

**Van:** 10.2.e  
**Aan:** 10.2.e @ec.europa.eu"  
**Cc:** 10.2.e

**Onderwerp:** RE: Austria - Additional items for Agenda / Working Group Novel Food January 25th 2013  
**Datum:** maandag 21 januari 2013 10:12:44  
**Bijlagen:** [image001.gif](#)  
[ATT00001.txt](#)  
[ATT00002.htm](#)

Dear Colleagues,

I have spoken with a company that were interested to seek a substantial equivalence for an egg product. My own initial view of the product is that it does not fall within the scope of Regulation EC No 258/97, but I would also like views from other Member States either by return email or when I raise it under AOB at Thursday's Working Group meeting in Brussels.

The product description by the company is given below:

10.1.c jo. 10.2.g is produced from intact, isolated 10.1.c jo. 10.2.g treated with a mixture of commonly-used food-grade hydrolases. 10.1.c jo. 10.2.g is intended to be used as a (relatively Trp-rich) source of amino acids in various product applications up to 4 g/day.

In my view the source 10.1.c jo. 10.2.g is not new and therefore the same amino acids are already available on the market in protein/peptide form. The enzymes used to break down the 10.1.c jo. 10.2.g to amino acids are commonly used apparently and therefore I cannot see a reason why this product would be in anyway novel, but I would appreciate any other views.

Regards,

10.2.e

10.2.e

Food Safety Authority of Ireland  
Abbey Court  
Lower Abbey Street  
Dublin 1

Tel: 10.2.e

Fax: 10.2.e

[www.fsai.ie](http://www.fsai.ie)

[www.facebook.com/FSAI](https://www.facebook.com/FSAI)

**From:** 10.2.e @bmg.gv.at]

**Sent:** 18 January 2013 11:33

**To:** 10.2.e @ec.europa.eu'

**Cc:** 10.2.e

10.2.e

**Subject:** Austria - Additional items for Agenda / Working Group Novel Food January 25th 2013

Dear 10.2.e,

Dear Colleagues,

As we informed 10.2.e already, we would like to put these topics on the agenda of the meeting „Working Group Novel Food“ on January 25<sup>th</sup> 2013.

- **Stevia rebaudiana:** Receipt of documents – preliminary views of Austria under “item 3 – Novel Food Catalogue”
- **Cistus incanus:** Request to all Member States (especially Italy “Gazzetta Ufficiale della Repubblica Italiana 2012”) under “item 3 – Novel Food Catalogue”
- **Standing Committee on the Food Chain and Animal Health, Section “General Food Law”:** Transmission of documents “Commission Implementing Decision” – Improvement of processes in preparation of the Standing Committee under “item 7 – Any other Business”

See you next week!

Best regards,

10.2.e

Ernährung, besondere Waren und Internationale  
Lebensmittelanlagen

10.2.e



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**Van:** 10.2.e  
**Aan:** 10.2.e @fsai.ie"  
**Cc:** 10.2.e 10.2.e  
**Onderwerp:** comments on 10.1.c jo 10.2.g  
**Datum:** donderdag 31 januari 2013 12:36:08

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Dear 10.2.e,

Unfortunately there wasn't enough time to present our view in the CAFAB meeting last Friday about the hydrolyzed 10.1.c jo 10.2.g. The information you provided was limited to only a short description, which makes it difficult to make up our mind. However, I have listed below some thoughts to take into consideration.

- Novelty and safety should not be mixed up. Whether a product is novel or not, depends on its history of consumption prior to May 1997. If one concludes that a product is safe, this in itself doesn't justify that it is not novel.
- It is an isolated ingredient from a common food. Furthermore, it is not clear if the enzyme is partially or fully hydrolyzed and whether the subsequent process includes a selective enrichment of certain components?
- Is the product meant to be 'just' an alternative source of protein or amino acids? From a nutritional point of view, however, it seems rather a special preparation rich in Trp. Moreover, consumption of a hydrolyzed polymer (enzyme) is not the same as consumption of the intact molecule.
- Is the proposed intake of (hydrolyzed) lysozyme higher compared with the usual intake of lysozyme in the normal diet? Is such an increase considered significant? Our Czech colleague, 10.2.e mentions an over 3-fold increase.

Generally speaking:

When a component increases by a factor greater than 'x' relative to that in the original food, we consider the change significant and thus the food 'novel'.

In the CAFAB meeting you addressed this fundamental issue when discussing the increased vitamin D- content (three dossier on UV-treated products). We have discussed this topic quite often with our experts and it is also addressed in a more general report on the framework of the Novel Food assessments, available via <http://www.cbg-meb.nl/NR/rdonlyres/1EF92245-A37A-4D80-B3E8-62DBE3F7AA57/0/veiligheidsbeoordelingNV.pdf>, see first paragraph of section 4.2 on p.97)

Sorry, that I cannot give you a simple answer as it differs from case-by-case.

- Safety information of normal eggs can provide a basis for an authorisation application

Beste wishes,

10.2.e

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De: 10.2.e @fsai.ie]

**Objet :** RE: Austria - Additional items for Agenda / Working Group Novel Food January 25th 2013

Dubbel zie doc.

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**Van:** 10.2.e  
**Aan:** 10.2.e @nutriclaim.com"  
**Cc:** 10.2.e  
**Onderwerp:** Re: Non-novelty 10.1.c jo. 10.2.g  
**Datum:** vrijdag 12 april 2013 11:09:59  
**Bijlagen:** image003.jpg

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Dear 10.2.e ,

Having read your message, I suggest you contact me by phone preferably on thursday 18 April in the morning. Hopefully, this suits you.

Kind regards,

10.2.e

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**Van:** 10.2.e @nutriclaim.com]  
**Verzonden:** Friday, April 12, 2013 09:18 AM  
**Aan:** 10.2.e  
**Cc:** 10.2.e @fsai.ie  
**Onderwerp:** Non-novelty 10.1.c jo. 10.2.g

Dear 10.2.e ,

As a brief introduction, my name is 10.2.e and I work as a consultant in Nutrition & Regulatory Affairs.

10.1.c jo. 10.2.g

10.2.e 10.1.c jo. 10.2.g

Following the CAFAB meeting of January 25<sup>th</sup>, you as well as your Czech and French colleagues raised a couple of issues which I subsequently addressed in the document that I herewith attach again.

Recently, you have indicated to 10.2.e that you might consider 10.1.c jo. 10.2.g a novel food. As a matter of fact, The Netherlands is the only Member State (MS) to take this point of view, whereas the not novel status of 10.1.c jo. 10.2.g is endorsed by all the other MS.

Besides your consideration that the 10.1.c jo. 10.2.g might be a novel food, I am not aware of the arguments which have led you to come to this conclusion. I regret that as it does not allow me to specifically consider and address the key issues that you have.

It is therefore that I would be much obliged if we could have a meeting or telephone conference in which we could discuss this matter. I expect that such a meeting or telephone conference would not take more than one hour, probably even (much) less.

For that matter, I will contact you by telephone next week.

Kind regards,

10.2.e

Senior Consultant

Beschrijving: NC logo8x2cm



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Aan: 10.2.e [REDACTED]  
Cc: 10.2.e [REDACTED]@fsai.ie; 10.2.e [REDACTED]@fsai.ie>  
Onderwerp: Non-novelty 10.1.c | o 10.2.g [REDACTED]

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