Super(?)foods and Supplements – Risky or Healthy?

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Imprint

BfR Abstracts

Super(?)foods and Supplements – Risky or Healthy?

All authors are responsible for the content of their respective abstracts.

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Dear Ladies and Gentlemen,

The term superfood was first mentioned in the mid 1980s, but has become talk of the town in recent years.

The global superfood market was valued at 137 billion US dollars in 2020; and it is expected to reach a value of 210 billion US dollars by 2026.

But, when it comes to defining this term and the science behind it, it becomes rather vague; and there is often disagreement as to what superfood is.

It is commonly defined as food that increases energy and vitality, regulates cholesterol and blood pressure and may help to prevent or fight cancer and other diseases. You also find that superfood strengthens the immune system or supports weight loss. Overall, superfood seems to work wonders! And it seems that if you eat superfood, you will stay healthy, fit and young.

Hit lists of superfood include both exotic and native foods. You will find blueberries, cranberries, kale, broccoli, nuts, seeds and herbs on those lists, but you may also find magnesium, CBD oil and plant extracts, for example from pepper or turmeric.

So, when we talk about superfood, we should keep in mind that not only traditional food, but also supplements may be marketed as superfood.

In spite of the fact that there is no precise definition of superfood, all so-called superfood is considered rich in vitamins, minerals or other substances, such as fiber, secondary plant compounds or essential fatty acids.

Superfood is thus considered beneficial to human health. However, the questions are whether the designation super is justified, and what consumers expect from superfood?

BfR has conducted a survey on consumers' understanding and perception of superfoods – and found that there are sex- and age-specific perceptions of superfood, but overall people who place particular importance on a health-promoting diet and pay attention to health claims on products are more likely to reach for products labelled as superfood. Moreover, these people thought that there were almost no health risks associated with superfood.

From other research we know that consumers are ready to pay a higher prize for food promoted as superfood, and that superfood is associated with sustainable production or processing or with a certain taste or even with a certain colour! By the way, the fact that many consumers associate blue and purple with better health has led to an extreme increase in the demand for purple- and blue-coloured food in recent years. By making claims about the effects of superfood, sales have drastically increased.

Moreover, many consumers believe that botanical dietary supplements will improve their health and are free from unwanted health effects, whereas manufacturers are very inventive in producing such supplements, thereby often ignoring that eating grapes or drinking wine is different from taking supplements that contain resveratrol or grape seed extract.

In the vast majority of cases, potential health benefits and risks of superfood have not been studied and assessed through a formal evaluation by BfR or EFSA. Besides, risk assessments of botanicals are often hampered by a lack of data. Thus, there is still much to be done. As superfood – but especially supplements marketed as superfood – presents great challenges to risk assessment, risk management and risk communication, BfR will carry on

tackling these challenges actively and will engage in risk assessment and consumer protection.

Looking at the agenda of our event, I am sure that by the end of the two days, we will know more about whether superfood is really super – but also what health risks they pose, especially in the form of supplements and what challenges this poses for the risk assessment, but also for risk management and risk communication.

I would like to thank all speakers and participants who will contribute to this event with presentations, expertise as well as with questions and discussion.

Professor Dr Dr Andreas Hensel,
President of the German Federal Institute for Risk Assessment (BfR)

Dear colleagues, Ladies and Gentlemen,

new nutrition trends often suggest health benefits to consumers. They are popping up all the time.

One of these nutrition trends, which has been actively promoted for years, are the so-called "superfoods". Again and again in this course, "health-promoting characteristics" are attributed to predominantly exotic food, which frequently exhibit a high portion of vitamins and/or minerals as well as secondary plant metabolites. Among these exotic foods are açai berries, goji berries, maca, chia seeds and many more. Increasingly, food supplements containing so called "superfoods" are also advertised.

Within the EU, there are almost no specific legal provisions with specifications or maximum amounts for the addition of "other" substances than vitamins and minerals, including botanical substances.

Products containing such substances often give rise to notifications in the European Rapid Alert System for Food and Feed (RASFF). Examples include Cannabidiol (CBD) or other unauthorised novel foods or medicinal products.

Regulations for certain "other substances" are on the horizon, but so far do not exist for the vast majority of these substances.

Consequently, only general food law applies here, in particular Article 14 of Regulation (EC) No. 178/2002, according to which foods that are "unsafe" may not be placed on the market. However, these abstract, general regulations are not always interpreted uniformly by EU member states' authorities nor by the 16 federal states at national level in Germany.

Therefore, food law is often interpreted and applied differently by competent authorities for enforcement and, as a consequence, time-consuming coordination processes within and between the enforcement authorities are necessary.

Harmonisation at EU level is limited due to the huge workload. To support this work, the European Heads of Food Safety Agencies established a working group "Food Supplements". Due to potential health risks of some substances, this working group is currently developing a list of substances with nutritional or physiological effects, such as plants, fungi and algae, which should not be used – or used only under restrictions – in or as food, including food supplements. This working group is chaired by Germany and the Netherlands. We will hear a presentation on this in Session 2 of this event.

Some of the so-called "superfoods" continue to pose legal challenges to regulatory agencies: On the one hand, there is a lack of a legal definition of "superfoods" and products are frequently advertised with health claims. On the other hand, there is a lack of scientific basis that clearly proves or disproves the advertised "positive" effects.

