Sea buckthorn leaves and the process of novel food evaluation

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What is novel food? Regulation from the year 1997

- It is food that hasn't been used for human consumption to a SIGNIFICANT DEGREE within the Union before the date of entry into force of Regulation on novel foods and novel food ingredients (EC) 258/97, which is 15 May 1997, and is
  - Genetically modified food -> got its own regulation on 2003 (EC) 1829/2003
  - Food with a new or intentionally modified molecular structure
  - Food from microorganisms, fungi or algae
  - Foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices **and having a history of safe food use**
    - *For example Stevia leaves are not accepted as food, because no history of use in EU, and not even as novel food because safety assessment has been insufficient*

What is novel food? Regulation on novel foods (EU) 2015/2283 that comes into force 2018

- It is food that hasn't been used for human consumption to a SIGNIFICANT DEGREE within the Union before the date of entry into force of Regulation on novel foods and novel food ingredients (EC) 258/97, which is 15 May 1997
  - BUT if the food has history of use outside EU (have been consumed in at least one third country for at least 25 years as a part of the customary diet of a significant number of people) -> considered as traditional food
  - Food with a new or intentionally modified molecular structure
  - Food from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae
  - Food from microorganisms, fungi or algae
  - Food from material of mineral origin
  - Food consisting of engineered nanomaterials
  - Food from animals that are not produced by traditional breeding practices

What is novel food? Regulation on novel foods (EU) 2015/2283 that comes into force 2018

continues…

- **Food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union** and the plant is produced by traditional propagating practices or non-traditional, but without changing the composition of the plant

Why to even think about that sea buckthorn leaves could be novel food?

- If a food was commercialised in at least one Member State before 15 May 1997, it can be marketed elsewhere in the EU under the 'principle of mutual recognition' and the Novel Foods Regulation does not apply.
  - If we can find significant history of use before 1997 in EU, then we have to show this data to authorities and they evaluate if it is traditional food
  - If there hasn't been significant food use, then in order to get it legally on the EU market as a food, application with safety assessment needs to be done

Sea buckthorn leaves: history of use before 1997 and to date

Before 1997 in EU

- Animal feed in ancient Greece (legend that can't be proved, I guess)
- Is there any tea use before 1997? In Baltic countries common use and commercialisation started in the beginning of 21st century. When it was used in Hungary? When it was used in Germany?
- No other use (?)

After 1997 in EU

- Use as a tea in several countries, can be found from stores
- Any other use?

Sea buckthorn leaves: history of use before 1997 and to date

continues…

Outside EU

- East Asia
  - No much information about ancient use of leaves. The main product has been berry and its juice and oil.
- Russia or former Soviet Union
  - Giporamin (=Hiporaminum, an antiviral medicine made of dry purified extract from SBT leaves, patent from the year 1994)
  - Several patents about leaves: SBT leaf oil, granulated tea, method for serotonin, non-alcoholic beverage
  - Use as a tea

-> if SBT leaves have been used, they have been used more for medicinal purpose than for food use

Sea buckthorn leaves: use in the future?

- **Animal feed** -> Reg. (EC) 767/2009 on the placing on the market and use of feed
- **Cosmetics** -> Reg. (EC) 1223/2009 on cosmetic products
- **Food additive** -> Reg (EC) 1333/2008 on food additives
- **Food supplement** is regulated as food -> Novel Food regulation and Directive 2002/46/EC relating to food supplements
- **Food and food ingredient** (tea, green powder for smoothie and bread…) -> Novel Food regulation
- What else?

Process of novel food evaluation

- Novel Food Catalogue

Novel food catalogue

Search

ALL TOPICS

Hamamelis virginiana
Harpagophytum procumbens
Helianthus annuus
Hesperidin
Hibiscus esculentus
Hieracium pilosella
Hippophaë rhamnoides
Hirneola polytricha
Hizikia fusiforme
Hoodia gordonii
Hordeum vulgare
Hovenia dulcis
Hydnum repandum
Hydrocotyle asiática
Hydroxy Citric Acid
Hygrophorus camarophyllus
Hylocereus megalanthus
Hylocereus undatus
Hypoxis hemerocallidea
Hypoxis rooperi
Hyssopus officinalis

