

The Consumer Voice in Europe

FOOD SUPPLEMENTS

Challenges & risks for consumers



Contact: Ilenia Passarani – food@beuc.eu

BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • www.twitter.com/beuc • consumers@beuc.eu • www.beuc.eu
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Why it matters to consumers

Weight loss, memory boost, easy sleep... Those are just a few of the promises food supplements make. About 20% of EU consumers use at least one food supplement to complement their diet or to maintain their health. And the trend is on the rise.

Consumers' safety can be at risk due to flaws in the EU and national legislations. They are exposed to potentially serious side effects, misleading information and to the risk of wasting money for products that do not live up to the promises they make.

Summary

As consumers rely more and more on food supplements it is crucial to guarantee that **they access safe products and they are able to make informed choices.**

However, the EU food supplements market is only partially regulated exposing consumers to potential risks and misleading information. In this light, BEUC calls for:

1. A **comprehensive regulatory framework ensuring the same level of consumer protection across the EU.** A patchy regulatory framework leads to varying safety standards and product classification strategies, creating confusion and unacceptable inequalities.
2. The **prevention and combat of adulteration of food supplements** with medicines and unauthorised substances.
3. The **establishment of maximum and minimum limits for vitamins and minerals** to prevent risks from overdose and the sale of useless and deceptive products.
4. **More information to consumers on food supplements to ensure their safe use.** Such information should help prevent undesirable side effects of food supplements and their potentially dangerous combination with medicines.
5. **An effective monitoring and reporting system of side effects of food supplements.**
6. **No spurious claims and no special treatment for claims on botanicals.** Health claims on any food supplement should not be allowed unless based on sound and independent scientific evidence. Expensive supplements may not harm people but can be a waste of money if they do not provide the expected effects.

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1. Defining food supplements and exploring their use

Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect aimed to supplement the normal diet. Food supplements can be marketed in “dose” form, such as pills, tablets, and capsules.

Food supplements either contain nutrients (vitamins and minerals), botanicals (i.e. plant-based products) or other substances (such as amino acids). Botanicals are plant parts, concentrated sources of plants or their extracts or derivatives with a physiological effect. Some well-used botanical supplement products include St. John's Wort, Ginkgo biloba (ginkgo), Valeriana officinalis (valerian), garlic, Echinacea purpurea (echinacea), Panax ginseng (ginseng), Aloe vera (aloe) and Vaccinium myrtillus (blueberry)¹.

The use of both nutrients and botanicals in food supplements may pose risks for human health. For minerals or vitamins the risk lies with potential overdose, while not all botanicals are safe for use in food supplements.

In particular, the term ‘botanical’ may have several confusing meanings and/or synonyms. The same botanical may be used simultaneously in a food supplement and as a medicinal product, depending on the product’s intended use. However, both food supplements and medicinal products may be available in the same form i.e. herbs, powders, pills or tablets. All these complexities make it difficult for consumers to distinguish between the thousands of products labelled as ‘herbal’, ‘botanical’, ‘natural supplement’, ‘plant food supplement’, ‘herbal medicinal product’ or even ‘medical device’.

It is estimated that **approximately 20% of consumers in several European countries use at least one food supplement.** In general, there are big variations between South and North with Northern population making more extensive usage² (e.g. 64% of Danes takes supplements³) with the market growing fast especially in Eastern Europe. According to a 2015 study⁴ from BEUC member APC, Romanian consumers spent 500 million euros on dietary supplements. The analysis also revealed that 90% of health claims on the dietary supplements assessed are misleading and that 67% of the food supplements APC tested contained titanium dioxide.

64% of Danes take food supplements” (DTU, 2016)

“In 2015 Romanian consumers spent 500 million euros in supplements” (APC, 2016)”

¹ Garcia-Alvarez A, Egan B, de Klein S, Dima L, Maggi FM, et al. (2014) Usage of Plant Food Supplements across Six European Countries: Findings from the PlantLIBRA Consumer Survey. PLoS ONE 9(3): e92265. [doi:10.1371/journal.pone.0092265](https://doi.org/10.1371/journal.pone.0092265), last accessed on May 23, 2016.

