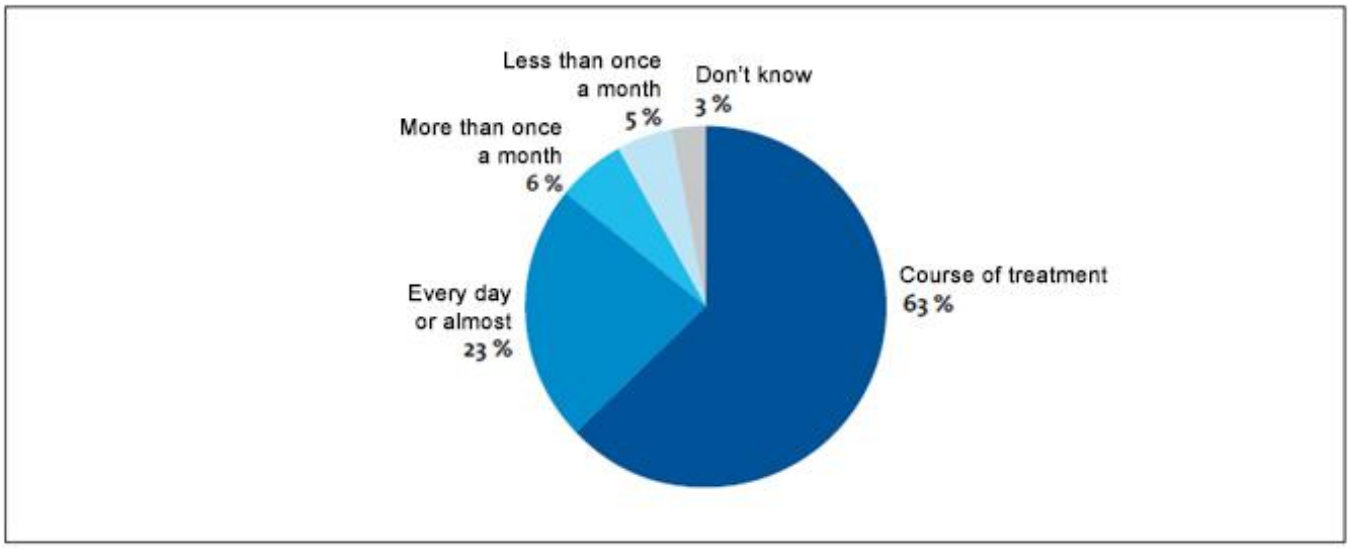
## How are food supplements consumed?

Nearly two thirds of food supplements are consumed as part of a course of treatment, whether in children or in adults. This occurs most often in winter (for 70% of children and 54% of adults) or in autumn (25% of adults and children).

The annual duration of a course of food supplements is on average four and a half months in adults and two and a half months in children, but this varies greatly from one person to the next, demonstrating a wide disparity in behaviour with regard to these products.

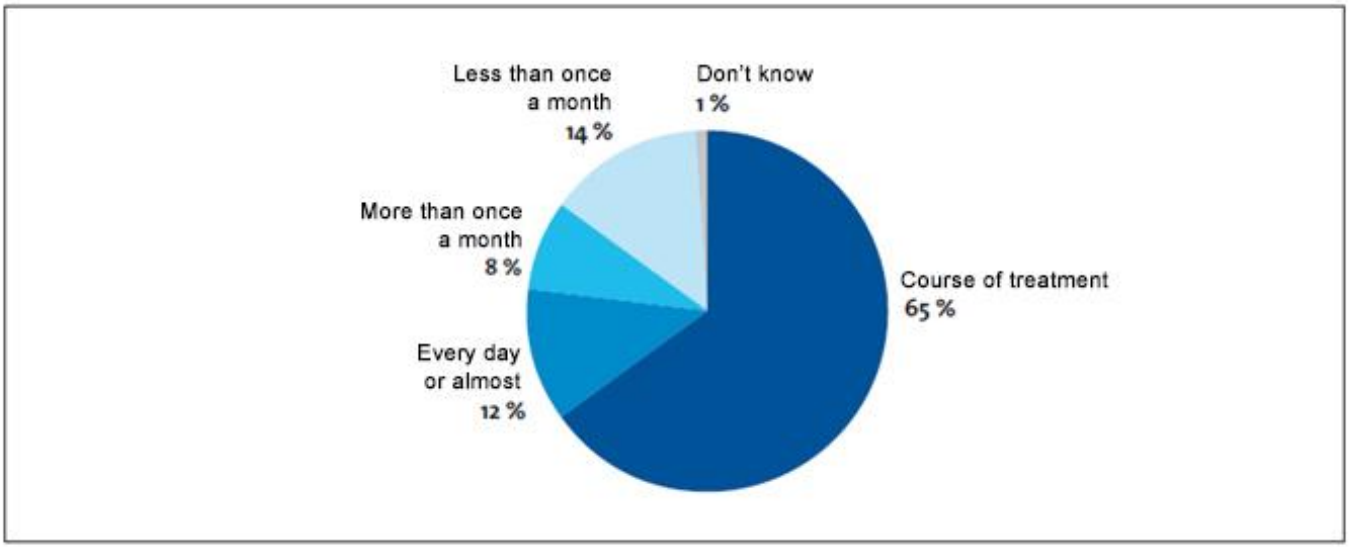
Alongside these courses of treatment with food supplements, INCA 2 also revealed long-term consumption in part of the French population. Thus, 23% of adults and 12% of children who consume food supplements take them all year round or most of the year.

