

# NORDIC WORKING PAPERS

## Safer food supplements in the Nordic countries

Report from a Nordic workshop  
November 21-22, 2018

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## **Report from a Nordic workshop November 21-22, 2018**

### **Safer food supplements in the Nordic countries**

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## Abbreviations

ADI	-Acceptable Daily Intake
DK	-Denmark
DMAA	-1,3-dimethylamylamine
EC	-European Commission
ED	-energy drinks
EFSA	-European Food Safety Authority
EU	-European Union
FI	-Finland
FSA	-Food Standards Agency (in UK)
IS	-Iceland
MOE	-Margin of Exposure
MOS	-Margin of Safety
NFA	-National Food Agency (in Sweden)
NFSA	-Norwegian Food Safety Authority
NKMT	-Nordic Working Group for Diet, Nutrition and Toxicology
NO	-Norway
NOAEL	-No Observed Adverse Effect Level
QPS	-Qualified Presumption of Safety
QSAR	-Quantitative Structure-Activity Relationship
RASFF	-Rapid Alert System for Food and Feed (in EU)
RYR	-red yeast rice
SE	-Sweden
VKM	-Norwegian Scientific Committee for Food and Environment
WADA	-World Anti-Doping Agency

## Introduction

Scientists and advisers at the Norwegian Institute of Public Health, the Finnish Food Authority and the Technical University of Denmark have arranged a Nordic workshop with the aim of establishing a network for sharing knowledge, experience and risk assessments of 'other substances' among the Nordic countries. The project and the workshop were funded by the Nordic Working Group for Diet, Nutrition and Toxicology (NKMT), the Nordic Council of Ministers.

The workshop took place on the 21st and 22nd of November 2018 in Oslo and was organized by a Nordic working group represented by:

**Inger-Lise Steffensen** (project leader), Department of Toxicology and Risk Assessment, Division of Infection Control and Environmental Health, Norwegian Institute of Public Health

**Sari Sippola**, Food Safety Department, Chemical Food Safety Unit, Food Composition Section, Finnish Food Authority

**Pelle Thonning Olesen**, Division for Risk Assessment and Nutrition, National Food Institute, Technical University of Denmark

The workshop included 9 presentations given by 7 speakers of both genders from Denmark, Finland, Norway and Belgium. The participants were from all the Nordic countries; 1 from Iceland, 2 from Finland, 2 from Sweden, 4 from Denmark and 32 from Norway, as well as 1 person each from Belgium, the Netherlands and Germany (in total 44, of both genders).

## Background

Studies have shown that the content of the food supplements sometimes differ from the information on their labels regarding which substances are in the products and their levels. There have been incidents of serious health problems, such as liver failure, from intake of supplements, also in the Nordic countries. Since the active substances in such products, the so-called 'other substances', are largely unregulated at the EU level, national regulations are needed. A cooperation and sharing of knowledge and methodology on risk assessment of these substances through a Nordic network will benefit and strengthen the cooperation between the Nordic countries in this area of consumer safety. The Nordic countries could benefit greatly from the shared costs in the development of their national regulations.

The Norwegian Scientific Committee for Food and Environment (VKM) has on request from the Norwegian Food Safety Authority (NFSA, Mattilsynet) during 2015-2017 performed risk assessments of in total 44 'other substances' sold on the Norwegian market (<https://vkm.no/risikovurderinger/allevurderinger/risikovurderingeravandrestofferikosttilskuddogenergidrikker.4.645b840415d03a2fe8f256aa.html>). These risk assessments were based on methodology established by VKM for evaluation of these substances, for which sufficient toxicity data are often lacking, and is described in a separate document (<https://vkm.no/download/18.645b840415d03a2fe8f25c37/1499326301370/a75fd54bf8.pdf>). The recommended doses of the products as given by the industry (producers and/or importers) were evaluated for safety, using information from previous risk assessments from the European Food Safety Authority (EFSA) and similar institutions, and scientific publications found by literature searches. A number of such products were found to be of potential health risk for one or several groups of consumers (among adult men and women, adolescents and children down to the age of 10 years).

The main goal of the project was to provide a higher level of safety for consumers of food supplements sold in the Nordic countries through sharing of knowledge and methodology.

To obtain this goal, the objectives of the project were to establish a network for sharing the already obtained knowledge and risk assessments of 'other substances', arrange a workshop and establish a basis for further cooperation in this area among the participating countries, and thereby contribute to development of national regulations of 'other substances' and to safer food supplements in the future.

While within the European Economic Area, these substances fall under the scope of the European Regulation (EC) No. 1925/2006 on the addition of vitamins, minerals and certain 'other substances' to foods and the European Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, 'other substances' remain largely unregulated. In order to ensure safe use of 'other substances', the countries that do not already have regulated their use at the national level, will benefit from this project. Also countries with an existing national regulation, such as Denmark, will benefit from an update and extension of the knowledge base for their national regulation. Many other countries, the EU and internationally, will also benefit from the results of this project for the same reason. The project will therefore strengthen the Nordic influence internationally.

## Presentations at the Workshop (Day 1 – November 21, 2018)

The workshop was arranged over two days. The first day was open to all interested and contained three sessions. The first session comprised talks on risk assessment and risk management (national regulations) of 'other substances' in the Nordic countries. The second session was about botanicals, i.e. substances from plants, fungi or lichens. Two examples of how botanicals are assessed in Europe were presented, since this is a challenging area that the Nordic countries have just started or will be starting to work on soon. The third session was on surveys of use of 'other substance' among young consumers and on illegal contents of food supplements bought on the internet, clearly showing why this focus on 'other substances' is important for consumer safety. The second day was for representatives from the authorities in the Nordic countries responsible for this area, where further collaboration as follow-up of this project was discussed in the fourth session.