² Rovira, Maria-Asunción et al., Dietary Supplement Use and Health-Related Behaviors in a Mediterranean Population, Journal of Nutrition Education and Behavior , Volume 45 , Issue 5 , 386 – 391, DOI: <http://dx.doi.org/10.1016/j.jneb.2012.03.007>

³ It is estimated that 64% of 18 to 75-year-olds in Denmark take supplements, Technical University of Denmark’s (DTU) National Food Institute (August 2016).

⁴ <http://www.apc-romania.ro/ro/i-suplimente-de-aditivi-alimentari-pentru-sanatatea-dumneavoastra/NDAwLTE.html>

However, comprehensive and reliable data on food supplements consumption in the EU are still scarce. **More EU-wide evidence is needed, both on the consumption of food supplements and especially on consumers' understanding of their use.** A recent survey conducted by the Technical University of Denmark's (DTU) National Food Institute revealed that users of food supplements have little knowledge on dietary supplements and that many choose to believe in a benefit of using the product rather than feeling a benefit. Users consider natural ingredients to be less dangerous than medicines and do not have information about dosages and interactions with medicines (see also point 2.2).

Many users choose to believe in a benefit of using dietary products rather than feeling a benefit.

2. Safety concerns

Food supplements' specific characteristics make the assessment of their safety particularly important. In particular, because food supplements usually consist of **concentrated sources of substances**, the safe level of doses and the long-term consumption should be carefully considered.

In the EU's Rapid Alert System for Food & Feed (RASFF) several notifications relate to food supplements. Some notified products contain **substances unauthorised for food use** or **novel ingredients**⁵, products with **too high concentrations of nutrients**⁶ and **other substances** or even cases of food supplement **ingredients contaminated with pathogenic organisms** or **intoxicants**⁷.

Only since the beginning of 2016⁸, almost 55 notifications related to an industrial chemical which is illegally added to dietary supplements and slimming aids (so-called fat burners) and called DNP (2,4 Dinitrophenol) have been recorded. Some notifications have led to a market withdrawal⁹ or even a recall from consumers¹⁰. Interestingly several **notifications come from within the EU**, which highlights the lack of a common harmonised system on food supplements safety standards and regulation¹¹. Alerts on the safety of supplements in intra-EU trade are varying and linked to the lack of a comprehensive regulatory framework under the EU food legislation. The current rules largely only apply to vitamins and minerals and do not even cover these products effectively.

Case 1 – Synephrine-containing supplements

Synephrine is naturally present in citrus fruits and consuming it through fruit does not expose consumers to risks. In 2009 ANSES, the French Agency for Food, Environmental and Occupational Health and Safety, identified 13 cases of patients incidents with a possible causal link between the consumption of weight loss supplements containing

⁵ https://webgate.ec.europa.eu/rasff-window/portal/?event=notificationDetail&NOTIF_REFERENCE=2016.AKA

⁶ [High content of vitamin D in super vitamin D3 – RASFF notification](#)

⁷ [Lead in food supplement – RASFF notification](#)

⁸ Data collection till June 22, 2016

⁹ [Risk of overdose with nicotinic acid \(1.372 g/100g\) from consuming food supplement from Hungary](#)

¹⁰ [Too high content of copper \(9 mg/kg - ppm\) and of selenium \(49.61 mg/kg - ppm\) in nutrition shake from Belgium, via the United Kingdom](#)

¹¹ The examples presented above in footnotes 1 & 2 refer to products originating from Hungary and Belgium and notifies from France (case 1) and Belgium, Greece, Ireland, Malta & United Kingdom (case 2) respectively.

synephrine and conditions including cardiovascular effects, liver and neurological damage.

In 2014, in light of the possible risk that synephrine can pose for human health ANSES modified its recommendations and proposed strict levels for daily intake. It also discouraged its consumption in several circumstances for example to individuals with high blood pressure and during physical exercise¹².

