

**AXON**  
science based lawyers

PIKED LEADERS  
IN THE FIELD  
CHAMBER OF EUROPE 2014

## ALTERNATIVE SOURCES OF PROTEIN

health  
food  
technology

Alternative Sources of Protein  
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### Introduction Axon Lawyers

**AXON**  
science based lawyers

- Amsterdam based law firm with international focus
- Fully dedicated to life sciences, familiar with food business
- Assisting high tech companies bringing innovative food products to the market
- Reporting current food law developments at blog FoodHealthLegal

 **Food Health Legal**  
legal and regulatory blog

### Agenda

- Rationale for this seminar
- Legal framework alternative protein products
- Examples
- Implications of Novel Foods legislation



### Rationale for this seminar (1)

Reason # 1 to eat less meat: **Health**

- **Scientific report WHO** (26 October 2015)  
*Consumption of processed meat increases colon cancer risk.*
- Dutch Health Council, **Guidelines Healthy Food** (4 November 2015):  
*Promotes a diet containing more plant based than animal based proteins.*



## Rationale for this seminar (2)

Reason # 2: to eat less meat: **Sustainability**



- Current food production methods require too much natural resources to be sustainable in 2050 (expectation: 9 billion people to feed).
- In-balance in consumption: > 1 billion people overweight, 800 million people undernourished.
- Increased prosperity → increased meat consumption, e.g. in China (1,3 billion inhabitants vs. 500 million inhabitants in Europe)

## Rationale for this seminar (3)

Reason # 3: to eat less meat: **Animal welfare**

- Although breeding of animals is regulated and well-being of animals is controlled, bottom line: less animal consumption is less animals killed.
- Outbreak of infectious diseases resulted into massive slaughter of animals, e.g. swine fever and mad-cow disease.
- Today, many meat alternatives.



## Legal framework alternative protein products (1)



- Novel Foods legislation is applicable framework for many protein rich products.
- **What are Novel Foods?** Food products that have not been used for human consumption to a *significant degree* within the EU prior to 1997.
- Cut-off date refers to current Novel Foods Regulation → in need of reform for several reasons:

- (1) streamlining authorisation procedure;
- (2) keeping up with technological & scientific developments;
- (3) facilitating introduction of traditional foods from third countries into EU.

## Legal framework alternative protein products (2)

**Revision NF-Regulation in a nutshell**



- December 2013: Commission proposal
- 16 November 2015: EP proposal accepted by Council
- Entry into force: publication in OJ + 20 days (early 2016)
- Date of application: 2 years after entry into force (*transition regime*)

## Legal framework alternative protein products (3)

Major changes of new NF-Regulation comprise:

- (1) one centralized procedure for NF assessment and authorisation;
- (2) simplified procedure for marketing traditional foods from third countries;
- (3) Definition of "Novel Food" considerably broadened: 4 → 10 categories



## Legal framework alternative protein products (4)

Centralised procedure for NF assessment & authorisation



- Pre-market authorisation requested directly from the Commission instead of from the MS authorities.
- If Commission requests safety opinion → EFSA shall render such opinion within 9 months from request.
- Publication of draft authorisation decision within 7 months of EFSA opinion.
- System of individual authorization replaced by system of generic authorizations
- Simplified procedure based on *substantial equivalence* will cease to exist.

## Legal framework alternative protein products (5)

Simplified procedure for marketing traditional foods

- History of safe use in a non-EU country for > 25 years should be demonstrated.
- Authorization if within 4 months after notification to Commission, no reasonable safety objections are received → Union list.
- Any safety objections? → EFSA opinion requested within 6 months of valid application.
- Commission shall publish draft authorisation within 3 months after publication of safety opinion.