### Session 1: Risk assessment and risk management of 'other substances' in the Nordic countries

#### The national regulation of 'other substances' in Denmark

Kirsten Pilegaard, Technical University of Denmark

The Danish regulation on 'other substances', a risk assessment of raspberry ketone (4-(4-hydroxyphenyl)-2-butanone) for use in food supplements and the worldwide health concerns of the use of 1,3-dimethylamylamine (DMAA) in food supplements, were presented in this talk.

The existing Danish regulation on 'other substances' is called in English 'Act on addition of other substances than vitamins and minerals to foods (no. 549, 28 May 2018) and in Danish 'Bekendtgørelse om tilsætning af visse andre stoffer end vitaminer og mineraler til fødevarer'. The act is regularly modified and updated. The act applies to foods, including food supplements. 'Other substances' are defined as substances other than vitamins or minerals having nutritional or physiological effects. Flavouring substances and food additives are included in the definition of 'other substances' provided they are added for their nutritional or physiological effect. Excluded from the 'other substance' definition is plant material in fresh, dried, cut or powdered form, aqueous extracts of plant materials (simple aqueous extraction followed by evaporation), enzymes and microbial cultures. Further, 'other substances' should have a purity of minimum 50% or be concentrated 40 times or more, and should normally not be ingested as a food or an ingredient. Some substances are already generally accepted for various food categories and are listed in an annex (Annex 1). The accepted level of a substance in a food category is the total content in the food, irrespective of whether the substance is added as 'other substance' or it is already present in the food. Specifications for identity and purity as well as analytical methods are described in another annex (Annex 2). Addition of a new substance or a level of an existing substance exceeding the accepted level needs authorization from the Danish Veterinary and Food Administration before placing on the Danish market. The approval is based on the outcome of an individual risk assessment carried out by the National Food Institute. If present, the risk assessment may

be based on health-based guidance values set by international scientific bodies, e.g. Acceptable Daily Intake (ADI) values, and intake data from national dietary surveys. The food categories may be e.g. beverages (non-alcoholic or with various percentages of ethanol), chocolate and bars, gels, biscuits and cookies, pastilles or boiled sweets, and food supplements. Examples on accepted 'other substances' are specified amino acids, caffeine, food additives, such as sorbitol, lycopene or lutein, ubidecarenone (coenzyme Q10), quercetin and epicatechin (the latter two from specified plants).

Raspberry ketone, 4-(4-hydroxyphenyl)-2-butanone, is the primary aroma compound (level of 0.009-4.3 mg/kg) of the fruit of raspberry (*Rubus idaeus* L.). It is also used as a flavouring substance. In recent years, raspberry ketone has been marketed as an ingredient in food supplements for weight loss in recommended daily doses of 100-1400 mg. European Food Safety Authority (EFSA) concluded that raspberry ketone as a flavouring substance would present no safety concern at the estimated level of intake from berries and flavourings of 2.4 mg/day (based on an estimation of Margin of Safety (MOS) equal to 2500). Other intake estimates range from 1.8-3.8 mg/day for an adult. The animal study used for deriving the NOAEL (No Observed Adverse Effect Level) for the MOS estimation was an unpublished 90-day study in rats from 1970. No chronic/carcinogenic, reproductive or developmental studies with raspberry ketone were identified in the literature. Investigations of raspberry ketone in Quantitative Structure-Activity Relationship (QSAR) models indicated potential cardiotoxic effects and potential effects on reproduction/development that need further elucidation. MOS values for raspberry ketone intake from food supplements varied from 3-165 calculated based on daily raspberry ketone intakes of either 100 or 1400 mg for an adult (70 kg) and NOAELs (70, 100 or 280 mg/kg bw/day derived from two 90-day rat studies). The MOS values for raspberry ketone are below the MOS of  $\geq 200$  (200 instead of 100 due to limited toxicological data) that is usually considered sufficient to conclude that there would be no safety concern at the estimated level of exposure.

Raspberry ketone was classified as a novel food by the Food Standards Agency (FSA) in UK (March 2014). It was stated that raspberry ketones other than raspberry fruit extracts prepared using water or 20% ethanol (1:4 ethanol:water) are novel and should fall within the scope of the EU legislation on novel foods. This information is not found at the homepage of FSA (November 16, 2018). Some notifications calling raspberry ketone an unauthorized novel food ingredient (newest 2016) are published on the EU RASFF (Rapid Alert System for Food and Feed) portal. The substance is not found in the Novel food catalogue (November 16, 2018). Whatever the legal status, raspberry ketone is still marketed as an ingredient in food supplements in EU; now in even higher recommended doses (up to 2000 mg/day).

DMAA is an obsolete medicine, withdrawn from the market in the 1970ies. DMAA was claimed to be a natural occurring substance in geranium (*Pelargonium graveolens*), was patented in US under the name 'Geranamine' in 2005, and was thereafter introduced as an ingredient in food supplements. In New Zealand, it was also sold as a recreational drug. It was added to the list of substances prohibited in competition published by the World Anti-Doping Agency (WADA) in 2010. The substance acts on the sympathetic nervous system and e.g. constricts blood vessels. Only limited toxicological data exist. Serious adverse effects after intake of DMAA have been reported in humans, including e.g. high blood pressure, hemorrhage in various brain areas and deaths. Marketing of DMAA has been prohibited in EU member states, USA, Canada, Australia and New Zealand, but not at the same time. DMAA is occasionally found in food supplements marketed in the Nordic countries also in 2018.

## Regulatory framework of 'other substances' in food supplements in Finland and risk profile of plant food supplements

Tero Hirvonen, Finnish Food Authority

Risk profiles are based on the EU project PlantLibra. The data was collected in 2011-2012. The risk profiles concern the following plants: *Echinacea spp.*, *Foeniculum vulgare* (fennel), *Zingiber officinale* (ginger), *Equisetum arvense* (horsetail), rice (red yeast rice, *Monascus purpureus*), *Soya max* (soy), *Salvia officinalis* (sage), *Camellia sinensis* (green tea), *Thymus vulgaris* (thyme).