Between May and June 2016 BEUC and its members conducted a shopping exercise in both local and online markets for food supplements containing synephrine through bitter orange (*Citrus Aurantium*) ingredient. Our findings indicate that food supplements containing this substance - mainly slimming and fat burning products - are widely available.

In the Spanish market, our member OCU detected a product named "OBESLINE"¹³ containing synephrine in daily doses of 360mg. The intake dose is eight times higher than the 20mg limit recommended in France or the 30mg permitted in Italy¹⁴ where this botanical is officially regulated. Our Portuguese member [DECO](#) found another product available online¹⁵ and noticed it failed to declare the synephrine content. Other products declared partial synephrine presence without stating the amount.

Case 2 – Supplements high in nicotinic acid

In April 2016, the Food Safety Agency of Ireland (FSAI) issued an alert, accompanied by a recall, to a US-based company for an athletes' supplement. It contained **niacin in the form of nicotinic acid, also known as vitamin B3, 2.5 times more than the tolerable upper intake level set by the European Food Safety Authority (EFSA)**. Niacin has a wide range of uses in the body, helping functions in the digestive system, skin and nervous system but the intake of more than 10g of nicotinic acid per day could lead to low blood pressure¹⁶.

Case 3 – Dangerous DNP available to European consumers

The DNP¹⁷, a fat burner used in weight loss and body building supplements¹⁸, is still marketed although it has been associated with some deaths in some EU countries. Although DNP is forbidden for human use in the UK, British citizens can still purchase it online¹⁹. In other countries, where DNP is not explicitly banned, competent authorities can do little to prevent sales of products containing DNP as far as the stated dose is too low to pose a risk in human health. This shows **the current legislation fails to guarantee that only safe food supplements reach the market and does not guarantee adequate enforcement mechanisms**.

¹² [Dietary supplements for weight loss containing p-synephrine & Today ANSES publishes its recommendations on dietary supplements for weight-loss containing p-synephrine](#)

¹³ <http://www.novadiet.es/index.php/productos/control-de-peso/item/185-obesline.html>

¹⁴ <http://www.trovanorme.salute.gov.it/norme/renderPdf.spring?seriequ=SG&datagu=21/07/2012&redaz=12A07895&artp=1&art=1&subart=1&subart1=10&vers=1&proq=001>

¹⁵ <http://celeiro.pt/produtos/350495-depuralina-gorduras-0-gramas-cps-theralab>

¹⁶ [Recall of Musclepharm Assault Hybrid Series Supplement Due to the Presence of Elevated Levels of Nicotinic Acid](#)

¹⁷ 2,4-Dinitrophenol


¹⁸ A. Tewari, A. Ali, A. O'Donnell, and M. S. Butt, Weight loss and 2,4-dinitrophenol poisoning, Br. J. Anaesth. (2009) 102 (4): 566-567 [doi:10.1093/bja/aep033](https://doi.org/10.1093/bja/aep033)

¹⁹ <http://www.food.gov.uk/news-updates/news/2016/14913/man-arrested-in-dnp-operation>

2.1. Food supplements-medicines interactions and side effects

Consumers tend to believe that botanicals are safe because they are natural²⁰. This perception is reinforced by these products being easily accessible in health shops and supermarkets. They often carry a misleading 'natural' wording, are coloured in green shades and photos of plants cover a great part of the label surface. However, the side effects of food supplements' simultaneous consumption with specific foods, other supplements or medicinal products may pose risks for consumers.

Overdose effects can happen when nutrients-containing supplements are consumed along with fortified foods. **Many interactions between herbal substances and conventional drugs have been reported.** For instance, people using anticoagulants should not take Angelica sinensis (Dong Quai) supplements and women taking oral contraception should avoid Hypericum perforatum (St. John's wort)²¹.



