# New Food Ingredients
# US and EU Requirements and Strategic considerations
# EU regulations

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# What does “new” mean

- New food = new composition / new recipe
- New Ingredient
- New substance
- **Novel food** = Not consumed as a food before 15 May 1997 : subject to pre-market approval
  - Reg 258/97 until 31 December 2017 : http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01997R0258-20090807&qid=1492447204879&from=EN
  - Reg 2015/2283 as of 1st January 2018 : http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&rid=1

# Novel Food / Novel Ingredient

The new regime as of January 2018 :

. All « novel foods » authorized since 1997 will be authorized for all, and not anymore for the sole applicant. The current list :see novel food catalogue http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm

. But new authorization may be kept « proprietary » for 5 years, if justified

- And history of use outside the EU can be taken into account for a simplified procedure (under certain conditions)

# Which « food » are you talking about ?

- Ordinary food (normal consumption) ? With addition of nutritive substances ?
- Food for specific uses ?
  - Baby food (infant formulae and follow on formuale)
  - Medical food
  - Meal Replacement for slimming purposes
  - For sportsmen
- Food supplements ?

# Specific texts

– Foods for specific uses : Reg 609/2013 :

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0609&rid=1

– Food supplements : Dir 2002/46 :

http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1492449271625&uri=CELEX:02002L0046-20150402

– Fortified foods : (addition of nutrients, vitamins and minerals) : Reg 1925/2006 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1925-20150401&qid=1492449429488&from=EN

# Which technology ?

- Additives
- Processing aids
- Physical processes
- Enzymes

# Additives and Processing aids : Definitions

- Both are
  - Not consumed as foods
  - Used for technological purposes
- Additives are components of the final foods.
- Processing aids have no function in the final food

# Additives

- Subject to prior approval at EU level

Reg 1333/2008.

Positive list with conditions of use, by category of foods

http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1492447956793&uri=CELEX:02008R1333-20170320

- Technical specifications :

http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1492448117417&uri=CELEX:02012R0231-20170317

# Processing aids

– Not regulated at EU level, except :
  - Extraction solvents
  - Enzymes (list in process of  being established)

  http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1332-20121203&qid=1492448281163&from=EN

– Regulated in France (including enzymes)

– Enzymes regulated in Danemark

# Which properties do you intend to claim ?

- Nutrition claims ? See list in Reg 1924/2006 :

  http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1924-20141213&qid=1492450769145&from=EN

- Health claims ? Same regulation, + EU register of authorized claims : http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home

- Others ? Natural ? Check national rules

# Is your product/ Ingredient « safe » ?

- Reg 178/2002, article 14 : foods must not be « unsafe », i.e. « *injurious to health* », or « *unfit for human consumption* »: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20140630&qid=1492956874988&from=FR
- The authorization procedure, whether it is a « novel ingredient », or an additive, or an enzyme, will include two steps :
  - The demonstration of its safety, which lies upon the operator in its dossier, and will be assessed by the EFSA who gives an opinion (risk asessment) (www.efsa.europa.eu)
  - The decision of the Commission, on the basis on the EFSA opinion, and which may also include « other factors », and should take into account, in case of uncertainty, the precautionary principle (risk management)

# How safety is assessed ?

- Article 14 iof Reg 178/2002 :

  *In determining whether any food is injurious to health, regard shall be had:*

  *(a) not only to the probable immediate and/or short-term and/or long- term effects of that food on the health of a person consuming it, but also on subsequent generations;*

  *(b) to the probable cumulative toxic effects;*

  *(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers*

# What are the « other factors » ?

- Not a final list, but for instance :
  - Not misleading the consumer
  - Taking account of ethical considerations,
  - Etc.

# Questions ? Remarks ?

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# “New” Food Case Study

Learning objective:

1) Understand what makes a food “new” or “novel”

2) Discuss the differences in requirements for ingredient/product launch in the US vs. the EU

3) Understand regulatory strategies behind decision to launch a “new” food in the US vs. the EU

3)

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# What is “new” or “novel”?

- Do the US FDA regulations:
  - define “new” or “novel” in the context of foods?
  - have an established regulatory pathway for such ingredients or products?
- Do the EU regulations:
  - Define “new” or “novel” in the context of foods?
  - have an established regulatory pathway for such ingredients or products?

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# US-based definitions

- Food additive
- GRAS
- Food contact substance
- Processing aid
- Color additive
- Safe (as applied to added substances)
- Safe (as applied to “whole” foods)

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# EU-based definitions

- Additive
- Processing aid

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# Plant-based hydrolyzed protein

- I would like to launch a beverage that includes as an ingredient a protein meal made from sunflowers.
- Manufacture of the protein meal involves grinding up the whole sunflower seeds, which then undergo a $CO_2$ extraction to yield a de-fatted powdered protein meal.
- I would like to further process the protein meal with an enzyme (to hydrolyze the protein). The preferred enzyme is a protease commonly used to hydrolyze proteins, and produced by a genetically modified microorganism, *Aspergillus oryzae.*
- The final beverage product also includes carrageenan, noted for its technological function of thickening.

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