None of these plants were toxic in the amounts used. Red yeast rice (RYR) food supplement use seemed to be the most problematic substance, since majority of RYR food supplement users did not comply with manufacturer's dosing instruction and they had more medical conditions (e.g. diabetes, heart disease) and took more regular medications than other users. There were also two users (6%) who had self-reported elevated serum liver enzymes. In addition, for green tea supplements the margin of exposure (MOE) was rather low. Furthermore, the risk of interactions with medications was significant in ginger and horsetail, with medications which are metabolized via the metabolic liver enzyme CYP3A4 (e.g. warfarin). However, there is a considerable uncertainty concerning these interactions, since data in humans is scarce.

## Risk assessment of 44 'other substances' by the Norwegian Scientific Committee for Food and Environment (VKM)

Inger-Lise Steffensen, Norwegian Institute of Public Health/Norwegian Scientific Committee for Food and Environment

The Norwegian Scientific Committee for Food and Environment (VKM) has on request from the Norwegian Food Safety Authority performed 44 risk assessments of 'other substances' in 2015-2017. 'Other substances' are defined as substances with a nutritional or physiological effect that are not vitamins and minerals, according to Directive 2002/46/EC. These substances are used in food supplements, energy drinks and sports products, and comprise a variety of chemical substances. They may be botanicals, for instance caffeine, piperine and curcumin, and they may occur in regular foods. Others are found in the body naturally, such as coenzyme Q10, carnithine and choline, but may still be harmful if consumed in too high amounts. There have been incidents of serious health problems, e.g. liver failure, from intake of food supplements.

These risk assessments were based on an approach established by VKM. Since these substances are produced naturally in the body and occur in food, most of the available literature is on positive effects. Therefore, sufficient toxicity data is often lacking. The recommended doses of the products sold on the Norwegian market as given by the producers and/or importers were evaluated for safety, using information from previous risk assessments from the European Food Safety Authority (EFSA) and other risk assessment institutions and scientific publications found by literature searches.

A number of such substances were found to be of potential health risk for one or several groups of consumers (among adult men and women, adolescents and children down to the age of 3 years). Within the EU and the European Economic Area, 'other substances' remain largely unregulated. In order to ensure safe use of 'other substances', some countries have therefore established a national regulation of these substances. These risk assessments performed by VKM will be the basis for a national regulation in Norway.

### Proposal for a new national regulation of 'other substances' in Norway Merethe Steen, Norwegian Food Safety Authority

Some decades ago, the Norwegian consumers took only a few supplements; cod liver oil and Sanasol (liquid vitamins and minerals with a taste of orange). Now, there are more specialized and complex supplements on the market with 'other substances' after a huge development and innovation in this field. The food supplement market is growing. In Norway, there is a very high consumption of food supplements compared to other countries in Europe. 'Other substances' are mostly found in food supplements, energy drinks and sports products. The Norwegian Food Safety Authority (NFSA, 'Mattilsynet') is concerned about the situation – are the products safe for the consumers? 'Other substances' are added to foods and food supplements to have a positive effect on the persons who use these products, however, an excessive intake of certain 'other substances' may be associated with serious health risk and in worst case death. The type and extent of possible health risks will depend on which substance is consumed and in which amount. Today, there is no specific regulation of 'other substances' in foods or food supplements in the EU. The general requirement is that the addition of 'other substances' to food products should be safe according to the Food Law (Regulation (EC) No 178/2002) article 14. Since this field is not harmonized in the EU, member states have the opportunity to regulate 'other substances' nationally. This applies also to Norway.

It is the responsibility of the companies/business operators to ensure that products with 'other substances' on the market are safe. Today, it is very complicated and time-consuming for the inspectors in NFSA to perform inspections of products added 'other substances', since they have no lists or guidance documents to get information from to conclude on safety. In addition, it can also be unclear whether products with 'other substances' should be classified as food supplements or drugs, further complicating inspections.

The European Commission published a report in December 2008 on the use of 'other substances' in food supplements where they concluded that it was not necessary to develop specific regulation in this field. The EU commission believed that other EU regulations such as the Directive on food supplements (2002/46/EC) and the Regulation on nutrition and health claims ((EC) No 1924/2006) and the Regulation on addition of vitamins and minerals and of certain other substances to foods ((EC) No 1925/2006) would adequately cover this field. However, many EU member states want this area to be harmonized with a common EU regulation. This has been communicated to the EU Commission several times, but the EU Commission has not yet addressed this issue. In the absence of a common EU regulation, some countries have made national regulations and other countries have guidance lists. Denmark has implemented a national regulation for 'other substances'. To develop the proposed regulation of 'other substances' in Norway, NFSA has been in a close dialogue with Danish

colleagues to gain experience and discuss upcoming questions. Belgium, France and Italy have made a common guidance list (the BELFRIT project) for the regulation of botanicals in food supplements. Spain and some other member states have some national regulation of 'other substances'.

Norway has proposed to regulate nationally the addition of 'other substances' to foods and food supplements. The purpose of the proposal is to reduce health risks that may occur when consuming 'other substances', thus securing safe products on the market. The aim is also to simplify and make the inspections more efficient and uniform, as well as to establish equal competition conditions for the business operators.

The proposal from NFSA is to establish a positive list of 'other substances'. This means that only the substances on the list are allowed to be added to foods and food supplements and the business operators have to fulfill the criteria and conditions in this list. The scope of the regulation includes amino acids, essential fatty acids and miscellaneous bioactive substances, such as caffeine, coenzyme Q10, creatine etc., and does not include plants or parts of plants, microorganisms or novel foods. These substances that are added to foods or food supplements shall be in accordance with purity requirements of at least 50% or be concentrated 40 times or more, analogous to the criteria in the Danish regulation. This positive list is dynamic and it will be updated and modified on the initiative from the business operators. Therefore, the levels of the different substances set out in this list are not necessarily maximum levels, but contain the highest levels on the market today. The business operators may propose a change in the level of a substance listed in the positive list by notifying NFSA or they may send an application to expand the positive list with a new 'other substance' that are not at present listed on the positive list. In both cases, all the information required in Annex 4 of the proposed regulation must be included, and they will have to pay a fee.