**Natural does
not mean safe!**

There is a lack of studies and monitoring of the side effects and interactions of these products. Monitoring is carried out just at the Member States level (e.g. in France) on a voluntary basis and to a varying extent. And where scientific evidence exists, **as far as food supplements are deemed foodstuffs, there is no further requirement for consumers' information through labelling.** Information is provided only unilaterally on the medicinal product when a potentially dangerous interaction is known. For botanicals in particular, necessary warnings against possible contraindications, interactions and undesirable effects on label - or in information leaflet - are required under the herbal medicine status²² but not when the product is considered a botanical food supplement.

3. Food fraud in the food supplement market

Food fraud and adulteration incidences are often related to food supplements.

Margins for adulteration and fraudulent practices are another deficiency of the grey legal zone where food supplements are marketed.

A recent French research²³ showed that **from the 164 examined weight loss food supplements which were labelled 100% natural, more than 40% were adulterated with medicinal substances.**

In the USA, another study from 2016²⁴ showed that **43% of the examined body building and weight loss supplements marketed contained a pharmaceutical stimulant called oxilofrine, which is normally used to increase blood pressure.** The

²⁰ Technical University of Denmark's (DTU) National Food Institute, 31 August 2016, <http://www.food.dtu.dk/english/news/2016/08/plant-based-food-supplements-are-seen-as-a-kind-of-insurance?id=1a5afd69-40b5-4a89-8d07-4a4e9cebc828>

²¹ [European Medicine Authority](#) - [ellaOne: EPAR - Product Information](#) - p.4.

²² Directive 2004/24/EC: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2004_24/dir_2004_24_en.pdf

²³ Rabab Hachema et. al, Proton NMR for detection, identification and quantification of adulterants in 160 herbal food supplements marketed for weight loss, Journal of Pharmaceutical and Biomedical Analysis 124 (2016) 34–47, [doi:10.1016/j.jpba.2016.02.022](https://doi.org/10.1016/j.jpba.2016.02.022)

²⁴ Cohen, P. A., Avula, B., Venhuis, B., Travis, J. C., Wang, Y.-H., and Khan, I. A. (2016) Pharmaceutical doses of the banned stimulant oxilofrine found in dietary supplements sold in the USA. Drug Test. Analysis, [doi: 10.1002/dta.1976](https://doi.org/10.1002/dta.1976)

substance, which was not named as such but under its various synonyms, was found in many products. It was present in such levels that, according to the recommended daily intake, a human could ingest 5 times the maximum prescribed daily dose of oxilofrine when the latter is used in medicines.

Although such practices fortunately do not characterise the majority of food supplements on the market it is worrying that there are insufficient rules at EU level to prevent and combat food supplements fraud incidences.

4. Are consumers granted the same level of protection within the EU?

In the EU, only vitamins and minerals are substantially regulated for their use in food supplements. As regards food supplements, the Directive 2002/46/EC provides a relatively **loose regulatory framework** and has not been updated since it was adopted almost 15 years ago.

The Directive's potential to harmonise the food supplement market rules and important measures for better implementation is untapped. For instance **dosage limits for minerals and vitamins in food supplements are still missing**. Moreover, the Directive does not provide for any guidance on product or substance classification.

Consumers should benefit from the same level of protection across the EU. A patchy regulatory framework leads to varying safety standards and product classification strategies, creating confusion and unacceptable inequalities.

4.1. The products' classification: a difficult puzzle

At EU level, **products containing nutrients, botanicals or other substances find their way onto the market under many different product categories:** food supplements, foods for sports persons, traditional herbal medicines or medical devices. Therefore, products can escape the strict rules of the Regulation on health and nutrition claims (No 1924/2006) by being classified in another category with looser claims rules such as the legislation on medical devices.

As BEUC's French member [CLCV](#) recently noticed²⁵, some French firms no longer sell their products as a 'food supplement' but as a 'medical device'. **This trick allows them to claim lawfully a health effect even if it is not allowed for food.** For example, because food supplements cannot claim an effect on urinary health, the producer *Juvamine* sells its cranberry-containing supplement as a medical device called 'Urinary infections'²⁶.

