

Reporting adverse events linked to the consumption of food supplements and other food products: an audit of Nutrivigilance newsletters

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Food supplements, as defined in EU⁽¹⁾ legislation, are concentrated sources of nutrients or other substances, marketed and sold in dose forms (e.g. capsules, powder, liquid), which are intended to supplement the normal diet. Notwithstanding legislation and directive within individual Member States (e.g. UK/Ireland), some food supplements can cause adverse effects (AE) when consumed. To promptly identify such AE, some European countries have adopted a Nutrivigilance system to better protect consumer health⁽²⁾. The aim of this project was to conduct an audit of the information reported in newsletters produced from the Nutrivigilance system in France.

Monthly newsletters (n 13; Aug-19 to Aug-20) were obtained from the French Nutrivigilance system, which is supported by The French Agency for Food, Environmental and Occupational Health & Safety (ANSES). Each newsletter reported the clinical cases of AE linked to food supplements, novel foods, fortified foods and energy drinks. The following information was collated for all cases: product name (producer) or description; main active ingredients; age or age range of case(s); specific AE, causality (less likely; possible; likely; very likely); number of cases. Scientific publications cited within each newsletter were also collated, summarising the research design, country and number of subjects (where relevant), as well as general bibliographic details.

During the audit timeframe, a total of 170 AE cases were recorded (approx. mean 13 per month), with the likelihood of the product directly causing the AE classified as possible (28%), likely (51%) or very likely (16%); only 5% were deemed less likely or were not classified. Twenty products were linked to >1 reported AE (n 78 cases; range: 2–28). Cases were reported across a wide age range of adults (18–90yrs) with approx. 10% reported in children and often in children <5yrs. Varying degrees of severity of AE were noted, spanning many different bodily systems and conditions. Gastrointestinal, allergic, hepatic and cardiovascular-related symptoms were commonly reported. The scientific publications noted in the newsletters (n 69; approx. 5 per month) were international in nature, recently published (i.e. 2018–2020) from 35 countries. The aims of these articles were also varied. The top three research designs included observational studies (e.g. from questionnaires or surveys), literature reviews and case-reports (e.g. from medical notes).

This audit provides an evidence-based insight into clinical cases of AE associated with the consumption of food supplements and other food products from the French Nutrivigilance system. These findings may inform the translation of the French Nutrivigilance system as a model for the identification, reporting and monitoring of suspected AE related to the use of such products in other countries. Subsequently, this may improve knowledge of food supplement use and consumer safety, thus informing public health recommendations in this area which are currently limited.

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References

1. EU Food Supplements Directive (2002). [Available at: <https://eur-lex.europa.eu/eli/dir/2002/46/2017-07-26>]
2. French Agency for Food, Environmental and Occupational Health and Safety (ANSES) (2021) *Everything you need to know about the Nutrivigilance scheme*. [Available at: <https://www.anses.fr/en/content/everything-you-need-know-about-nutrivigilance-scheme>]