The positive list of 'other substances' with maximum levels was based on risk assessments of 44 'other substances' performed by the Norwegian Scientific Committee for Food and Environment (VKM) (see [www.vkm.no](http://www.vkm.no)). VKM identified vulnerable groups in the population, which are protected by labeling communicating that a substance may have a negative health effect for a certain group, for instance, L-tryptophan 'Should not be used by people who take antidepressants'. NFSA hopes to implement this proposal of a positive list of 'other substances' with specific levels into national law in 2019.

## Session 2: Risk assessment of botanicals

### EFSA's work on hazard identification of botanicals

Kirsten Pilegaard, Technical University of Denmark/European Food Safety Authority (EFSA)  
Working Group on Compendium of Botanicals

EFSA's Scientific Committee published in 2004 a discussion paper on botanicals and botanical preparations that expressed concerns about quality and safety issues. The terminology botanicals is covering e.g. whole, fragmented or cut plants, plant parts, algae, fungi and lichens. By botanical preparations are meant all preparations obtained from botanicals by various processes, e.g. pressing, squeezing, extraction, fractionation, distillation,

concentration, drying up and fermentation. Since then, EFSA has published a number of tools to assist risk assessors responsible for the evaluation of botanicals or preparations hereof and to help food manufacturers in their consideration of the safety of ingredients that they may use in their products. In the following, a brief presentation of these tools is described.

In 2009, EFSA published a guidance document for the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. The document describes the scientific data needed to carry out a safety assessment of a botanical or a botanical preparation. It also proposed a two-tiered scientific approach for the safety assessment depending on the available knowledge on a given botanical and the substance(s) it contains. This science-based framework was tested on six examples selected in order to address various safety issues, such as misidentification/adulteration, liver toxicity and possible presence of genotoxic and carcinogenic compounds.

In 2014, EFSA considered the possible application of the Qualified Presumption of Safety (QPS) approach, initially developed for the assessment of microorganisms added to the food chain, for the assessment of botanicals benefiting from a long tradition of use. Unfortunately, the particularity of botanicals that may be presented in a wide variety of forms or whose morphology and chemical composition may be markedly affected by plant part, or geographical and environmental factors, makes the possibility to establish QPS status at high taxonomic levels quite limited.

Additionally, EFSA developed a Compendium of Botanicals reported to contain naturally occurring substances of possible concern for human health when present in food. The Compendium is intended to facilitate hazard identification by providing information on composition, toxicity (including genotoxicity) and reported adverse effects for around 2700 plants. It is not intended to conclude on the safety or non-safety of the listed botanical species or the preparations. The Compendium currently does not include algae, cyanobacteria and fungi. They will be considered for possible inclusion in the future. First and second versions of the Compendium were published in 2009 and 2012. In 2016, EFSA developed a web-searchable version of its Compendium of Botanicals and the information for 900 plants is available at present. Eighteen hundred additional plants are currently being validated and will be added to the database in the end of 2019. Botanicals are listed whether or not they are novel foods.

## Botanicals

Joris Geelen, Food Compliance International PTE LTD

European legislation for food supplements with botanicals is not harmonized and not adapted to meet the particular challenges of these heterogeneous ingredients. Faced with this situation, the Belgian, French and Italian authorities, each assisted by a renowned scientific expert, decided to develop a common approach for the evaluation of botanicals in the 'BELFRIT' project in 2012.

A first step in this initiative was the compilation of a list of plants whose use in food supplements could be possible, provided that the necessary measures to ensure consumer

safety were respected. It provided a precise identification of the plants, indicated some key points in the production to be controlled, while also taking traditional knowledge into account. This harmonized list is a pragmatic tool for risk managers and operators and an important piece of the puzzle for harmonization of this field. A version of the list was adopted in Belgium in 2017, and in Italy 2018. France has not yet adopted this list in their national regulation.

In Belgium, a scientific advisory commission does the risk assessment of food supplements with botanicals. This commission can require the necessary information and analyses and can propose adequate and proportionate measures by requiring mandatory warnings (e.g. for population groups at risk) or with maximum levels for substances of concern or active ingredients. This way the safe marketing of the food products and food supplements can be guaranteed. This information is made public. However, the required data and evaluation methods should be harmonized between member states.

To further enshrine a practical and pragmatic control of food supplements market control is quintessential. In the 'BELFRIT' countries, a digital notification system was introduced which ensures complete traceability. Specific supplements, botanicals or 'other substances' which require a full safety assessment can be filtered out. These systems could be connected to create a network to increase communication and information between authorities.

Further consultation and cooperation have stagnated. Most member states are awaiting the report on the REFIT (the European Commission's regulatory fitness and performance programme) evaluation. A revival of the consultation on the basis of a structural consultation body under the supervision of the EC would be helpful.

### Session 3: Surveys on use of 'other substances'

Children and Youth. Surveys from November 2015 and September 2018 - on consumption and habits related to protein powder, 'health food products' and energy drinks among young people

Gunstein Instefjord, Norwegian Consumer Council

Summaries of surveys from 2015 and 2018 on consumption and habits related to intake of protein powder, 'health food products' and energy drinks among young people were presented. The main findings were:

- Six in 10 aged 10-18 years used protein shake/powder weekly or more often. Fifteen % of boys aged 16–18 years used protein shake/powder daily.
- Seven % of 10-18-year-old youth used herbal and botanical 'health food products'. The number was 12% of 16-18-year-old youth.
- Seven % of 10-18-year-old youth said they used weight loss pills. The number was 12% of 16-18-year-old youth.
- Half of the children and youth aged 10-18 years consumed energy drinks (EDs). Boys drink more than girls, and the proportion of youth that consume EDs increased with age.

