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# Position Paper

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## EDA Position Paper on the regulatory situation in the EU on lab-grown ingredients

For over 30 years the specific EU legislative framework on the protection of dairy terms has provided European citizens a clear knowledge of what milk and milk products are and has protected them from being misled. EDA and its members are committed to consistently protect and preserve dairy protected terms, now and in the future.

### I. Introduction

For some years now start-up companies have been experimenting and developing new food technologies that make it possible to grow in the laboratory specific bio-identical proteins imitating e.g., milk proteins without the use of animals. Some novel food applications have already been submitted to the EU Commission. A group of startups (Formo, Better Dairy, Imagindairy, Onego Bio, Those Vegan Cowboys) have recently launched an association, “Food Fermentation Europe” (<https://www.foodfermentation.eu/>) to specifically address issues from labeling and nomenclature for ‘animal-free’ proteins in Europe. Another coalition of companies has created “Cellular Agriculture Europe” (<https://www.cellularagriculture.eu/>). At global level, an alliance called “Precision Fermentation Alliance” has been created (<https://perfectday.com/newsroom/press-release-precision-fermentation-alliance/>).

As these are new products that are not yet on the EU market, the paper looks at the different technologies currently used as well as at the regulatory aspects for placing such products on the EU market (GMO/Novel Food). The paper also addresses the question of labelling of the novel food ingredients as well as the final foods where they are incorporated. For the sake of this paper we will call these products “lab-grown ingredients”.

### II. Technologies

So far, two production technologies exist:

- **“Cell Culture Technology”**: extraction of cells from a living animal that are grown and multiplied in a bioreactor. The cells are fed an oxygen-rich cell culture medium made up of basic nutrients such as amino acids, glucose, vitamins, and inorganic salts and supplemented with proteins and other growth factors. This mimics the natural processes that occur in animal bodies. The composition of the medium is “tweaked” to trigger immature cells to form specific cells.



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- **“Precision Fermentation”**: This method uses microorganisms rather than cell cultures to produce proteins. These products can be grown directly from microorganisms which are introduced into microflora such as yeast. Microbes are used “cell factories” for producing specific functional ingredients. The range of outputs is vast. Examples include everything from whey and casein, proteins found in milk, to soy leghemoglobin used to imitate red meat juices in the Impossible Burger. The technology works by manipulating the DNA of microorganisms like yeast or fungi. These microbes are then tasked to create the target animal proteins when supplied with the appropriate nutrients and sugar in fermenters. This process is similar to what is done during beer brewing. During fermentation, these unique microbes produce proteins identical to those found in animal products. These proteins can then be processed into a protein isolate that can be used to create a range of products, including dairy, animal fat, and egg alternatives.

## III. Regulatory requirements for placing on the market of lab-grown ingredients

### 1. Novel Food or GMO?

Cell culture-derived food is a novel food unless the technique used to culture it falls under the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed. The same applies to food produced by precision fermentation. Indeed, the provisions of the Novel Food Regulation are superseded by the GMO regulation. Alternative protein products that contain or consist of a genetically modified organism (“GMO”) are subject to the GMO Regulation 1829/2003.

However, the European regulation makes a distinction between food produced from a GMO and food produced with a GMO. Under recital 16 of Regulation (EC) No 1829/2003, the Regulation covers food and feed produced ‘from’ a GMO but not food and feed ‘with’ a GMO. The decisive criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed.

During a meeting held on September 24<sup>th</sup> of 2004, the Standing Committee on the Food chain and Animal health concluded: *“Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is*

*- kept under contained conditions and is not present in the final product are not included in the scope of Regulation (EC) No 1829/2003. These food and feed have to be considered as having been produced with the GMM, rather than from the GMM.*

*- present in the final product, totally or partially, whether alive or not, are included in the scope of Regulation (EC) No 1829/2003, in regard of both authorisation and labelling”.*

The decisive criterion is therefore whether the final product contains host DNA-proteins or not.



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## 2. Novel food

All non-GM novel foods are currently evaluated under the 'new' Novel Food Regulation that was adopted in 2015 (EU/2015/2283). The Regulation applies to all foods that were not consumed in Europe before 1997.

EFSA mentioned during the two days colloquium organized in May 2023<sup>1</sup>: *“So far EFSA has not been asked to evaluate any food derived from cultured animal cells. But we have assessed several novel food ingredients produced through precision fermentation”*. As an example, in early 2023 an authorization was granted to MycoTechnology for their pea and rice protein fermented by shiitake mushroom mycelia.