Many of these Superfoods are offered with insupportable promises – very often online. In such cases the competent authorities are claimed – in particular, if the products contain risks to human health. It is our aim to discuss amongst experts how to best address these challenges.

Today, in Session 1, we will give a general overview of the topic of so-called "superfoods". Afterwards, the current market development and the legal aspects will be highlighted. The session will be rounded off by a presentation on consumer perceptions of "superfoods", which will also provide an outlook for the second day of the event.

In Session 2, regulatory aspects will be presented in more detail. First, the novel food status of some “superfoods” will be considered. Especially for exotic plants and plant substances, often no significant consumption is known before 1997. Accordingly, these are to be considered novel foods and may not be marketed without prior approval by an EU authorisation process.

In the following presentation, the lists of substances of the Federal Government, the Federal States as well as Austria and Switzerland, the already mentioned Working Group “Food Supplements” of the Heads of Food Safety Agencies and finally pharmacologically active substances in products sold as food supplements will be discussed.

The first day will then be concluded with a presentation on borderline products. With these products, it is not always clear whether they have to be classified as food or medicinal products.

Tomorrow's second part of the event will focus mainly on aspects of risk assessment, consumer perception and nutrivigilance.

Let’s look forward to a varied programme of talks and inspiring discussions following the presentations.

Friedel Cramer,
President of the German Federal Office of Consumer Protection and Food Safety (BVL)

1 Programme

Thursday, 30 June 2022

11:00–11:25 am
Welcome speeches
Andreas Hensel, President of the German Federal Institute for Risk Assessment (BfR)

Friedel Cramer, President of the German Federal Office of Consumer Protection and Food Safety (BVL)

11:25–11:45 am
EFSA's role in the assessment of health claims and novel foods including nutrient sources
Ana Afonso, European Food Safety Authority (EFSA), Italy

11:45 am–12:15 pm
"Superfoods" and supplements – an overview
Marc Birringer, University of Applied Sciences, Fulda, Germany

Session I: "Superfoods" and Supplements – industry and consumer perspectives

12:15–12:45 pm
The evolution of global regulatory frameworks for food supplements
Simon Pettman, International Alliance of Dietary/Food Supplement Associations (IADSA), United Kingdom

12:45–02:15 pm Lunch break

02:15–02:45 pm
Consumer perception of "superfoods"
Mark Lohmann, BfR

Session II: "Superfoods" and supplements – regulatory aspects

02:45–03:15 pm
"Superfoods", supplements, novel foods
Isabelle Laquiere, Federal Public Service Health, Food Chain Safety and Environment (FPS Public Health), Belgium

03:15–03:45 pm
Classification of other substances –
the D-A-CH-lists of substances and other lists on the national level
Klaus Riediger, Austrian Agency for Health and Food Safety (AGES), Austria

03:45–04:15 pm
Initiative on European level (Heads of Agencies) for classification – pharmacologically active substances in food supplements
Jacqueline Steenbergen-Biesterbos, Netherlands Food and Consumer Product Safety Authority (NVWA), The Netherlands

04:15–04:45 pm Coffee break

04:45–05:15 pm
Borderline medicinal products/foods – limits of "dual use"
Tomas Nilsson, Swedish Medical Products Agency (MPA), Sweden

05:15 pm Get-together

Friday, 01 July 2022

Session III: "Superfoods" and supplements – risk assessment

10:15–10:45 am
Risk assessment approaches and methodology – an overview
Karen I. Hirsch-Ernst, BfR

10:45–11:15 am
Risk assessment of "superfoods" and supplements (examples)
Susanne Alban, Christian-Albrecht University of Kiel, Germany

11:15–11:45 am
"Superfoods" – contribution to health and well-being: expectations and reality
Anika Wagner, Justus Liebig University Gießen, Germany

11:45 am–01:00 pm Lunch break

Session IV: "Superfoods" and supplements – consumer perception, research, nutrivigilance

01:00–01:30 pm
The global internet market/surveillance of "superfoods" and supplements – results of governmental monitoring
Georg Schreiber, BVL

01:30–02:00 pm
How is food transformed into "superfood"?
Julia Sausmikat, Consumer Association North Rhine-Westphalia, Germany

02:00–02:30 pm
Combatting counterfeit "superfoods"
Peter Nick, Karlsruhe Institute of Technology (KIT), Germany

02:30–03:00 pm Coffee break

03:00–03:30 pm
Nutrivigilance of food supplements in Europe
Gwenn Vo Van-Regnault, French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France

03:30–04:00 pm
Reflections/closing remarks and farewell
Georg Schreiber, BVL

Tanja Schwerdtle, Vice President of the BfR

2 Abstracts

2.1 EFSA role in the assessment of health claims and Novel foods including Nutrient sources

Ana Afonso
European Food Safety Authority (EFSA), Italy

The food supplements industry sector has been growing over the years, with innovative products introduced on the EU market. Food supplements related possible safety issues are regularly reported in the European Union Rapid Alert System (RASFF) and brought up by EFSA emerging risks identification networks. The Heads of Agencies (composed of Member States Competent Authorities) have also established in 2020 a working group on food supplements to better coordinate assessments and management measures.

The objective of the presentation is to provide an overview of EFSA risk assessment activities, and the challenges related with Food supplements safety and efficacy assessment using some examples of recent work.

EFSA mission and tasks are defined by the EU General Food Law and sectorial legislation such as the regulations defining preauthorisation for Novel Foods, Nutrient sources, Foods for specific population groups and Health claims.