- 13-15-year-olds drank EDs more often than the other age groups; 28 % drink EDs 1-2 times a week, compared to 7% and 21% of 10-12-year-olds and 16-18-year-olds, respectively.
- Nearly half of the children and youth have experienced side-effects after drinking EDs. At least one in ten have experienced headaches, hyperactivity, palpitations and tremors, while others have experienced sleep disturbances (17%). More than every fifth (22%) have experienced first high energy and a subsequent sudden drop in energy after drinking EDs.
- Youth in all age groups have drunk EDs to stay awake during school work. This trend increased with age: 15, 21 and 51% in the respective age groups, 10-12-, 13-15- and 16-18-year-olds.

#### Monitoring and control of food supplements in Norway. Results from 2015, 2016 and 2017 Anne Kristi Sommer, Norwegian Food Safety Authority

Since 2014, the Norwegian Food Safety Authority (NFSA) has been analyzing food supplements for illegal and undeclared ingredients. This program, the OK-program, focuses on different product categories every year, such as sports products, products for better joint health, sexual performance, slimming and energy etc.

In the past few years, we have observed an increase in sales of food supplements, online sales in particular. We find that an online sale of supplements is less transparent and more difficult to control. In order to address these challenges and to protect consumers from unsafe food supplements marketed specifically to athletes, we have collaborated with Anti-doping Norway in 2015 and 2016. Anti-doping Norway, with their expertise on the doping scene in Norway, supported NFSA's OK-program.

In 2015, NFSA purchased food supplements for athletes, both online and from physical stores. In total, 116 products were analyzed for drugs and doping substances.

In 2016, NFSA collected 53 products directly from Norwegian companies. Ninety-five products were ordered anonymously online, by Anti-doping Norway. The products purchased were all sports products and many of these were marketed to young athletes.

In 2017, NFSA focused on product categories such as painkillers, products for sexual performance, slimming and energy. NFSA collected 101 products from Norwegian producers and importers.

In addition, NFSA asked the customs to collect 70 products imported for personal use, purchased from foreign companies. The products were analyzed for drugs and other illegal and undeclared ingredients.

Analysis results for products collected in 2015, 2016 and 2017 will be presented.

## Discussions on further collaboration at the Workshop (Day 2 – November 22, 2018)

Twelve persons participated in these discussions, 6 persons from Norway (NO), 3 from Denmark (DK), and one person each from Sweden (SE), Finland (FI) and Iceland (IS), representing both risk assessors and risk managers.

### ‘Other substances’

DK has already a national regulation of ‘other substances’ with a positive list of approved substances.

In NO, a new national regulation of ‘other substances’ is underway and is expected to be implemented in 2019. It will consist of a positive list of approved ‘other substances’ that may be added to food supplements intended for adults over the age of 18 years. Some of the substances will have upper limits, and some will be labelled with warnings for specific vulnerable groups. The Norwegian regulation will be fairly similar to the national regulation in DK.

The new regulation to be implemented in NO is based on risk assessments of 44 ‘other substances’, used in food supplements and/or energy drinks, performed by the Norwegian Scientific Committee for Food and Environment (VKM) during 2015-2017. All these risk assessments, written in English with Norwegian abstract, are available to anybody interested at [www.vkm.no](http://www.vkm.no). NO is prepared to share experiences, documents and advice regarding the risk assessments and implementation of the national regulation of ‘other substances’ with other interested countries.

It is expected that when the new national regulation is implemented in Norway, the business operators, such as producers/importers of ‘other substances’, may apply to the Norwegian Food Safety Authority (NFSA, ‘Mattilsynet’) in order to have new such substances added on to the positive list or to apply for use of higher levels of already approved substances on the list. It was suggested that the work with these new risk assessments could be shared between NO and DK, since DK probably also has applications for updating of their positive list.

In SE, there is no work going on regarding ‘other substances’ for the time being. The same applies for FI, but EU novel food regulation is used actively in the actual control of ‘other substances’ in food supplements.

The authorities in IS do not have any risk assessment activities in this area. For some questions regarding safety of substances, requests are being sent to the University of Iceland. IS also uses existing positive lists, most often from DK. Information and advice are also obtained from the Medicines Agency in Iceland for substances also used as medicines. IS uses information from a database of substances and plants from Canada/USA (link: <https://naturalmedicines.therapeuticresearch.com/>). IS does not have any plans for a national regulation of ‘other substances’.

FI and NO mentioned that the authorities, as well as the business operators, would prefer an EU regulation rather than a common regulation only in the Nordic countries. However, an EU regulation of ‘other substances’ does not seem realistic in the foreseeable future, therefore, national or common Nordic regulations are necessary.

The EU regulation on novel foods could possibly be used more than at present for regulation of 'other substances'. However, this regulation cannot be used for substances that were on the market before 1997, as they are not considered 'novel'. In these cases the fortification regulation (EC) 1925/2006 could be used to restrict or forbid the use of certain 'other substance' in foods, including food supplements. This requires risk assessments demonstrating a human health risk from the consumption of the substance of concern either from member states or the European Food Safety Authority (EFSA). Examples are green tea extracts and monacholin K. The use of these existing EU regulations may be the reason why the EU Commission has not seen the need for separate legislation for 'other substances' in food supplements.

### Maximum levels of vitamins and minerals

Maximum levels of vitamins and minerals in food supplements are not covered in the regulation of 'other substances'. The related topic of establishment of maximum levels of vitamins and minerals was also discussed and compared between the countries.