For those food supplements containing only vitamins and minerals, classification is relatively straightforward. These products fall under the harmonised European rules²⁷ unless they contain:

- a) A non-authorized substance: in this case, the EU law provides for a list of permitted substances to be used in food supplements which makes the classification of the product rather simple.

or

²⁵ <http://www.lepointurlatable.fr/le-blog-de-celia/les-pieds-dans-le-plat/dispositif-medical-et-complement-alimentaire.html>, CLCV, September 2016.

²⁶ <http://www.cocooncenter.com/juvamine-infections-urinaire-14-gelules/26592.html>

²⁷ [Directive 2002/46/EC](#)

- b) High vitamin or mineral content: it is more complex because they may have adverse effects. Although the EU Directive requires the European Commission to establish minimum and maximum levels for vitamins and minerals content in food supplements, no such proposal has been presented to date. As a consequence Member States follow their own policies. Today **less than half of EU countries (12 out of 28) have established maximum levels for mineral & vitamin content in food supplements.**

When it comes to food supplements containing botanicals, the situation is even more complex. The classification normally depends on the presentation or intended use of the products, i.e. is it to cure or prevent a disease or just to maintain normal health? It also depends on its effect in/on the human body, i.e. does it have a therapeutic effect or physiological/nutritional effect?

The decision is not always straightforward and due to a lack of harmonisation at the EU level, Member States have different national rules in place.

In the EU, 17 countries sustain some lists of substances either permitted, prohibited or both. The current situation is quite chaotic with each Member State enforcing its own laws based on different levels of precaution and safety standards.

This results in many inconsistencies in the classification, circulation and presentation of the botanical products. **The same product can be considered as a botanical food supplement in one EU country and as an herbal medicine in another country.** The same substance can sometimes be marketed both as food supplement and herbal medicine within the same country. This situation can lead to **several problems for consumers: confusion, product misidentification, frustration, and waste of money** because of ineffective products.

Food supplements containing other substances are confronted with - more or less - the same challenges as botanicals. **No specific EU rules exist for other substances' classification, safety assessment and marketing.** The marketing of other substances could be a highly controversial issue among EU Member States as **only 9 EU countries keep lists of permitted or banned substances for use in food supplements.**

Amino acids that fall under this category are a debatable category of substances. BEUC's research in national legislations has shown that specific forms for amino acids are regulated and approved for use in food supplements in Croatia, Italy and Slovenia. Yet amino acids are treated as additives in Germany and as 'forbidden but tolerated' substances in The Netherlands (except for methionine). In most of the other EU countries they are not regulated at all.

Supplement or medicine?

Valeriana officinalis is found to be missing from the top list of botanicals used in supplements in Germany (survey results of PlantLIBRA project), whereas 1,852 products containing Valerian exist on the market. How is this possible? In the German market, *Valeriana officinalis* is dominant as an herbal medicine product, not as a supplement.

Usage of Plant Food Supplements across Six European Countries: Findings from the Plant LIBRA Consumer Survey, 2014

5. Inside the label-jungle: lost in translation

Consumers are not adequately informed about food supplements. The absence of specialized labelling requirements for food supplements and the huge variety of different but hardly distinguishable products fuel consumers' misinformation. A proper labelling of herbal substances should not be restricted to the plant's name but should also indicate the active substances and their amount. Consumers should also be adequately informed about the possible effects of food supplements when used in combination with medicines or other foodstuffs.

Non-prescription herbal medicines, food supplements and cosmetics could be found side by side on food outlet shelves in several countries. In many countries it is also permitted - or rather made possible by the lack of legal provisions - to use the same trade name for both medicines and food supplements²⁸. Such double use could bias consumers and even provoke health risks from wrong-product consumption.

The most important issue about consumers being misled is the mention of **health and nutrition claims on botanical food supplements**. Unlike "well-established" herbal medicines, which have a recognised efficacy and are eligible to full market authorisation, so-called "traditional" herbal medicines and botanical food supplements respectively benefit from a simplified registration procedure or no approval at all. They can legally refer to "long-standing use and experience" or unauthorised food claims to profess efficacy.