Frequency (%) of consumption of food supplements by adults aged 18-79 years taking food supplements in the 12 months prior to the INCA 2 study




Source: AFSSA, INCA 2 study 2006-2007

Frequency (%) of consumption of food supplements by children aged 3-17 years taking food supplements in the 12 months prior to the INCA 2 study




Source: AFSSA, INCA 2 study 2006-2007

## Why do consumers take these supplements?

In both men and women, consumption of food supplements is primarily driven by a desire to maintain good health. Indeed, the three fundamental expectations, which account for 70% of responses, are "combating fatigue" (33%), "solving specific health problems" (21%) and "keeping healthy or combating illness" (17%).

On the other hand, motivations more directly associated with food, such as "maintaining a balanced regular diet" or "supplementing inadequate dietary intakes" are rarely mentioned. Lastly, certain expectations depend on the individual's sex: they relate to needs associated with sporting activity in men (10%), and beauty (8%) and needs associated with pregnancy (6%) in women.

When vitamins or minerals in drug form are also taken into account, the consumption of food supplements is primarily driven by medical prescription (32% of adults and 39% of children) or the advice of a healthcare professional (23% of adults and 31% of children). The purchase of food supplements by adults may also be prompted by the advice of family or friends (14%) or the discovery of the product on sale in a shop or on the Internet (15%).

## Where do consumers obtain food supplements?

Most food supplements are purchased from pharmacies, both for adults (54%) and children (78%). However, in adults a significant share of purchases are also made in supermarkets (14%) and health food stores (9%).

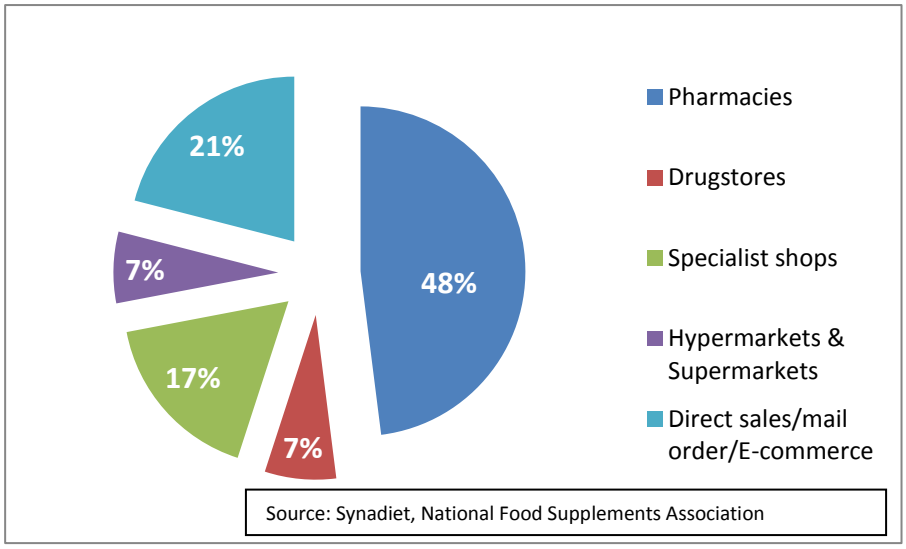
**INCA 3: the data is currently being updated**

In 2007, INCA 2 was the only national public study available on individual consumption of food supplements. The third INCA study is currently in progress. Its results, which will be available in late 2015, will enable data on the consumption of food supplements in France to be updated.