Regarding food supplements no EU pre-market authorisation for substances other than vitamins and minerals exists but it is possible under Regulation (EC) 1925/2006 (fortification of foods) to prohibit, restrict or put under scrutiny the use of other substances added to foods based on safety concerns.

Regulation (EU) 2015/2283 defines the concept of Novel foods, foodstuffs not consumed to a significant degree in the EU prior to 15 May 1997. Novel foods could be new substances, new food sources, produced using new techniques as well as traditional foods from non-EU countries. The regulation can be relevant for novel substances intended to be used in food supplements.

The Claims Regulation (EC) No 1924/2006 regulates the scientific assessment by EFSA before an authorisation to made a health claim on a food is granted.

2.2 “Superfoods” and Supplements – an Overview

Marc Birringer
University of Applied Sciences, Fulda, Germany

Exotic and traditional food products as well as nutritional supplements with supposed health promoting properties are successfully marketed under the global trend of superfoods. Despite the absence of a legal definition and differing regulation under the European food law, superfoods are well established in grocery stores and on e-commerce websites. Products labelled as superfoods often exhibit high concentrations of micronutrients and secondary plant ingredients and suggest beneficial effects on health. Though evidence for actual health impacts is rather limited for products without authorised health claims, the assumed nutritional benefits of superfoods are likely to influence the consumers’ perception and purchasing behaviour. In recent years, the global superfood trend has increasingly been criticised as related produces have raised concerns for food safety and sustainability issues.

2.3 The evolution of global regulatory frameworks for food supplements

Simon Pettman
International Alliance of Dietary/Food Supplement Associations (IADSA), United Kingdom

The frameworks that regulate how food supplement products access markets across the world have developed considerably over the past years. This presentation will address the key elements of regulation outside the European Union, including the cultural issues that have shaped and continue to shape developments. It will also consider the important role that the EU Food Supplements Directive and the Codex Guidelines on vitamin and mineral supplements have played in the process of developing national and regional frameworks worldwide. It will also address how attitudes and approaches to botanical ingredients have shaped the way these products are addressed in regulation and in international trade. While the EU may have been the first region to agree 'harmonised' regulation in this area across member states, some other regions, and particularly ASEAN, have subsequently engaged in such work. The presentation will therefore provide an overview of such work, where there are similarities and where there are differences.

2.4 Consumer perception of “superfoods”

Mark Lohmann
German Federal Institute for Risk Assessment (BfR)

There is quite a number of studies investigating the influence of food usually labelled as superfood on human health. However, yet little is known about the perception towards this food group. For example it is unclear, what consumers think of when hearing about superfoods, and what they think what kind of food this term is referring to.

In general, food preferences and choices are based on a complex process and can be influenced by diverse factors, including physiological, situational, sociocultural, and psychological ones as well as extrinsic product characteristics. Moreover, individuals differ systematically in the way they process information about food products, such as packaging and labelling of products. Therefore, people who particularly value health claims or care about a conscious diet may be more appealed to products that are labelled as superfood. In addition, explicit and implicit gender norms can drive eating behaviour, with women being more exposed to gender specific advertisement, expected body discipline and dietary self-control in contrast to men. Thus, superfood products may be more appealing for women than men.

As there is a lack of a clear definition of superfood and the term itself is mainly shaped by marketing and media, such insights in the public’s understanding of the term are helpful to systematically clear up the confusion when handling with this term. Following these considerations an online survey was conducted (N = 1,006 respondents) to assess the public’s understanding of superfood in Germany. The questionnaire addressed three major topics: conceptual understanding of the term superfood, corresponding consumption behaviour, and risk-benefit appraisal. More specifically, it was the aim to find out whether the general public has heard of the term superfood, what properties they think superfood products have, which specific food products they would call a superfood, and how they rate potential health benefits versus risks. Furthermore, the consumption frequency and reasons for consumption versus non-consumption as well as differences in the understanding of the superfood term based on gender, dietary style, and age were analysed.

2.5 Superfoods, food supplements, novel foods

Isabelle Laquiere, Jean Pottier
Federal Public Service Health, Food Chain Safety and Environment (FPS Public Health), Belgium

So called “Superfoods” are typically used for “new” products placed on the EU market claiming exceptional nutritional or beneficial health properties. Are they really new and can they make such claims?

The term “Superfood” should be considered as a non-specific health claim as it suggests a health benefit, and should therefore be accompanied by specific authorised or on hold health claims. This term is not an officially recognised term for a specific category of food, but a marketing invention. Such marketing terms must be able to be supported by convincing health claims. That the product is solely a source of a certain vitamin can be considered as misleading.

These ‘superfoods’ can be food ingredients in normal foodstuffs or food supplements. Food supplements need to be notified in many EU Member states, but **a notification can not be regarded as a pre-market authorisation**. The food business operator remains the first responsible to put safe products on the market with a known history of consumption as foodstuff (or in food supplements).

Therefore in all cases they have to comply with the (new) **‘novel food’ regulation EU 2015/2283.**

Novel Food is defined as food (food ingredients) that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel food came into force.

The underlying principles underpinning Novel Food in the European Union are that Novel Foods must be: safe for consumers, properly labelled, so as not to mislead consumers and if novel food is intended to replace another food, it must not differ in a way that the consumption of the Novel Food would be nutritionally disadvantageous for the consumer.