The lack of enforcement of food and food supplements' legislation leads to unconcealed consumers deception, misleading information and possible financial loss.

Case 4 - Colloidal Silver & Silver Hydrosol (I)

Some Colloidal silver products notified for sales in Romania²⁹ exemplify the issue of lack of enforcement. Proponents of colloidal Silver supplements claim they are effective against viruses and bacteria however they are also known to raise safety concerns³⁰. Examples include Nano Silver or Crystal Silver Natur Power supplements that claim the benefits of nano-structure of silver content, namely more effectiveness inside the body than in the colloidal class. However, the original list of ingredients does not appear on the retailer's online shop. The available composition paragraph refers only to "purified water through reverse osmosis and filtered, extract of grapefruit seeds" as the only active substances while the several sale pages³¹ claim the curing power of the supplement on numerous diseases. So, these products may not be dangerous but are likely to be just a waste of money.

²⁸ According to the AESGP publication "Legal and Regulatory Framework for Food Supplements" of 2012, in Austria, Bulgaria, Denmark, Germany, Netherlands and Poland it is possible to use the same trade name for food supplements and medicines while in another 8 EU countries there are no provisions regulating trade names use.

²⁹ [p.184, No.4976](#) and [p.239, No.6044](#)

³⁰ See part 7.

³¹ http://www.olimpigstemxcell-vitacrystal.ro/produse/crystal_silver_natur_power_500_ml-138.html
<http://flavonoide.ro/p/vita-crystal/crystal-silver-natur-power-500-ml#detalii-ingrediente>
http://www.flavin-7.ro/crystal-silver-500-ml-flavin_detaliiprodus-86-42
<http://vitamin-kezeles.hu/crystal-silver-natur-power.html>
http://www.nanosilver.ro/produse/nano_silver_argint_coloidal_500_ml-138.html

6. Grandma's remedies or proven health effects?

The vast majority of botanical supplements make "only" small promises such as healthy nail, hair, joints, wellbeing... **Whatever the extent of the advertised improvement it is vital to guarantee that consumers can trust the claims on these products.** They should not spend their money on products bearing false promises. Therefore, botanical claims – just like other claims made on foods – should undergo a rigorous scientific assessment according to the highest possible standards.

Many botanical claims are still on hold pending evaluation by EFSA. This follows the publication in 2010 of a series of EFSA opinions assessing the evidence on 44 botanical claims. EFSA concluded all the 44 claims were not scientifically proven. Some have argued that EFSA's evaluation was too strict and have called for a special treatment to allow the approval of botanical claims on the basis of the "tradition of use", instead of submitting more robust data from clinical studies.

6.1. No special treatment for claims on botanicals

It is crucial that claims on botanical supplements follow the same scientific assessment procedure as all food supplements and are thoroughly evaluated by EFSA.

We strongly warn against moving away from the rigorous scientific assessment that has been the rule to date. **"Tradition of use" does not equate efficacy** as shown by EFSA's negative verdict in 2010. Although such claims were widespread across the EU, they turned out to be scientifically unsound. Therefore they should not be used anymore.

The EU should end its special treatment to botanicals and move forward with the claims evaluation. If it fails to do so, the EU would fail to protect consumers from exaggerated and unsubstantiated claims. It would also mean that all the claims rejected by EFSA could be re-submitted for re-evaluation through new weaker standards.

7. Food Supplements & Free Trade Agreements: less scrutiny & controls for poorly regulated products

As mentioned above, the rather vague and incomplete regulatory regime covering food supplements in the EU is already a problem for European consumers. **If the EU does not clarify first its own rules for products' safety evaluation and marketing, any new free trade deal (e.g. the Transatlantic Trade and Investment Partnership TTIP) targeting its supplements' market would complicate the rules.**

As long as the EU has no comprehensive rules in place, it is likely that free trade partners may be able to access at once the EU market with no prior assessment of their rules' adequacy and efficiency by Member States. **Products of debateable safety might multiply in the EU market.**

Case 5: Colloidal Silver & Silver Hydrosol (II)

Despite safety uncertainties, silver hydrosol or colloidal silver is used in food supplements for its alleged support to the immune system. Silver is neither explicitly banned nor permitted for use in food supplements according to EU legislation. As a result each Member State can decide whether to authorise or ban the substance on its territory.