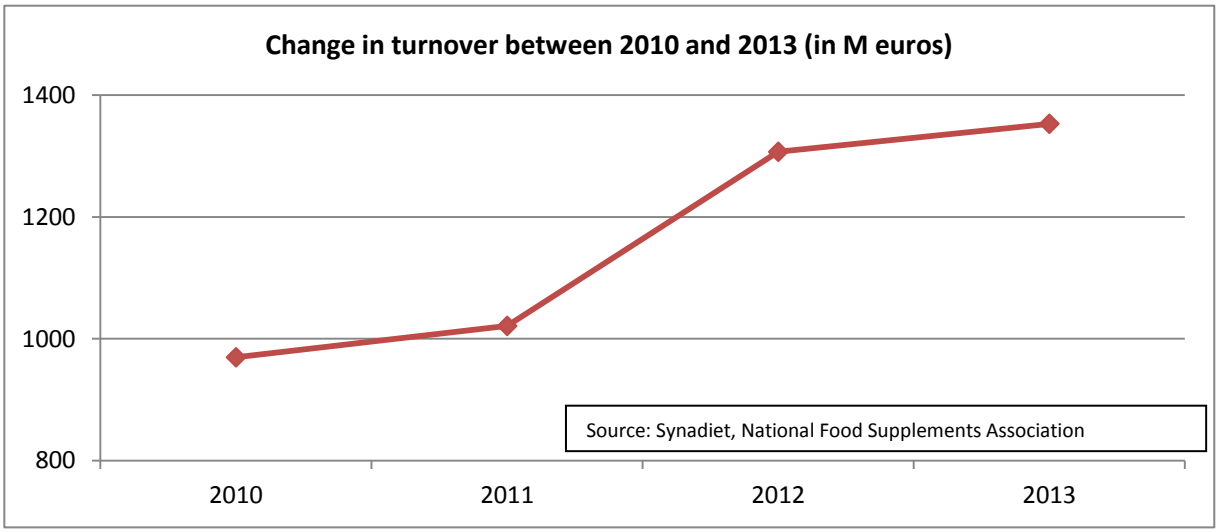
## The food supplements market in France

Sales of food supplements generated turnover of 1.353 billion euros in 2013 (source: Synadiet). Pharmacies are the leading channel for sales of food supplements in France. Direct sales, mail order and e-commerce are increasing, and in terms of turnover these represented the second largest distribution channel in 2013.