Pre-market authorisation of Novel Foods on the basis of an evaluation in line with the above principles is necessary.

Food business operators can place a novel food on the European Union market only after the Commission has processed an application for the authorisation of a novel food, and has adopted an implementing act authorising the placing on the market of a novel food and updating the Union list. Thus, before placing a novel food on the European Union market, the applicant must first submit to the Commission an online application for authorisation.

In order to determine if the novel food is liable to have an effect on human health, the Commission will request the European Food Safety Authority (EFSA) to carry out a risk assessment. Taking into account EFSA’s opinion, the Commission shall submit to the Standing Committee on Plants, Animals, Food and Feed a draft implementing act authorising the placing on the market of a novel food. Once the act receives a favourable vote from the Standing Committee and is adopted and published by the Commission, the novel food can be lawfully placed on the European Union market.

As with other novel foods, **traditional foods from a third country** can only be placed in the European Union market only after the Commission has processed a notification, has adopted

an implementing act authorising the placing on the market of the traditional food and updating the Union list. Thus, before placing a traditional food on the European Union market, an applicant must first submit to the Commission an online notification for authorisation.

Upon reception of a notification the Commission assesses the validity of the application, its completeness and the presence of the required information. The Commission then forwards the valid notification to the EU countries and to EFSA. Within four months, Member States or EFSA may submit to the Commission duly reasoned safety objections to the placing on the market of the traditional food concerned. Where no duly reasoned safety objections have been submitted, the Commission will authorise the placing on the market of the traditional food and update the Union list. If one or more EU countries or EFSA submit duly reasoned safety objections, the Commission cannot authorise the placing on the market of the traditional food concerned or update the Union list. In that case, the applicant may submit an application to the Commission.

The Union list covers all authorised novel foods with their specific conditions (conditions of use, additional labelling requirements, eventually proprietary data and detailed specifications). https://ec.europa.eu/food/safety/novel-food/authorisations/union-list-novel-foods_en

More information on the procedure, the Union list of authorised novel foods and the ongoing applications and notifications can be found here: https://ec.europa.eu/food/safety/novel-food_en

How to prove a food is not novel (in food supplements)? The proofs have to be provided by the food business operator in case of control or upon request by a competent authority. The European novel food catalogue provides a useful tool to check the novel food status: https://ec.europa.eu/food/safety/novel-food/novel-food-catalogue_en

In case of plants or fungi, it is particular important to take into account the plant/fungi part and if it concerns an extract or not. In case of extracts, a history of consumption of the specific extract needs to be proven.

Article 4 of the novel food regulation EU 2015/2283 requires food business operators to verify if the food they intend to place on the EU market falls within the scope of the novel food Regulation or not. In other words, they need to be certain that the food is novel or not.

If after considering all the information available the food business operator is still unsure about the novel food status, they may consult the competent authorities of the EU country where they first intend to place the food on the market. Once that EU country reaches its conclusion on the novel food status of a food, the Commission will publish that information on the Commission's website.

More information on the consultation process: https://ec.europa.eu/food/safety/novel-food/legislation_en

Contact details of the EU countries' authorities responsible for the consultation process on novel food status of a food

2.6 Classification of other substances – The D-A-CH-Lists of substances and other lists on the national level

Klaus Riediger
Austrian Agency for Health and Food Safety (AGES), Austria

The Food Supplements Directive 2002/46/EC lays down a harmonised list of vitamins and minerals that may be added for nutritional purposes in food supplements (in Annex I to the Directive) but it does not cover any “other substances” with nutritional or physiological effects such as plant, plant preparations and plant extracts. Neither legal binding specifications nor maximum levels are set, yet.

Nevertheless, harmful effects are known or suspected for several “other substances” used in food. Therefore, a legal framework was set in Article 8 of Regulation (EC) No 1925/2006 for substances prohibited, restricted or under Community scrutiny. It offers the opportunity to list those substances in Annex III, Part A, B or C.

Unfortunately, only a few substances are listed, yet.

In the short term, no further harmonisation from the European legislator is to be expected with regard to the classification of “other substances”.

For these reasons, member states have started to create their own lists of substances in different categories.

The working group for the “D-A-CH lists of substances” currently consists of representatives from Germany of the responsible federal authorities (BVL, BfR, BfArM) and representatives from Germany of the testing facilities of the federal states. Representatives from Switzerland and Austria as well as external experts from the respective specialist areas have also joined the working group as members.

The lists of substances can provide guidance for evaluation of substances as food or food ingredients, even in Austria and Switzerland. It is possible, that individual classifications in Austria or Switzerland differ from the lists of substances. The relevant statutory regulations of Austria and Switzerland are to be respected in any case.

The working group develops lists of substances, taking into account scientific findings and legal requirements for an active contribution to consumer health protection. The focus here is on the classification of substances with regard to their use as medicinal substances or foodstuffs and with regard to their novel food status but also an overview of the critical ingredients as well as the associated risks is given. The lists of substances are intended to make it easier for control authorities and food companies to classify botanical-based substances with regard to their use as food or food ingredients and thus represent a recommendation regarding the marketability of substances as food.