In 2008, EFSA was unable to assess the safety of silver hydrosol and the bioavailability of silver from this source³². In March 2016, a request has been re-submitted to EFSA³³ for a scientific opinion on silver hydrosol.

Food supplements containing silver are legally marketed in the United States with a consumer warning. The warning was issued by the FDA in 2009 and states that the product is “sold for its supposed immune system ‘support,’ it can permanently turn skin bluish-grey.” Although some blue-turning skin incidences have been reported in the USA³⁴ years ago the product is still available to European consumers for online purchase.

8. What should be done for consumers?

8.1. Long-term demands

Concrete rules and harmonisation

To enhance consumer protection, **food supplements should be better covered under the EU food law.**

Several Member States acknowledge it is necessary to harmonise the rules. For botanicals some harmonisation efforts have been put in place between Belgium, France and Italy as part of the BELFRIT project. However such efforts are far from meeting consumer expectations and ensuring legal certainty at the EU level.

We call on the Commission to end the confusing situation in the food supplements’ market and harmonise upward. All types of supplements must be within scope. The EU Commission should keep in mind that **consumers need to access high-quality and safe products that bear reliable information and deliver their health promises.**

Highlighted food supplements’ particularities

Supplements are concentrated sources of substances marketed in dose form while food is marketed neither in dose form nor in high concentrations³⁵. It is true that many food supplements may contain ingredients that are deemed safe. Examples include nutrients already existing in foods and plant-derived botanicals.

However, the high content of several substances in food supplements may not be safe for human consumption. Especially for botanicals, important risk factors should not be underestimated. They include **the combined effect of different substances into mix-type of products and the accumulation of toxicant and/or carcinogenic compounds naturally present in plants and herbs.**

Retaining food supplements under the current EU food law, **the Directive 2002/46/EC needs to be adapted to take into account the food supplements’ particularities.**

³² [EFSA’s opinion - Inability to assess the safety of a silver hydrosol added for nutritional purposes as a source of silver in food supplements and the bioavailability of silver from this source based on the supporting dossier - Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food \(ANS\) - November 2008](#)

³³ [EFSA’s register of Questions - EFSA-Q-2016-00235](#)

³⁴ <http://www.consumerreports.org/cro/2012/05/dangerous-supplements/index.htm>

³⁵ Schümmelfeder, L.K. (2016). The legal framework surrounding Plant Food Supplements: Is a legal change necessary to ensure their access to the market, free movement and consumer protection? (Unpublished Master’s Thesis). Wageningen University, Wageningen, the Netherlands.

Clear lines for product classification

The categorisation of a product as food supplement or traditional herbal medicine should be based on multiple factors: presentation, function, dose and induced effect (taking the homeostasis³⁶ concept into consideration).

'Naturalness' and long-time traditional use are not enough to guarantee a high safety level for consumers

Alleged naturalness and well-established traditional use is no evidence to guarantee a high safety level for consumers. Even single-

compound supplements of proven safety may induce side effects when combined with other foods or medicines and enclose risks for human health. Vitamins and mineral can maintain well-being in the adequate dose but may have adverse health effects in pretty high doses.

BEUC calls for a **clear legal framework that provides for the classification of products** that should take at least into consideration:

a) The effect on human body and health, whether it is about a nutrition, physiological or health effect, and

b) The safety of the proposed dose. Food Supplements should include only substances of proven safety and only in the recommended safe doses. It would be useful to introduce **separate dose thresholds for all substances classification** (nutrients, botanicals and other substances) for food and medicine.

