

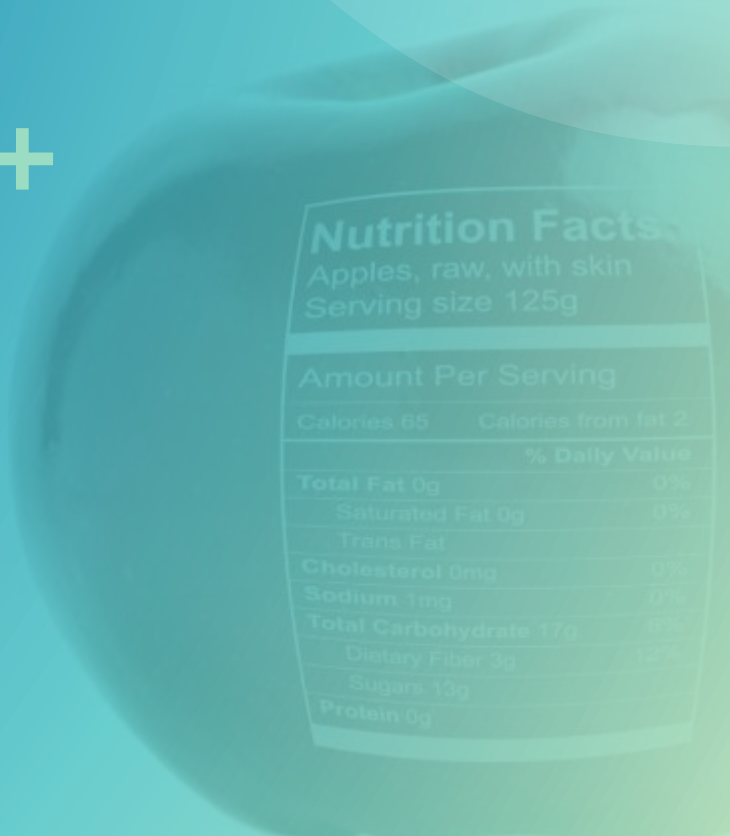


BeReady™

Novel Foods



Flexible Solutions for your Needs



Nutrition Facts	
Apples, raw, with skin	
Serving size 125g	
Amount Per Serving	
Calories 65	Calories from fat 2
% Daily Value	
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat	
Cholesterol 0mg	0%
Sodium 1mg	0%
Total Carbohydrate 17g	6%
Dietary Fiber 3g	12%
Sugars 13g	
Protein 0g	



Novel Foods

Regulation (EU) 2015/2283 NOVEL FOODS

What is Novel Food?

Any food that had not been consumed to a significant degree by humans in the EU before 15 May 1997

Which foods are authorized under the Novel Food Regulation?

Novel Food can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside of the EU.

Novel Food Regulation does not apply:

- Food additives
- Food enzymes
- Flavourings
- GMOs for food and feed
- Xtraction solvents used in the production of foods

However, these products fall in other particular authorization requirements.

PRODUCTS AUTHORISED AS NOVEL FOODS



- i) New foods
- ii) Food used exclusively in **food supplements**, when it is intended to be used in other type of foods
- iii) Food produced using **new technologies**
- iv) Food produced of **microorganisms, fungi or algae**
- v) Food consisting of engineered **nanomaterials**



+ Marketing Authorisation



Know Your Portfolio

- ✓ Is it Novel?
- ✓ Is it Traditional Food from 3rd country?
- ✓ What are the Regulatory Requirements?



Determine Safe Use

- ✓ Ask for consultation on the necessary toxicological studies
- ✓ Compile a Risk Assessment and Safe Use Report



Apply for Marketing Authorisation

- ✓ Express your interest for the formation of Consortia
- ✓ Check for data protection eligibility
- ✓ Cover all requirements
- ✓ Submit a full dossier



Post Authorisation Procedures

- ✓ Labelling elements
- ✓ Health Claims
- ✓ Post-Marketing monitoring according to regulatory requirements



Case Study: Cannabis & Cannabinoids

Novel or not?

Hemp
Seed
Oil

Hemp
Seeds

Defatted
protein

CBD oils

Leaf
extracts



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BeReady™

EU-PCN+



Flexible Solutions for your Needs



EU-PCN

European Poison Centre Notification

Companies placing hazardous mixtures on the market have to submit information about these mixtures to specific bodies appointed by Member States. Poison centres use this information to give medical advice in the case of an emergency.

Greek Poison Centre:

Poison Information Centre, Children's Hospital "P & A Kyriakou"

Greek CA for collecting data:

General Chemical State Laboratory

Legislation:

- *Regulation (EC) 1272/2008: CLP Regulation*
- *Regulation (EU) 2017/542: Harmonised Information Relating to Emergency Health Response*



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EU-PCN
In a Nutshell
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Importers & Downstream Users

All companies responsible for placing chemicals on the market



All Hazardous Chemicals

Except for:
food or feeding stuffs (Reg EC No 178/2002)
food additive (Dir 89/107/EEC)
flavouring (Dir 88/388/EEC and Dec 1999/217/EC)
Additive (Reg EC No 1831/2003)
Animal nutrition (Dir 82/471/EEC)



4 x Deadlines

- 1st January 2020: Consumer Goods
- 1st January 2021: Professional Goods
- 1st January 2024: Industrial Goods
- 1st January 2025: End of Transition



IUCLID

Online/Offline Dossier Compilation via IUCLID6
Electronic Submission via ECHA Submission Portal (REACH-IT)

+ What's New

UFI – Unique Formula Identification

The UFI is a unique code to be printed on the label of the product. It creates an unambiguous link between a product placed on the market and the information on that specific mixture submitted to poison centres, so that the chemical formulation of the product can be precisely and rapidly identified. A precise identification is necessary to provide appropriate curative measures in the case of an emergency call.

XML - Harmonised Notification Format

A harmonised format for submitting information to CA. The new format will gradually replace the current national information requirements.

Information to be provided relates to the chemical composition of hazardous mixtures, identity and concentration ranges of ingredients, toxicological information and the product category according to a harmonised **European product categorisation system** (EuPCS).

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Thank You
for your attention +



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