After the publication of the 2nd edition of the foreword and the list of plants, as well as the 1st edition of the list of fungi in 2020, the working group on the list of substances has now (2022) drawn up the 3rd edition of the foreword and the 1st edition of the list of algae. Algae have been part of the diet for some time. Since they are also traded as “super foods” due to their high nutrient content, which also appear suitable for sustainable biomass production thanks to their rapid growth, algae are currently increasingly being placed on the market as food. In order to provide manufacturers and distributors as well as authorities and consumers with a recommendation for the classification of algae and products made from them, the working group on the list of substances has drawn up this algae list.

To ensure a uniform system, the entries in the lists are referred to as “substances”, even if they are not chemically defined individual substances. “Substances” in the sense of the lists have so far been plants and parts of plants as well as fungi and algae. The substances are considered and categorised as such. A major problem in the classification of substances is also posed by extracts, which are often no longer comparable with the original plant or part of the plant occurring in nature, although they were obtained from the same plant/the same part of the plant. Depending on the extraction method used, the composition of the active ingredients can vary considerably. Therefore, for each extract as an independent active ingredient, taking into account the drug-extract ratio, the extraction agent and/or standardisation to a lead substance, it must be checked whether the findings on the parent plant can also be transferred to the extract.

As part of their regulatory systems, some Member States have already drawn up their own national lists in the form of so-called positive and/or negative lists of plants and parts of plants, which allow or prohibit their use. The cooperation project known as “BelFrIt” between Belgium, France and Italy was launched in 2013 for international harmonisation with the aim of creating a common positive list of plant and plant parts to be used in food supplements. The BelFrIt list with a total of 2425 listed entries is not legally binding, but can be used as a guide for assessing substances. In contrast to the German list of substances, the BelFrIt list is not based on a decision tree, but on the authors' empirical knowledge.

After the BelFrIt list was published, Belgium, France and Italy each derived their own national legally binding lists for the use of plants and parts of plants in food supplements.

Parallel to the list of plants, the DACH working group on the list of substances has also drawn up a positive list for fungi and algae based on the same decision tree. For this purpose, the fungi species (BE; IT; AT; SE; UK) and algae species (BE; FR; SE) were identified and evaluated from the lists of various Member States and Switzerland, which represent potential candidates for inclusion in a corresponding list of substances.

Further changes to the list of substances are currently being worked on, among other things the list of substances is to be published as a database in the future to enable easier research.

The D-A-CH lists of substances of the federal and state governments provides distributors and the official food control with recommendations for the classification of substances, which were made on the basis of a decision tree that reflects the current legal situation.

In principle, however, further harmonisation of the regulations for “other substances” at EU level would be desirable in order to increase legal certainty for food business operators and control authorities. To this end, it might make sense to draw up a common positive and negative list containing the “other substances” for which there is consensus among all Member States.

2.7 Initiative on European level for classification pharmacologically active substances in food supplements

Jacqueline Steenbergen-Biesterbos
Netherlands Food and Consumer Product Safety Authority (NVWA), The Netherlands

Directive EU 2002/46 defines food supplements. However the definition might be out of date as the directive is almost twenty years old. The definition of might lead to misinterpretation and miscommunication between EU member state as they talk about the same but mean something different. In general three types of food supplements can be distinguished: vitamins & minerals, botanicals and other substances. Concerns regarding safety are mainly raised by the use of botanicals and other substances. The intake of food supplements might lead to adverse health effects when someone takes more pills than prescribed on the label or also takes other medicines (interactions) or performs strenuous exercise. Especially when the ingredients are not or not correctly labelled. This might also lead to a positive doping test.

The enforcement of food supplements is complex. First of all the status of a supplement has to be determined (new psychoactive substance, medicine or food). The Netherlands has limited national legislation only regulating the limitation of certain herbal substances in food supplements. This differs from other EU member states who might have positive of negative list of substances that are permitted or not permitted in food supplements. On an EU level only regulation (EU) 1925/2006 permits the use of ephedra and yohimbe in food supplements. No further specific regulation regarding food supplements exist in the EU. Therefore harmonisation of a regulatory framework of food supplements on an EU level is needed and this has been recognised. However, the European commission does not prioritise this harmonisation except setting maximum levels for vitamins and minerals.

Food safety agencies struggle with the lack of EU harmonised regulatory framework. Therefore, a Heads of Food Safety Agencies (HoA) working group was started. The purpose of this working group is to establish a list of substances (botanicals and other substances) that need to be limited or forbidden for their use in food supplements.

2.8 Borderline medicinal products/foods – limits of "dual use"

Tomas Nilsson
Swedish Medical Products Agency (MPA), Sweden

Many substances could be included in both foods and medicinal products dependent on the purpose of the product. What constitutes a food and a medicinal product is defined in the food legislation and the medicinal legislation respectively, both based on union law. Sometimes these definitions overlap. The regulations for foods and medicinal products differs significantly and a product could not be sold under both legislations concurrently on the same market. To clarify situations where both definitions are fulfilled, EU law states that the medicine's legislation has precedence. If a product is a medicinal product it is not allowed to be sold as foods. But even if the definition of a medicinal product is stated in the Human Medicines Directive (2001/83/EC), the legislation is not completely harmonised. The decision whether a product is a medicinal product or not is made by national authorities under the supervision of national courts. For the decision, the authority needs to assess the specific product and all its characteristics. Two similar product could therefore be sold under different regulations in different countries or even within the same country. The evaluation whether a product fulfils the definition of a medicinal product could also not be made *per se*, but has to consider adjacent legislations and how substances are otherwise used. The European Court of Justice has several times interpreted wordings of the definition of a medicinal product that national authorities and courts have to take into account in their decisions.