**The food supplements market in 2013**

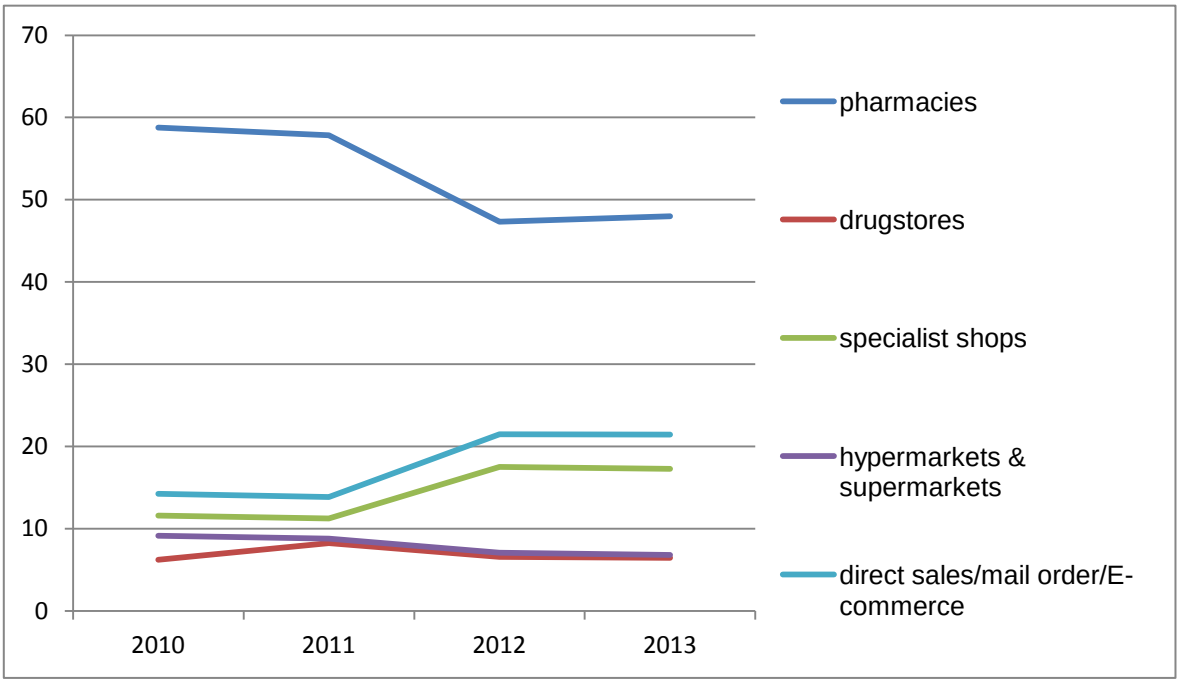



Whether in pharmacies, drugstores or hypermarkets and supermarkets, slimming supplements are still the top-selling products, along with "vitality/energy" and "beauty" supplements.



Pharmacies remain the leading channel for sales of food supplements in France. In 2013 this accounted for 48% of turnover, down sharply compared to previous years (60%). On the other hand, direct sales, mail order and internet sales increased substantially (13% in 2012, 21% in 2013), as did distribution in hypermarkets and supermarkets (from 9% to 17% between 2012 and 2013).

**Change in breakdown by distribution channels from 2010 to 2013**



# ANSES and nutrivigilance

## Main opinions and follow-up actions

**Once analysed, the reports received through its nutrivigilance scheme enable ANSES, with the help of its experts, to establish its priorities in terms of risk assessment.**
**In this context, ANSES has published around a dozen opinions (see box) on a wide range of products monitored by nutrivigilance, especially concerning the risks associated with the consumption of certain substances found in food supplements (lutein, zeaxanthin, synephrine, red yeast rice, etc.), so-called energy drinks, and beverages other than breast milk and its substitutes in the diet of infants under one year of age.**

**As an indication, the last three subjects addressed in the context of nutrivigilance are reviewed below.**

- **Assessment of the risks associated with the consumption of so-called energy drinks**

So-called energy drinks are fortified soft drinks whose principal common factor is their high caffeine content. Because of their composition, these beverages have a stimulating effect which, when associated with certain behaviours (alcohol consumption, sport, etc.) can give rise to serious cardiac accidents in consumers with genetic predispositions which frequently go undiagnosed.

ANSES has been investigating the safety of so-called energy drinks for several years via the nutrivigilance scheme.

The analysis of reported cases enabled ANSES to issue a series of recommendations in October 2013 aimed at both consumers and healthcare professionals:

- avoid the consumption of so-called energy drinks in association with alcohol or during physical exercise;
- be particularly vigilant concerning caffeine intake, especially via so-called energy drinks, in particular in pregnant women and nursing mothers, children and adolescents, and individuals sensitive to the effects of caffeine or suffering from certain pathologies (certain cardiovascular, psychiatric or neurological disorders, kidney failure or serious liver diseases);
- in general, moderate the consumption of caffeinated beverages.

Furthermore, the Agency has called on healthcare professionals, and especially doctors, to include questions about the consumption of so-called energy drinks when interviewing patients with relevant symptoms (high blood pressure, convulsions, etc.) and to try and determine as early as possible the level of caffeine consumed.

- **Assessment of the risks associated with the consumption of food supplements containing red yeast rice**

"Red yeast rice" is a red mould grown on rice which is used in many food supplements claiming to "maintain a normal level of cholesterol".

In an opinion published at the beginning of 2014, the Agency considered that taking red yeast rice food supplements containing monacolins (substances similar to statins) may expose consumers, especially those who are particularly vulnerable due to genetic predispositions, pathologies, ongoing treatments, etc., to health risks such as muscle and liver damage. The Agency recommends that individuals falling into these categories seek medical advice before consuming these products. It emphasises that these supplements must not be used by patients taking statin-based medications, nor by those who had to stop taking these medications due to adverse effects ("statin-intolerant" patients). Vulnerable individuals (pregnant or breastfeeding women, children and adolescents, people over the age of 70 or suffering from certain pathologies, people who consume large amounts of grapefruit, etc.) should also avoid taking red yeast rice supplements.