In NO, the former maximums limits for vitamins/minerals in food supplements were established in the 1980s and they were expelld in 2017. New maximum limits are established for five vitamins and minerals for different age groups. Currently, NO is working on establishing maximum limits for several vitamins and minerals, which are planned to be implemented in 2019.

NO is willing to collaborate and share experiences, documents and advice also within this area with the other Nordic countries.

In SE, work is undergoing on this topics, with the aim to establish national maximum levels for vitamins and minerals in food supplements in the cases where this is deemed necessary.

FI is also interested in establishing maximum levels of vitamins and minerals. FI and SE, who both are in the process of starting work in this area, could collaborate, and also benefit from experience and information from the process just finished in NO on regulation of maximum levels of vitamins and minerals. NO may consider to adjust their national regulation in order to obtain a harmonized regulation in this area in the Nordic countries.

It was informed that also Switzerland has adopted a regulation on the maximum level of vitamins, minerals and 'other substances' in food supplement in 2016 (link: <https://www.admin.ch/opc/de/official-compilation/2017/1285.pdf>).

### Energy drinks

Some of the substances recently risk assessed by VKM in NO are used in energy drinks as well as in food supplements, for instance D-glucurono- $\gamma$ -lactone, inositol, taurine and caffeine. VKM has performed updated assessments of energy drinks and caffeine on request from NFSA, which was published February 1, 2019 (link: <https://vkm.no/download/18.2247e3031686ea532e0e66ec/1548960118318/Energy%20drinks%20and%20caffeine.pdf>).

In SE, a risk assessment regarding caffeine in energy drinks has recently been performed and subsequent risk management decisions have been prepared. The report of this work was finished in December 2018.

## Plants and substances in plants

New uses of traditional plants, or other parts of the plants than traditionally were used, have been a health problem. Examples from DK are rhubarb leaves added to smoothies or recipes in cookbooks suggesting it could be eaten as spinach, and elderberries not being cooked as in traditional use, but used fresh in smoothies and ice-cream.

NO is implementing new national regulations stepwise. Next, NO wants to start to look into the area of plants/plants parts used in food supplements. NO wants to obtain more knowledge in this area. With this, NO can consider how NO thinks this area can be managed.

In the Nordic countries, to begin with, a compilation of all available lists of plants and substances in plants may be obtained and collected together at the same website.

DK has an old list of herbs ('Drogelisten', link: <http://www.food.dtu.dk/english/publications/nutrition/dietary-supplements-and-fortification>). The first list was published in 1989 and it was regularly updated as a booklet until 2000, afterwards more evaluations have been added up to 2011 ('Drogelistens tillæg'). New risk assessments are still performed but the list has not been updated recently. Information can also be found in the EFSA Compendium on Botanicals, which is a comprehensive hazard database of plants (<http://www.efsa.europa.eu/en/press/news/160705>). At present, DK is performing single plant evaluations from specific companies on a case-by-case basis instead of doing generic assessments on the substances, which are labour-intensive and much less efficient.

From a control campaign, DK also collected a list of about 50 plants that could be used in food, as part of the 'new Nordic kitchen'. This list also contains information on plants that can be used in limited amounts in food, or that cannot be used before being approved as novel food, or not being used before safety is documented. This list can be found here (in Danish): [https://www.foedevarestyrelsen.dk/Foedevarer/planteliste/Sider/Plantelisten\\_til\\_erhvervs\\_maessig\\_brug.aspx](https://www.foedevarestyrelsen.dk/Foedevarer/planteliste/Sider/Plantelisten_til_erhvervs_maessig_brug.aspx). Both history of use and safety were taken into consideration. Some substances in plants and in spices are used in food in low doses, but would not be acceptable as food supplements in higher doses. Also a scientific paper on wild and cultivated flowers that can be used in food is published and can be found here: <https://www.ncbi.nlm.nih.gov/pubmed/29981787>. Plants used in liquor were not included in the project. Use in herbal tea only was not considered as food use and was not mentioned in the evaluations.

SE has no national legislation in this area. Risk assessments are done on a case by case basis and most often the EU novel food regulation is being used to control botanicals in food supplements.

FI is using the EU novel food regulation for control of plants in food. FI has compiled an overview of various national lists where it is possible to search the novel food status of different substances/plants: <https://www.ruokavirasto.fi/en/companies/food-sector/production/common-requirements-for-composition/novel-foods/establishing-novel-food-status-of-a-food/>. Additionally, FI has allowed small-scale use (in tea, spices, for decoration) of certain wild plants, if this kind of traditional history of use has been documented. However, if these plants would be used differently than in the traditional way, more widely in several foods or in bigger amounts, a novel food authorization would possibly be required. FI has listed these wild plants in a table, which can be found here: <https://www.ruokavirasto.fi/globalassets/yriytykset/elintarvikeala/valmistus/yhteiset->

[koostumusvaatimukset/uuselintarvikkeet/luonnonvaraisten-kasvien-elintarvikelaytto\\_29092016.pdf](#). FI has also a list of herbal substances that are being used as medicines ([https://www.fimea.fi/web/en/supervision/classification/list\\_of\\_medicines](https://www.fimea.fi/web/en/supervision/classification/list_of_medicines)). Previously, it was written in the legislation that food supplements could not contain substances/plants which were mentioned in the list of medicines, but this changed in 2003 when the Decree concerning food supplements was changed. Now, the herbal list still exists in the list of medicines, but the same plants/herbal substances can be used in foods if they are safe and not novel. FI also has a guideline on insects used as food (<https://www.ruokavirasto.fi/en/companies/food-sector/elintarvikkeiden-alkutuotanto/elaimista-saatavat-elintarvikkeet/insects-as-food/>).