The definition of a medicinal product basically emanates from two aspects of the product; the actual effects of the product on the human body and how the consumer perceives the effects of the product. Assessments of both aspects are influenced by knowledge both of use of the included substances as medicines and as foods. The presentation describes how the medicine's legislation relates to different parts of the food legislations, both regarding included ingredients and marketing claims. Examples are how authorised health claims and novel food status influence a decision and the legal basis for this. To illustrate the balance between aspects of both legislations, products with melatonin and products with cannabidiol are discussed. Both these substances have been thoroughly discussed internationally the last couple of years, both from the perspective of legislation for foods and the legislation for medicines.

2.9 Risk assessment approaches and methodology – an overview

Karen I. Hirsch-Ernst
German Federal Institute for Risk Assessment (BfR)

The term “superfood” is often used in the context of marketing of certain foods to imply that these foods might enhance well-being and have beneficial effects on human health. However, associated claims are generally not focused on addressing potential adverse effects of such foods or other safety-related aspects of human health.

European General Food Law Regulation (EC) No 178/2002 requires food to be safe for consumers. Superfoods that are regarded as being Novel Foods are subject to authorisation procedures within the EU along the Novel Food Regulation (EU) 2015/2283 (Article 10 procedure for authorising the placing on the market within the Union of a Novel Food, or Article 14 procedure regarding notification of a traditional food from a third country). The European Food Safety Authority EFSA has developed scientific and technical guidance for the submission of applications for authorisation of Novel Foods which also provides information on data required to assess the safety of individual Novel Foods under their proposed conditions of use (Article 10 procedure), or guidance to substantiate the history of use in a third country (Article 14 procedure).

However, many foods claimed to be superfoods, including certain substances other than vitamins and minerals that are added to food supplements or fortified food products, are being marketed without having undergone an authorisation procedure and currently do not have Novel Food status.

Although in such cases, risk assessors may be asked by risk managers to provide scientific advice on safety-related aspects of these foods, no specific general data requirements for human health risk assessment of “other substances” used in food supplements or fortified foods are in place. Rather, scientific risk assessment is based on the scientific data and information available. As far as the available data situation allows, the general approach for scientific human health risk assessment is followed, involving hazard identification, hazard characterisation (including characterisation of dose-response relationships, identification of reference values such as “no observed adverse effect levels” and consideration of appropriate uncertainty factors), exposure assessment and risk characterisation.

In practice, however, scientific assessments of “other substaces” face substantial challenges and uncertainties that may impede the elaboration of comprehensive complete scientific risk assessments. For example, often information on the composition of foods in question is incomplete, data from animal or human studies are limited and/or studies, if available, are of poor quality.

Examples of risk assessments presented here regard certain substances used in food supplements that have been promoted as being superfoods (isolated concentrated piperine, hydroxycitric acid and botanical extracts of *Garcinia cambogia*). These examples illustrate challenges encountered in the course of assessment of these substances and indicate that certain foods currently marketed as superfoods may be associated with human health risks.

2.10 Risk assessment of “superfoods” and supplements (examples)

Susanne Alban
Christian-Albrecht University of Kiel, Germany

The food supplements (FS) market is continuously growing with a CAGR (compound annual growth rate) of more than 5 %. Similarly, the range of products is increasing; besides the classical vitamins and minerals, they contain a huge variety of ingredients. Especially natural substances and herbal preparations are becoming increasingly popular. In addition, “superfoods” (SF) have evolved as a new trend over the past years. This marketing term means foodstuffs for normal consumption with alleged special health benefits.

Both FS and SF fall under food regulation and thus shall not be placed on the market if they are unsafe, i.e. if they are considered injurious to health or unfit for human consumption (Article 14, Reg. (EC) No 178/2002). Consequently, the declaration of FS usually contains health claims, but no information about potential health risks. Accordingly, the majority of consumers assumes that these products are beneficial and safe and – in contrast to medicinal products (MP) – have no side effects. But in fact there are risks associated with the consumption of FS and possibly also SF.

A basic cause of both the missing risk awareness and numerous safety issues occurring in reality is the different regulation of MP and foodstuff. Contrary to food, MP require a marketing authorisation by the competent authorities to be placed on the market (Article 6, Dir. 2001/83/EG), which is based on the assessment of their quality, safety and efficacy. Moreover, approved MP are subject to ongoing pharmacovigilance to detect and prevent MP-related risks. Accordingly, the safety of MP and their quality – as fundamental prerequisite of safety and efficacy – are tightly controlled, whereas there are no comparable mandatory surveillance systems for food products and the official food monitoring is overstretched given the flood of products. Only novel foods require a marketing authorisation approving that they do not, on the basis of the scientific evidence available, pose a safety risk to human health (Reg. (EU) 2015/2283). Altogether, the knowledge about the frequency and the extent of safety risks of foodstuffs is lower than that of MP and the risks of individual products is often hardly to assess due insufficient evidence.

Compared to FS being concentrated sources of nutrients or other substances, the risk potential of SF can be supposed to be lower, as they are foodstuffs for normal consumption and are partly traditional components of Western diet. But improper consumption of SF such as of unusually high amounts, of special SF combinations or by special populations can lead to health risks (e.g. overdose of iron, CYP3A4 inhibition, salt overload).