According to recent information, Perfect Day has applied in June 2023 for a novel food authorization for a protein that it has presented as a whey protein like produced by precision fermentation. The novel food approval process used to be long. From submission of a full application to publication in the Union List of novel foods, it takes about two years.

During the seminar, EFSA said: *“We expect to receive novel food applications on cell-culture derived foods in the coming months and years. So, we are keeping pace with the science to stay prepared when such applications arrive.”*

It can be noted that the protein produced by this kind of technology may be considered a novel food, although the production organisms itself would not fall under the Novel Food Regulation. Some of the microorganisms used have a long history of use in the EU. For instance, one of the most successful microbial protein products is Quorn, which is produced from the mycoprotein of *Fusarium venenatum microfungus*.

## IV. Labelling aspects

### 1. Labelling of the novel food ingredient

It is up to the applicant to propose the labelling of the novel food ingredient in its application. It is paramount it is in accordance with EU law (e.g. Regulation (EU) 1308/2013 - protection of dairy terms, Regulation (EU) 1169/2011 etc.).

Novel food is subject to the general labelling requirements laid down in (Regulation (EC) No 1169/2011). Specific additional requirements for the labelling of a novel food may also apply, if necessary, to properly inform the consumer. The label must mention the name of the food, and, where appropriate, specify the conditions of use. Any nutrition and health claim should only be made in accordance with the requirements of the Health and Nutrition Claims Regulation (EC) No 1924/2006.

<sup>1</sup> <https://www.efsa.europa.eu/en/events/efsas-scientific-colloquium-27-cell-culture-derived-foods-and-food-ingredients>



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Concerning the name of the food, according to the rules for the protection of dairy terms laid down by Regulation 1308/2013 (see also [EDA Guidelines on the principles and enforcement of the Protection of Dairy Terms - July 2000](#)), a dairy designation cannot be used to describe a food that does not come from the mammary secretion of an animal. Whey and caseins are explicitly listed in Regulation 1308/2013 as reserved for dairy products as well as cheese, butter, cream, etc.

In addition, Regulation 1308/2013 states even more broadly that “*b) names within the meaning of Article 17 of Regulation (EU) No 1169/2011 actually used for milk products (...) shall be reserved exclusively for milk products*”. Therefore, the legal protection covers all dairy denominations.

In the Codex Alimentarius Standard on the Use of Dairy Terms (GSUDT), the same rules apply:

*“Milk is defined as the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.”*

*“Milk product is a product obtained by any processing of milk, which may contain food additives, and other ingredients functionally necessary for the processing.”*

*“Composite milk product is a product of which the milk, milk products or milk constituents are an essential part in terms of quantity in the final product as consumed, provided that the constituents not derived from milk are not intended to take the place in part or in whole of any milk constituent”.*

Therefore, similarly to EU law, GSUDT also prohibits the use of dairy terms for cell culture products or products produced by precision fermentation.

However, GSUDT, even when implemented, is not interpreted with the same rigor in all countries. In some third countries (e.g., US), companies using fermentation to produce animal-free dairy, eggs, and other novel proteins have not fully aligned on terminology for products or ingredients derived from precision fermentation. The ingredients disclosure on labels for products made with ingredients from Perfect Day, use “non-animal whey protein”.



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## 2. Labelling of the final food

Many foods produced by cell culture technology or precision fermentation are intended to be used as ingredients in dairy products, raising the question of the name of the final products.

According to Annex VII of Regulation 1308/2013, *“For the purposes of this Part, “milk products” means products derived exclusively from milk, on the understanding that substances necessary for their manufacture may be added provided that those substances are not used for the purpose of replacing, in whole or in part, any milk constituent”*. As we have seen, the same rule exists at international level in the GSUDT.

Any ingredients produced by cell culture technology or precision fermentation would be considered as substituting milk constituents if used in a dairy product. Therefore, under EU rules - now and in the future - a product consisting wholly or partly of such ingredients could not use a dairy designation.

The protection granted by EU rules is absolute: the addition of descriptive mentions to inform the consumer that the product does not come from milk in the meaning of milk definition has no influence on the prohibition. Indeed, in its judgment [in Case C-422/16 Verband Sozialer Wettbewerb eV v TofuTown.com GmbH](#), the European Court explains that the addition of descriptive or clarifying additions indicating the plant origin of the product concerned, such as those used by TofuTown, has no influence on that prohibition. By analogy, in case of culture cells products or products produced by fermentation, the indication of the non-animal origin of the product will not have any influence on prohibition.