IS uses the Belfrit list of plants as a guideline list, which is adopted in Belgium and Italy, but not yet in France (link for searches: <http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2010&num=249>) and the German stoffliste on pflanzen (link: <http://agendario.forumrio.org/ebooks/download/id=861704&type=stream> or DOI [10.1007/978-3-319-05807-8](https://doi.org/10.1007/978-3-319-05807-8)) for guidance of which plants may be used in food supplements. It is acknowledged that the business operators in Iceland would welcome a regulation specifying the upper levels of 'other substances' and botanicals that can be used in food supplements.

### Suggestions for further Nordic collaboration

It was considered likely that the business operators (producers/importers) of 'other substances' would benefit and want a common regulation at least in the Nordic countries, in the absence of an EU regulation. The authorities in the food area, such as NFSA in NO and the National Food Agency (NFA, 'Livsmedelsverket') in SE, recognize their responsibility to better the situation for the business operators in the area of 'other substances'. The need for this has been emphasized from the authorities both in NO and SE.

NFSA in NO suggested to start a new collaboration in the Nordic countries on regulation of plants and/or substances in plants that may be used in food supplements, recognizing that this area is even more complicated than regulation of other types of 'other substances'.

This collaboration process must start as an initiative of the risk managers in the Nordic countries, who then need to specify what they need from the risk assessors. The purpose of such a collaboration must be that the maximum levels to risk assess are relevant maximum levels in all the participating countries, so that new national risk assessments would not be necessary. This information must be obtained and made available before any work on risk assessments can start.

It could be a good idea to first collect information about which plants are used in supplements sold on the Nordic market, and to start to assess these. Useful information regarding this could be obtained from notification systems that are in place in some Nordic countries, for instance in FI.

DK suggested that another way to simplify this work is to start to identify all plant substances that are genotoxic and evaluated to be probable human carcinogens, since these will not be allowed on a positive list. Plant containing substances with chemical groups that are genotoxic will quickly be eliminated from use without need for further assessment. Genotoxic substances are also found in some spices. This work should not start with the most challenging

cases, but with substances such as pyrrolizidine alkaloids, aristolochic acids, ptaquiloside or furocoumarins.

It will be important that all finished risk assessments are made available to all participating Nordic countries. They will also be of large interest to other European countries who are in the same situation struggling with implementing national risk assessments and regulations of 'other substances' and botanicals with limited human and economic resources, as well as for EFSA. Therefore, all risk assessments should ideally be written in English, with abstracts in the respective Nordic languages, or be made available also in English. As it has been the situation for instance in DK, risk assessments only written in the national language constitute a barrier for further Nordic and European collaboration. All outcomes of such a collaboration project must be openly available on a specified website.

Funding may be tried obtained from the Nordic Council for the cost of this collaboration. The next deadline for applications is in February 2019. Such a Nordic collaboration may also be a basis for even larger research applications from EU in the future.

To be successful with a future Nordic collaboration in this area, the risk managers and risk assessors, respectively, must collaborate closely within each country. An excellent example is the way new requests of risk assessments from NFSA to VKM in NO are being thoroughly discussed before the work starts, in order for the outcome documents to be useful and fit for purpose.

#### Actions taken to continue the collaboration

- The **presentations** from Day 1 of the workshop will be sent to all participants.
- A **contact list** of participants will be collected and distributed, in order to keep each other informed about plans for new risk assessments, new regulations or inspections and market surveys, and benefit from each other's experience on already finished projects.
- The most important immediate action is to arrange a **meeting with risk managers** from each Nordic country to discuss and make decisions on how to proceed with this collaboration.
- A **follow-up workshop** in this area could be arranged in a few years.

The immediate action for all participants was to identify at least one risk manager at their institution that has the authority to make decisions on how to proceed with a Nordic collaboration in this area. Their contact details should be sent to the Norwegian Food Safety Authority in Norway, who has kindly accepted to be responsible for inviting these persons to a meeting to start the discussions on further collaboration. The meeting should preferably be held at the beginning of 2019, in order to have the possibility to apply for funding for this collaboration from the Nordic Council (deadline in February 2019).

The topic of food supplements is of large interest also to the general public and the media. To disseminate the outcome of the project and workshop also to a wider audience, information was made available on the participating institutions' websites. Further risk assessments as a result of this cooperation will be available nationally and internationally as risk assessment reports.

## Conclusions

It was clear from the talks during the first day and the discussions on the second day of the workshop that the Nordic countries have already or are planning to start to work on many of the same topics. From this project, Nordic experts involved in risk management and risk assessment of 'other substances' have increased knowledge of this subject and about what is going on in this area in each of the Nordic countries. Through the obtained contact list of participants from all the Nordic countries, as well as Belgium, Germany and the Netherlands, they are now part of a useful network of people working in this field. More collaboration in the future will increase the common capacity for risk management and risk assessment of these substances in the Nordic countries. An initiative is well underway planning the next meeting to continue this collaboration.

## Appendices

Appendix A. Programme for Nordic Workshop ‘Safer food supplements in the Nordic countries’, Oslo, November 21-22, 2018



Norwegian Institute of Public Health

# Nordic workshop on ‘other substances’ – ‘Safer food supplements in the Nordic countries’

**Day 1: Wednesday, November 21, 2018, Oslo**

**Location: Nationaltheatret Meeting Center KS Agenda Meeting Center, Room Lindesnes, Haakon VII's street 9, 0161 Oslo (<http://www.ksagenda.no/en/>)**

**09.00 – 10.00: Registration and coffee**

**10.00 – 10.15: Welcome and introduction**

Inger-Lise Steffensen ([inger-lise.steffensen@fhi.no](mailto:inger-lise.steffensen@fhi.no))

Norwegian Institute of Public Health/The Norwegian Scientific Committee for Food and Environment (VKM)

***Session 1: Risk assessment and risk management of ‘other substances’ in the Nordic countries***

**10.15 – 11.00: The national regulation of ‘other substances’ in Denmark**

Kirsten Pilegaard ([kpil@food.dtu.dk](mailto:kpil@food.dtu.dk))