There are several sources of FS and SF-related health risks: (1) the FS or SF itself, (2) contamination, (3) geographic origin, legislation, (4) the consumer.

Complex-composed botanical FS and SF may contain compounds potentially causing adverse reactions, intolerances and interactions with medicinal products, respectively (e.g. kava, red rice, almonds, cinnamon, ginseng, St. John’s wort, grapefruit, goldenseal rhizome, ispaghula husk). The risk potential is generally higher with herbals or compounds not well investigated. Particular caution is, therefore, recommended with herbal drugs and preparations from non-European plants like products of traditional Chinese medicine and Ayurveda, which may contain toxic compounds (e.g. aristolochic acid, aconitine), sometimes also due to confusion or adulteration. Moreover, there are FS containing not only herbal ingredients, but also vitamins and minerals (to utilise their health claims as there are no allowed ones for botanicals). Their intake in addition to other sources of the corresponding nutrients may result in

overdosage and adverse reactions. Finally, the contents of the ingredients of FS sometimes extremely vary from placebo doses up to critically high doses (e.g. vitamins, curcumin).

Risks can be caused by a wide range of contaminants. Contamination can occur accidentally or deliberately, which means fraudulent adulteration. Herbal FS and SF may be contaminated with heavy metals, pesticides, mycotoxins, microorganisms (e.g. *Salmonella*, *E. coli*, moulds), or pyrrolizidine alkaloids. In contrast to foodstuffs, herbal MP approved or registered in the EU have to be tested for all these contaminants before batch release to prevent associated risks. A recent example is the contamination of FS and SF (but not medicinal products) with ethylene oxide or 2-chloroethanol, respectively, although ethylene oxide gassing is forbidden in the EU.

Considerable risks have “natural” products offered in the internet and being produced in non-European countries, where the quality and safety awareness may be different. They have frequently poor quality and are even falsified by pharmacologically active substances (e.g. sibutramine, cortisone, ephedrine, sildenafil, testosterones) or cheaper herbal drugs.

The consumer considerably influences whether potential risks become manifest and result in adverse reactions. Despite corresponding warnings, “health products” are purchased over the internet or in non-European countries. Overdosed consumption or the combined intake of several FS containing the same or similarly acting ingredients may lead to adverse reactions (e.g. Vitamin A, B12, A, beta carotene, selenium, green tea extract, algae (iodine), CBD plus berberine). Pharmacokinetic or pharmacodynamic interactions with prescribed MP can increase MP-related side effects or reduce their efficacy (see above, antioxidants in cancer, curcumin). Finally, the intake of accordingly advertised “natural” products instead of the indicated MP is mostly not a good choice (e.g. red rice, cinnamon).

In conclusion, FS and SP can pose health risks, but a significant part of them is in principle avoidable. This includes quality-related risks that could be reduced by stricter quality requirements and control systems. For another part of the risks, the consumers themselves are responsible by consuming (individually) inappropriate (amounts) FS and SF due to missing knowledge or misleading advertising. This underlines the importance of proper information and education of the public about risks of FS and SP, risk prevention measures and limited, questionable or absent benefits, respectively.

2.11 "Superfoods" – Contribution to health and well-being: expectations and reality

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The term 'superfood' has been introduced to describe foods exhibiting additional health benefits. This notion has been generated by marketing experts and there is currently no generally accepted scientific definition. In general, 'superfoods' are thought to provide benefits to health and well-being due to their higher amounts of specific ingredients such as vitamins, minerals and antioxidants compared to other foods. Mostly, it is certain plants as well as fruits and vegetables that are categorised as 'superfoods'. These include exotic foods such as chia seeds, moringa leaves, goji berries and acai berries as well as local foods such as linseed, blueberries and kale. What they all have in common: they are touted for their health-promoting properties including anti-inflammatory, anti-oxidant and anti-diabetic effects. It has been suggested that these properties are mainly mediated by certain nutrients present in these foods, although the method of administration in the studies must be taken into account when interpreting the results. There is a big difference in effects if the foods when the foods were administered as an extract or as a whole food or just as the leading phytochemical compound in the food. It further has to be considered that most of the postulated health-promoting effects refer, if any, are based on data obtained *in vitro* or *in vivo* in animal models that do not allow for transfer to humans, or only to a limited extent. This shows the need to perform randomised controlled trials (RCTs) to translate the obtained results to humans. RCTs have already been conducted for some 'superfoods' but with inconclusive evidence. One example for a 'superfood' is green tea which contains relatively high amounts of epigallocatechin gallate (EGCG), a polyphenol thought to be responsible for its health-promoting properties. A study with fruit flies (*Drosophila melanogaster*) has demonstrated that a green tea extract with a high EGCG content has significant effects on the fly's energy metabolism which is reflected e.g. in lower glucose levels. Human studies investigating the glucose-lowering effects of green tea support these findings to some extent, but with low quality evidence.

Overall, most of the 'superfoods' investigated in various experimental settings have been shown to exhibit health-promoting properties. However, when interpreting these results, it must be taken into account that (a) these effects mainly derive from *in vitro* and *in vivo* studies and (b) mostly extracts or only a leading phytochemical and not the food as such were analysed.