As a first step towards a harmonised classification system, the EU should start establishing **common lists** of permitted and prohibited substances for use in food supplements. The authorisation or prohibition should be based on **independent and sufficient scientific evidence. EFSA should play a pivotal role in the risk assessment part.**

Several Member States have had national classification systems in place for many years³⁷. Where scientific evidence for the safety of substances used in food supplements exists at the national level, the EU Commission should use this as a basis to establish the first common lists of permitted and prohibited substances at the EU level.

It is also vital to put in place an effective system of monitoring and reporting of side effects of food supplements, including interactions with medicines and other products.

³⁶ Homeostasis is a model to distinguish between foods and medicines. It was developed by the [Council of Europe in 2008](#).

³⁷ Most of the EU countries have specific Committees in place in order to give opinion or decide on borderline products. In many countries (Belgium, France, and Slovakia i.a.) use joint Committees from food and medicine authorities or multi-disciplinary panels. The decision – or opinion – may not be only on the medicinal/non-medicinal classification but also specific categorization of the products. Ireland, Malta and United Kingdom have further published guides in order to help manufacturers in product classification.

8.2. Immediate action to better protect consumers

Make full use of the existing legislation

The European Commission can restrict or prohibit the use of substances – other than vitamins and minerals – if a possible harmful effect on human health is identified³⁸. Despite the many reported incidences connected with adverse effects on human health, this provision has been only used twice until now: for the prohibition of *Ephedra herb* and the scrutiny of *Yohimbe* and its preparations.

BEUC calls on the European Commission to take immediate action to safeguard consumer protection and temporarily restrict the use of substances reported to be possibly harmful for human health.

Claims on food supplements should fall under the EU Regulation on health and nutrition claims (No 1924/2006). Consumers should not be exposed to spurious claims and should not suffer from economic detriment because of ineffective products that do not live up to the promises they make. Consumers who are victims of unfair commercial practices should have a right to individual remedies and to claim compensation. Moreover the European Commission should ensure that the Unfair Commercial Practices Directive (UCPD) is properly enforced.

Establish minimum & maximum levels for vitamins & minerals

The establishment of **minimum and maximum levels for vitamins and minerals content in food supplements** is a **long overdue obligation** of the European Commission. Both lower and upper limits, as well as deviation margins should be established **as soon as possible** in order to protect consumers from ineffective products (too low content) and overdose adverse effects (too high content). EFSA should complete this task as soon as possible and **by means of robust independent scientific evidence**.

Mandate further information disclosure

The food supplements should not provide for less information than medicines on the possible adverse effects or abstract instructions of use just because they are classified as foods. Except from the recommended dose and the maximum daily intake, **information about possible side effects due to the combined use of food supplements with other products** (foods, food supplements or drugs) **should be stated on the label**. No exception should be granted for unintended compounds that are present in food supplements when the latter are suspected of possible adverse effects for human health.

Maintain and better enforce the current health claims' regime

As already explained, health claims should be permitted only when based on **robust scientific data**. **No exception should be provided** on the ground of “long-standing use and experience” or otherwise demonstrated “plausible” efficacy. With regard to the botanical food supplements, the existing Regulation (EC) 1926/2006 on health claims³⁹ provides for sufficient consumer protection if properly implemented. The exact same system should be used to clear the market from **food supplements promising fictitious effects**.

³⁸ Under Article 8(2) of the existing [Regulation \(EC\) No. 1925/2006](#) on the addition of vitamins and minerals and of certain other substances to foods.

³⁹ Consolidated version of [Regulation \(EC\) 1926/2006](#)

Improve hygiene in food supplements' production

What is more, it is also crucial to **guarantee food supplements' hygiene and low contamination risks**. To do so, the European Commission should initiate and promote the creation of sector-specific **guidelines for good manufacturing practices and hygiene control** in food supplements production with a strong focus on **the traceability and high standards in ingredients' supply**.

That is the least to be done to **guarantee safe products "from nature to capsule"**.

ENDS



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