DTU Food, National Food Institute, Technical University of Denmark

*DTU Food provides risk assessments on ‘other substances’ and botanicals used as ingredients in food supplements as part of its consultancy within food safety to the Danish food authorities. The presentation will include an introduction to the regulation on ‘other substances’ and some examples of risk assessments performed on ‘other substances’ and botanicals.*

**11.00 – 11.45: Regulatory framework of "other substances" in food supplements in Finland and risk profile of plant food supplements**

Tero Hirvonen ([tero.hirvonen@evira.fi](mailto:tero.hirvonen@evira.fi))

The Finnish Food Safety Authority Evira

*Tero Hirvonen is a senior researcher in Risk assessment Research Unit in the Finnish Food Safety Authority. He has been the first author in Risk profile of plant food supplements.*

**11.45 – 12.30: Risk assessment of 44 'other substances' by the Norwegian Scientific Committee for Food and Environment (VKM)**

Inger-Lise Steffensen ([inger-lise.steffensen@fhi.no](mailto:inger-lise.steffensen@fhi.no))

Norwegian Institute of Public Health/Norwegian Scientific Committee for Food and Environment (VKM)

*Inger-Lise Steffensen is a senior scientist at the Norwegian Institute of Public Health and Chair (2010-2018) of the Panel on Food additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics, in the Norwegian Scientific Committee for Food and Environment (VKM). This panel carried out these risk assessments of 'other substances' together with the Panel on Nutrition, Dietetic Products, Novel Food and Allergy in VKM.*

**12.30 – 13.30: Lunch**

**13.30 – 14.15: Proposal for a new national regulation of 'other substances' in Norway**

Merethe Steen ([Merethe.Steen@mattilsynet.no](mailto:Merethe.Steen@mattilsynet.no))

The Norwegian Food Safety Authority (NFSA, Mattilsynet)

*NFSA believes that the addition of 'other substances' is not adequately regulated within the EU/EEA countries. NFSA has recently sent a draft regulation on public consultation where it is suggested to regulate 'other substances' in food supplements/foods. NFSA wishes to regulate 'other substances' to reduce health risks, increase the consumer protection, to simplify and make the inspection more efficient and to equal conditions of competition for the business operators.*

**Session 2: Risk assessment of botanicals**

**14.15 – 15.00: EFSA's work on hazard identification of botanicals**

Kirsten Pilegaard ([kpil@food.dtu.dk](mailto:kpil@food.dtu.dk))

DTU Food, National Food Institute, Technical University of Denmark

*Kirsten Pilegaard is a member of EFSA's Working Group on Compendium of Botanicals. Since its creation in 2002, EFSA published a number of guidance documents to assess the safety of botanical materials and preparations used i.a. in foods and food supplements. These tools are*

intended to facilitate the hazard identification of plant-based products by listing the data and information needed for the assessment, and by providing information on plant composition of relevance when assessing the safety of the final product that will be put on the market.

### **15.00 – 15.45: Botanicals**

Joris Geelen ([joris.geelen@FOODCOMPLIANCEINT.COM](mailto:joris.geelen@FOODCOMPLIANCEINT.COM))

Food Compliance International

*When working at the Belgium Ministry of Health, Joris Geelen together with the authorities of France and Italy started the harmonization project on botanicals called Belfrit. He was later responsible for the notification of a Belgian decree to the European Commission to update the decree on botanicals in Belgium. Now he is working as a Food Regulatory Expert with expertise in scientific and regulatory aspects of botanicals in food, supplements and other products in the company Food Compliance International.*

### **15.45 – 16.15: Coffee break**

**Session 3: Surveys on use of 'other substances'**

### **16.15 – 17.00: Children and Youth. Surveys from November 2015 and September 2018 - on consumption and habits related to protein powder, «health food products» and energy drinks among young people**

Gunstein Instefjord ([Gunstein.Instefjord@forbrukerradet.no](mailto:Gunstein.Instefjord@forbrukerradet.no))

Norwegian Consumer Council

The Norwegian Consumer Council has done a survey on the use of sports products among adolescents and is now doing new surveys of attitudes, knowledge and intake of energy drinks among children and adolescents.

### **17.00 – 17.45: Monitoring and control of food supplements in Norway. Results from 2015 - 2017**

Anne Kristi Sommer ([Anne.Kristi.Sommer@mattilsynet.no](mailto:Anne.Kristi.Sommer@mattilsynet.no))

Norwegian Food Safety Authority (NFSA, Mattilsynet)

*NFSA carried out a monitoring and control program, in collaboration with the Norwegian customs, who collected 70 food supplements imported for personal use, purchased from foreign companies. The analyzes of these products revealed presence of illegal substances, such as medicines, anabolic steroids and herbs classified as medicines and drugs.*

## Day 2: Thursday, November 22, 2018, Oslo

Location: Nationaltheatret Meeting Center KS Agenda, Room Fredriksten, Haakon VII's street 9, 0161 Oslo (<http://www.ksagenda.no/en/>)

### *Session 4: Discussions of how to collaborate on 'other substances' in the future*

*Overall aim: A cooperation and sharing of knowledge, methodology and risk assessments of 'other substances' through a Nordic network will benefit and strengthen the cooperation between the Nordic countries in this area of consumer safety. Thereby, we will contribute to development of national regulations of 'other substances' and to safer food supplements in the future.*

## Suggested agenda

### **09.30 – 10.30: Group discussions**

*We will exchange views on how we can collaborate in the future on risk assessment and risk management of 'other substances'*

### **10.30 – 11.30: Plenary presentations of group discussions**

**11.30 – 12.00: Summary of suggestions for future collaboration on 'other substances' and concluding remarks**

**12.00 – 13.00: Lunch**

**Goodbye and safe journey home!**

Appendix B. Contact list.

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