2.12 The global internet market/surveillance of “superfoods” and supplements – results of governmental monitoring

Georg Schreiber
German Federal Office of Consumer Protection and Food Safety (BVL)

Food supplements are foods that contain vitamins, minerals or other nutrients in concentrated doses and are intended to have a nutritional or physiological effect. To place them on the market, no authorisation is required. In many cases, however, products are marketed as food supplements that do not comply with the legal requirements, especially in the internet trade. In the best case, they are only ineffective. In the worst case, they contain dangerous ingredients and are harmful to health. In the past 3 years alone, almost 900 notifications of potentially harmful food supplements have been shared via the European Rapid Alert System for Food and Feed (RASFF).

To protect the consumer from illegal and harmful products from online commerce BVL has been operating the common central unit “G@ZIELT” since 2013, following a two years’ pilot phase. G@ZIELT acts on behalf and is financed by the German Federal States (Länder), for monitoring the eCommerce of food, feed, special non-food consumer products and tobacco products.

Within the scope of G@ZIELT are risk-based product searches on notifications in the RASFF and in the European Rapid Alert System for Dangerous Consumer Products (RAPEX). Information on offers/vendors addressing German consumers is forwarded to competent authorities within Germany, the EU and worldwide. Moreover, G@ZIELT together with the Länder sets-up risk-based coordinated control programmes and conducts comprehensive searches for German food business operators in the internet, allowing the local authorities to check the compulsory registration and subject vendors to official risk-based controls. With the onset of the Covid-19 pandemic in Germany, G@ZIELT conducted a very successful programme on targeted searches on offers and advertising for food supplements in connection with Covid-19. Various online traders were trying to exploit the uncertainty among the population in this situation and to increase the sales of their products with dubious or even illegal advertising claims. Within the framework of a coordinated eCommerce Action Plan of the European Commission G@ZIELT together with other EU member states identified 646 conspicuous websites across the EU.

In order to protect consumers equally effectively on the internet and to be able to carry out official controls as efficiently as in brick-and-mortar shops, new concepts as well as specific technical facilities and expertise are needed that go beyond the control procedures of conventional trade. However, there is a lack of important legal bases in particular.

2.13 How is food transformed into superfood?

Julia Sausmikat
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The superfood market has been growing steadily for years and reached a sales volume of almost 43 billion euros in 2016. In 2020, one third of the Germans surveyed said they consumed superfoods at least once a week. Social developments such as a growing health consciousness and a simultaneous rise in people's perception of stress have increased the demand for easy-to-implement compensatory measures. At individual level, consumers may be attracted by superfoods for different reasons, depending on their personal attitude. Research shows that certain consumer subgroups perceive superfoods rather as a luxury good than as a support for their health and wellbeing, for example. Various mechanisms contribute to transforming a food into a superfood. Developments in food technology, which made the global marketing of certain exotic foods possible in the first place, as well as the mass media coverage of the issue have contributed to the massive expansion of superfood-awareness among consumers. But first and foremost it’s a result of targeted marketing by providers if a food is perceived as an adorable superfood – often promoted through advertising on social media platforms. To address the complex relationship between superfoods and consumers also the impact of influencers and the role of food journalism needs to be reflected.

The presentation will give a brief overview and practical examples of how these aspects are used to transform (almost any) food into a superfood.

2.14 Combatting counterfeit superfoods

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An increasing awareness for health in wealthy, but ageing societies, and the trend to boost economic performance by self-optimisation has led to a boom of a new food category commonly known as “superfoods”. Industrialised countries, such as the US or Germany have become major importers for food and health products labeled as superfoods. Many “superfoods” are rooted in traditional medicinal systems, such as Ayurveda or Traditional Chinese Medicine, where functional food is a central element of preventive care. This means that these products often harbour pharmacologically active compounds, creating issues for consumer protection, leading to attempts to control import of such plant products by legislation, such as the Novel-Food regulation. The presence of potential counterfeit species that are often much cheaper than the real plant product calls for efficient systems to protect consumers from possibly toxic plants. However, while many countries routinely conduct authentication on the base of well-established pharmacopeias, the case of novel and often exotic plant products poses huge challenges, especially when these come in processed form, as powders, or smoothies. Metastudies on the use of genetic barcodes or of microscopic diagnostic show that a substantial fraction of traded plant products is wrongly declared. This is only partially due to criminal intentions or greed – often vernacular and scientific nomenclature are not compatible, leading to confusion under the conditions of botanical globalisation. Genetic barcoding can help to detect such non-intentional adulteration. Holy Basil, Chia, Goji and various Herbal Teas are used as case studies to demonstrate, how a combination of authenticated reference plants, microscopic diagnostics, genetic barcodes, and sequencing-free fingerprints can detect counterfeit superfood and ends with a plea for political actions to be taken to reconcile globalisation and consumer protection.

More: https://www.botanik.kit.edu/botzell/english/2415.php

2.15 Nutrivigilance of food supplements in Europe

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Even though food supplements (FSs) shall not be placed on the market if unsafe, some products may still expose the consumers to risks. The European Union legislation does not require the creation of national vigilance systems dedicated to FSs (Nutrivigilance). Nevertheless, six European Union countries have set up such systems which will be presented. Some other European systems for reporting on FSs safety exist (Rapid alert system for food and feed – RASFF; Emerging risks exchange network – EREN) but they are not suitable for reporting FSs adverse effects. Creating a harmonised European Nutrivigilance System will strengthen health risk assessment and improve public health by helping decision makers implement management measures when needed and set legal requirements at the European or country levels.

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