- **Assessment of the risks associated with the consumption of food supplements containing *p*-synephrine**

*P*-synephrine is found in the skin of bitter oranges (*Citrus aurantium* ssp. *aurantium*) and in other species of *Citrus*. *P*-synephrine, as well as other ingredients obtained from *Citrus* spp. fruits, is found in many food supplements which allegedly reduce body fat or alter body composition.

In its opinion published in March this year, the Agency considered that intake levels of *p*-synephrine via food supplements must remain below 20 mg/day. It also recommended not taking *p*-synephrine with caffeine, and particularly discouraged the consumption of these "slimming" supplements during physical exercise and by sensitive individuals such as people taking certain treatments, pregnant or breastfeeding women, children and adolescents.

**Developments following the Agency's opinions**

The first effect of the various expert appraisals conducted by the Agency has been to identify certain high-risk behaviour in consumers, and therefore to increase consumer vigilance. Without solving all the problems, they have given rise to various follow-up actions, which follow:

- regarding so-called energy drinks, certain manufacturers have lowered the caffeine content of their products;
- regarding food supplements containing *p*-synephrine, ANSES's recommendations in terms of maximum daily dose and avoiding co-consumption with caffeine have been incorporated into the Ministerial Order of 24 June 2014 establishing the list of plants authorised in food supplements.

In addition, the Agency's expert appraisals are behind the DGCCRF's implementation of several control plans (for green tea, *p*-synephrine, or meso-zeaxanthin).

**Opinions published following nutrivigilance reports from 2010 to 2014**

**November 2010:** Opinion on the safety of using yam (*Dioscorea*) alcoholic extracts in food supplements

**February 2011:** Opinion on the risk of allergic dermatitis induced by the consumption of lutein and zeoxanthin in food supplements

**July 2011:** Opinion on the relevance of work conducted by a supplier of food supplement ingredients to ascertain the safety of yam (*Dioscorea*) alcoholic extracts produced

**October 2011:** Opinion on the adaptation of an instant almond beverage to the diet of a 12-month old child, in terms of composition and conditions of use

**December 2012:** Opinion on the risk of liver toxicity associated with the consumption of foodstuffs containing green tea in particular

**March 2013:** Opinion on the risks of feeding beverages other than breast milk or breast milk substitutes to infants from birth to one year of age

**September 2013:** Opinion on the risks concerning the consumption of so-called "energy drinks"

**March 2014:** Opinion on the risks associated with the presence of "red yeast rice" in food supplements

**May 2014:** Opinion on the risks associated with the presence in food supplements of *p*-synephrine or ingredients containing it obtained from *Citrus* spp. fruits

## Three formal requests currently being addressed

- **Assessment of the risks associated with the intake, during pregnancy, of vitamins and minerals via food supplements**

Several reports of adverse effects potentially associated with the consumption of food supplements during pregnancy have been brought to ANSES's attention since the establishment of its nutrivigilance scheme. Fourteen of these reports have been ruled as admissible. The adverse effects reported were primarily endocrinological or obstetrical, with two pregnancies in particular that were terminated on medical grounds.

The severity of the effects, affecting vulnerable populations (pregnant women and newborns), and the occasionally high causality led ANSES to issue an internal request in order to assess the risks associated with the intake of vitamins and minerals during pregnancy.

Thus, ANSES's analysis will focus on:

- the composition of "pregnancy" food supplements implicated in nutrivigilance cases: description, pharmacology, metabolism and main effects observed;
- the specific needs and vulnerability of pregnant women and foetuses with regard to these compounds;
- the analysis of nutrivigilance cases in light of the literature data and mechanisms likely to explain the adverse effects observed.

The results of this expert appraisal will be published in an opinion in the first half of 2015.

- **Assessment of the risks associated with food supplements intended for athletes that seek to develop muscle mass and/or reduce body fat**

Several reports of adverse effects that may be associated with the consumption of food supplements intended for athletes have been brought to ANSES's attention via its nutrivigilance scheme. Eleven of these reports were considered admissible. The adverse effects described are primarily cardiovascular (tachycardia, arrhythmia, stroke) and neurological (tremor, anxiety disorders, dizziness).

In this context, ANSES issued an internal request with a view to undertaking an assessment of the specific risks. The Agency's expert appraisal was based on:

- the characterisation of these food supplements (types of products available on the market, composition);
- the analysis of nutrivigilance cases in light of the literature data and mechanisms likely to explain the adverse effects observed;
- the profile of consumers (age, effects sought);
- the nutritional benefit of these food supplements.