Hippophaë rhamnoides

Common Names

Seabuckthorne, Sea buckthorn (EN), Gemeiner Sanddorn, Sanddorn (DE), Duindoorn (NL), Argousier, argounnier (FR), Rokitnik zwyczajny (PL), Espinheiro-maritímo (PT), Tyrni (FI), Harilik astelpaju (ET), Rakytník řešetlákový (CZ), Espino falso (ES), Homoktövis (HU), ιπποφαές το ραμνοειδές (EL), Parastais smiltsērkšķis (LV), Navadni rakitovec (SL), Havtorn (SE, DK), Облепиха (RU), シーバックソーン（スナジグミ）(JP)

Common Names

Hippophaë rhamnoides (sea-buckthorn) belongs to the Elaeagnaceae family. It is native to northwestern Europe through central Asia to the Altai Mountains, western and northern China, and the northern Himalayas. The berries have been used in making juice and jam. Fruits may be picked from the bushes at any time between late autumn and early spring. Seeds may be extracted by running the wet fruits through a macerator and removing the pulp. The fruit is mentioned in directive 93/77/EC concerning fruit juice. **Only the use of the fruits (berries) of *Hippophae rhamnoides* as food or food ingredient is known in the EU.**

Status

What does it mean?

Last update: 30.07.2015 | Legal notice | Contact

Process of novel food evaluation
continues…

- If no history of consumption can be proved, then the food or food ingredient cannot legally be marketed in the EU until the necessary authorisation has been issued.
- **A novel food application is first made to a single EU Member State**. Scientific information and safety assessment report has to be submitted.
- The Member State has 90 days to produce an initial opinion. This opinion is then **circulated to all EU Member States**, who are then given a further 60 days to comment or make a reasoned objection. If there are no objections, the novel food will be authorised (or rejected) at the end of the 60 days in line with the initial opinion. **If necessary, the European Food Safety Authority (EFSA) will first be asked for its opinion** on any outstanding safety questions.

Process of novel food evaluation
continues…

Novel food application has to include (according to draft guidance 1 Feb 2016)

- description of the product
- production process
- characteristics and composition
- proposed uses and use levels
- anticipated intake
- history of its use
- absorption, distribution, metabolism, excretion
- nutritional and toxicological information
- allergenicity

Safety assessment is the most expensive part if not enough proper research results are already available

Examples of novel food evaluation:
Coriander seed oil -> authorised novel food on 2013
http://www.efsa.europa.eu/en/efsajournal/pub/3422

EFSA Journal 2013;11(10):3422

SCIENTIFIC OPINION

Scientific Opinion on the safety of "coriander seed oil" as a Novel Food ingredient[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on "coriander seed oil (CSO)" as a novel food ingredient (NFI) in the context of Regulation (EC) No 258/97. Petroselinic acid (PA) is the major fatty acid in CSO. Conventional edible oil technologies are used to manufacture the NFI. The NFI is intended to be marketed as a food supplement for healthy adults, at a maximum level of 600 mg per day (i.e. 8.6 mg/kg bw per day for a 70 kg person), which would lead to significantly higher intakes of CSO and PA than current background intakes. There are no safety concerns regarding genotoxicity. In rats fed high amounts of CSO, increased liver weight, marked to severe fat infiltration in the liver, and lower tissue arachidonic acid concentrations were observed. In the same study, similar affects were observed when feeding other vegetable oils, although not as severe as that seen for CSO. The dose level of CSO was more than a thousand fold higher than the proposed use level. In a subchronic study using 150, 450 or 1 000 mg/kg bw per day of CSO, a treatment-related effect was observed on blood glucose concentrations of male rats. Although this effect was not accompanied by any toxicological findings, its biological relevance is unclear and therefore the Panel considers the dose level of 450 mg/kg bw per day to be the NOAEL in rats. This is more than 50 fold higher than the proposed use level. No treatment-related adverse effect was observed in one human study using the NFI at the proposed use level for six months. The Panel concludes that the novel food ingredient, CSO, is safe under the proposed uses and use levels.