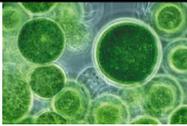
## Legal framework alternative protein products (6)

Broadened product definition of Novel Food, including

- food consisting of or isolated / produced from:



### Examples: algae (1)



- Algae are explicitly mentioned as being Novel Foods
- 2 granted authorisations for algae based products (algal oil)
- Many algae already marketed in EU prior to 1997. Examples include:
  - Chlorella pyrenoidosa (sorokiniana)*  Not subject to Novel Food legislation
  - Laminaria digitata*  Not subject to Novel Food legislation
  - Rhodomenia palmata*  Only used as a food supplement in the EU prior to 1997

### Examples: algae (2)

- EU Novel Foods Catalogue  
[http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/mod\\_search/index.cfm](http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/mod_search/index.cfm)
-  History of safe use; no NF authorization required
-  Only use as food supplement is known; NF authorization required
-  No history of safe use apparent from previous application: NF authorization required
-  Further information required

### Examples: algae (3)

The Dutch Weed Burger also contains 2 types of algae:

- burger → Royal Kombu (*Laminaria saccharina*)
- bun → *Chlorella sorokiniana* (+ soy snips)

Both types of algae have a history of safe use in Europe predating 1997 → outside the scope of the Novel Foods legislation.




### Examples: cultured meat burger

"Mark Post" burger is a typical Novel Food.

- Maastricht Prof. produces meat from cow cells outside the cow.
- He takes a few cells from a cow that divide by themselves, provides anchor points that will grow into muscle.
- Such high tech product will need to obtain NF clearance. And the Professor knows about it.





## Examples: MushroomMeat



### MushroomMeat

- Combination of mushroom mycelium (roots & stems) + substrate (growth medium).
- Mycelium is more concentrated than mushroom fruit body and can be quickly cultivated (2 > 5 weeks).
- Various sorts of substrate are possible to vary in taste, such as grains, carrots, pumpkin, shrimps shells or oat.
- Sterile production process is based on solid state fermentation.
- However this production process is new → safety must be confirmed on the basis of a NF-authorisation.

## Examples: insects

- **New:** insects are considered Novel Food ingredients under new NF-Regulation.
- Contrary to practise in various Member States: Belgium and Holland

Table 1. Insects for human consumption in the Netherlands

Latin name	Dutch name	Common English name	Stage of development	Quantities produced
<i>Tenebrio molitor</i>	Meeltor	Mealworm beetle	Larva	approx. 1500 kg/year
<i>Alphitobius diaperinus</i>	Piepschuimkever	Lesser mealworm beetle	Larva	approx. 1000 kg/year
<i>Locusta migratoria</i>	Europese treksprinkhaan	Locust	Adult	approx. 45 kg/year (25,000 animals each weighing 1.8 gram)



## Europa dreigt met halt productie en verkoop eetbare insecten

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 Laatste update: 07 oktober 2015 16:37



Het Europees Parlement dreigt de productie en verkoop van producten met insecten een halt toe te roepen. De Federatie Nederlandse Levensmiddelen Industrie (NFLI) noemt dit 'een stap terug' in de verduurzaming van ons eten.

## Examples: insects

EFSA scientific opinion 8 October 2015:

- a. production method
- b. the substrate used
- c. stage of harvest
- d. insect species and
- e. method of further processing



Relevant for risk evaluation → currently only limited data available → further research recommended.

- No immediate safety concerns. Shouldn't insects be considered 'safe' under food law?
- 'Safe' in food law means: food is safe until unsafely has been found.

## Implications of NF-legislation (1)

### Implications depend on type of product

- Cultured meat burger and MushroomMeat will definitely be subject to NF-authorization procedure.
- Algae products may not need authorisation at all, depending on type.
- For insect products, a distinction should be made for products marketed now and in future.

## Implications of NF-legislation (2)

### Insect based products and transition regime



- Products currently marketed do not need to be removed from market.
- However, for continued marketing an authorization should be requested before 2 years after the **date of application** of the new NF-Regulation.
- Also, future insect based products will – according to the new Regulation also need to request a market authorization.
- In this in line with created expectations at national levels?

## Implications of NF-legislation (3)

### Requirements authorization procedure

In future, authorizations will be generic → check Union List.

No third party authorizations? → individual application for authorization need to be filed substantiating the following.

- specification of the Novel Food
- effects of the applied production process
- background info on source of Novel Food
- expected uptake / frequency of use
- nutritional value
- microbiological information
- toxicological information

## Conclusions

1. Begin with the end in mind: before manufacturing and marketing an alternative protein product, know its regulatory status.
2. If the product/ingredient of your choice falls within the NF-legislation, pick the one for which a history of safe use exists (e.g. algae).
3. If no history of safe use exists, check the future Union List for third party authorizations.
4. Only when no third party authorizations have been published, you should file an application for NF-authorisation.