An opinion based on the results of this study will be published in the first half of 2015.

Work has also begun on **food supplements containing Spirulina.**

## ANSES's recommendations

Inadequate nutrient intake and deficiencies are very rare in the general population, and mainly concern a few specific substances (vitamin D, etc.) 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 should be prescribed by a doctor.

For a large majority of the population, **a balanced diet** provides most nutrients required to meet nutritional needs. ANSES wishes to reiterate that food supplements are not without danger. 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 seek advice from their general practitioner before consuming food supplements.

In general, the Agency reiterates the importance of:

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

**Healthcare professionals ensure consumer safety**
**by actively watching for and reporting adverse effects**

ANSES asks you to continue questioning your 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 you are made aware of.

Please also remind your patients about all of ANSES's recommendations.

## Did you know?

From adolescence, women are advised to ensure they cover their needs in terms of folic acid. A folate deficiency may affect foetal development during pregnancy.

Food supplements containing beta-carotene must not be consumed by smokers, in whom they increase the risk of lung cancer.

Women following vegan diets (consuming no animal products whatsoever) must receive vitamin B12 supplementation during pregnancy and when breastfeeding.

# Prospects for improving the nutrivigilance scheme

## Encouraging reporting by healthcare professionals

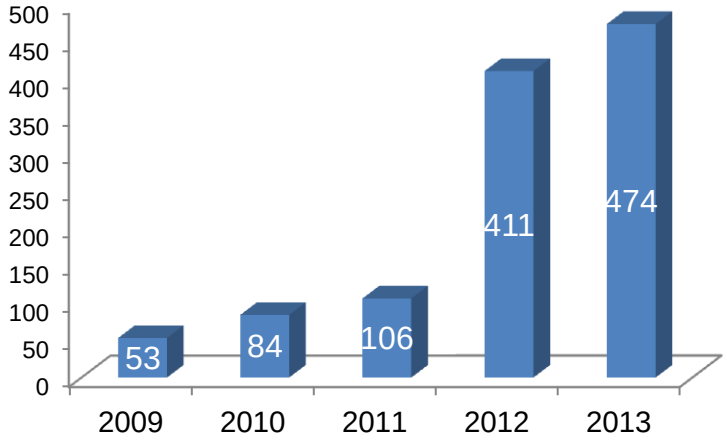
Since its creation, the number of reports received by the nutrivigilance scheme has continued to rise. Following a request by ANSES, there was a sharp increase in notified cases in 2012 due to manufacturers reporting cases brought to their attention. Since 2012 the number of cases has stabilised. In this regard, the Agency wishes to remind healthcare professionals of the importance of their participation as reporters, through notifying cases of adverse effects that they suspect of being associated with the consumption of food supplements.

To promote the nutrivigilance scheme to (future) healthcare professionals and encourage reporting, in 2015 ANSES intends to:

- launch an information campaign mainly in the trade press, to complement the distribution of a nutrivigilance leaflet in the 9 October 2014 issue of the *Quotidien du Médecin;*
- continue efforts to present its scheme in faculties of medicine and pharmacy.

It also intends to improve the system by which it provides reporters with feedback (case results sheets) by taking into account responses from professionals.

**Number of cases reported to the nutrivigilance scheme from 2009 to 2013 (excluding so-called energy drinks)**




## Communicating the results of case assessments to the public

In 2015, with the help of its legal department, the Agency will examine the best way of publicising the reports submitted to the nutrivigilance scheme, along with its findings, in addition to the cases covered by the opinions that are already available on its website.

## Encouraging information exchanges on nutrivigilance at European level

As part of the free movement of goods, it seems essential to pool knowledge of product composition and the cases reported in other European countries. After France's pioneering initiative in terms of nutrivigilance, several other countries are investigating or have already established a similar scheme (Italy, Sweden, etc.) and are liaising with ANSES.

In 2014, in order to bring these schemes together and raise awareness among other Member States, ANSES began setting up a European network on this topic. On 12 June 2014, ANSES held a kick-off meeting in Maisons-Alfort for this nutrivigilance information exchange network, attended by 13 Member States.

In 2015, the Agency will continue its efforts to encourage cooperation between the Member States and improve the flow of information, by:

- creating a newsletter compiled jointly by the Member States;
- coordinating a European methodology group to consider options for harmonisation;
- debating a common framework for the publication of texts and case analyses in the scientific literature.