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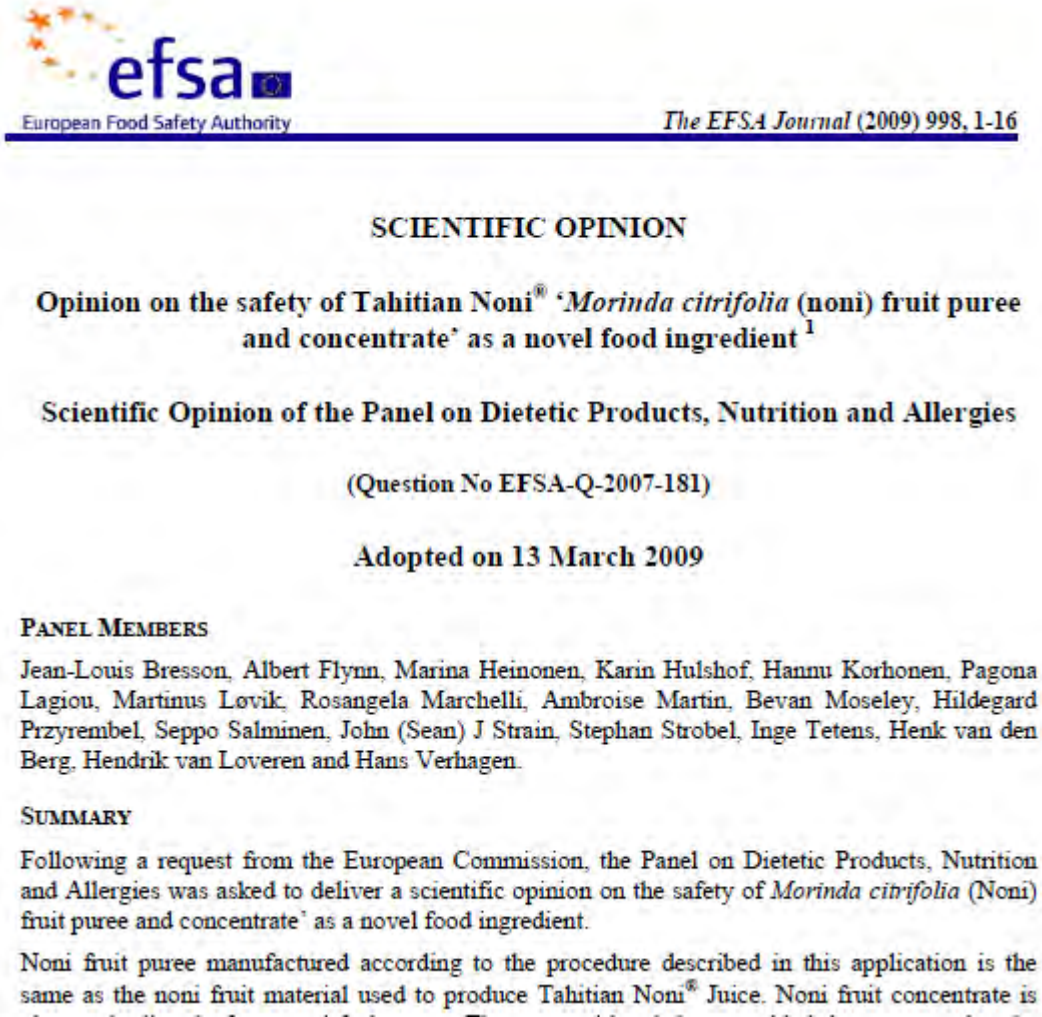
Examples of novel food evaluation:

Noni fruit puree and concentrate -> authorised novel food on 2009

http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2009.998/epdf



efsa
European Food Safety Authority

The EFSA Journal (2009) 998, 1-16

SCIENTIFIC OPINION

Opinion on the safety of Tahitian Noni® '*Morinda citrifolia* (noni) fruit puree and concentrate' as a novel food ingredient [1]

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2007-181)

Adopted on 13 March 2009

PANEL MEMBERS

Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Karin Hulshof, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Hildegard Przyrembel, Seppo Salminen, John (Sean) J Strain, Stephan Strobel, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver a scientific opinion on the safety of *Morinda citrifolia* (Noni) fruit puree and concentrate' as a novel food ingredient.

Noni fruit puree manufactured according to the procedure described in this application is the same as the noni fruit material used to produce Tahitian Noni® Juice. Noni fruit concentrate is

*Noni **juice** was accepted as novel food on 2002 -> Safety questions on possible hepatotoxic effects on 2006 -> Safety assessment of Noni **puree** and **concentrate** accepted on 2009*

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Open questions

- ***Is it worth to apply traditional food/ novel food status to sea buckthorn leaves?*** *It has a great potentiality as a super food/feed/cosmetics/additive... Other uses than as food would be easier to authorise, but safety assessment needs to be done in any case.*
- ***If it is worth to apply, who would do it?*** *The safety research is costly, but would be beneficial to all forms of use of SBT leaf*
- ***If the status is applied for tea and green powder, for example, how much it helps to any entrepreneur who has a product that is different to those?*** *At least the application would be easier when safety information is already compiled at some point.*
  - *Can we find financing to have a common European project to solve this novel food problem?*

Thank you!

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