

AGRICOLTURA CELLULARE ITALIA APS

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To Whom It May Concern,

Agricoltura Cellulare Italia APS is an Italian non-profit dedicated to advancing information, research and development in the field of cellular agriculture and its various aspects. Our organization is deeply committed to fostering cooperation among public and private stakeholders, promoting sustainable development, and facilitating innovation in cellular agriculture.

The purpose of this letter is to express our serious concerns regarding the DDL S. 651 recently proposed and approved by the Italian senate, and summarized in the TRIS notification sent to the European Commission on July 27th, 2023.

The proposed law seeks to introduce prohibitions on the production and marketing of food and feed derived from cell cultures or tissues of vertebrate animals, as well as restrictions on the labeling of products containing vegetable proteins as meat [1].

In light of the legislative developments, we wish to draw attention to the following key points of discussion:

- 1. European Legislation on Novel Foods:** The TRIS notification message cites the absence of specific European legislation as a basis for the proposed national measures [1], invoking the precautionary principle outlined in Article 7 of Regulation (EC) No 178/2002. However, it is essential to note that European legislation does indeed exist in the form of Regulation (EU) 2015/2283 of the European Parliament, which regulates Novel Foods. Given the existence of this comprehensive EU law, we believe the Italian draft legislation and this TRIS notification to be redundant. Moreover, it is important to emphasize that the precautionary principle should only be invoked in the presence of potential risks, and it should not be used to justify arbitrary decisions. Eventually, the precautionary principle requires the measure to be temporary and to encourage research in filling the knowledge gap [2].
- 2. Scientific Examination and Consultation:** We contend that the perceived adverse effects cited by the Italian Government are a result of an incomplete assessment of the scientific literature due to a lack of consultation with experts and researchers in the field, such as FAO and WHO [3]. Notably, some of the main actors of the Italian alternative proteins ecosystem (e.g., Bruno Cell) have not been heard during the auditions at the Senate and the Chamber. In opposition to our Government, as stated in [2] "The decision-making procedure should be transparent and should involve as early as possible and to the extent reasonably possible all interested parties." This lack of engagement with relevant experts raises concerns about the accuracy of the scientific examination conducted by the Italian government, as it fails to adhere to the principles outlined in COM(2000) 1 final, which emphasize the importance of comprehensive scientific assessments and the identification of topics for further research [4].
- 3. Risk Assessment:** The COM(2000) 1 final document underscores the importance of a thorough risk assessment process, which includes hazard identification, hazard characterization, appraisal of exposure, and risk characterization [5] most of which can be already found in FAO and WHO report on food safety of cell-based products [3]. The

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proposed law does not provide such information based on scientific evidence. Additionally, it is imperative to consider the role of the European Food Safety Authority (EFSA), which oversees the risk assessment and management of Novel Foods within the EU. Our concern lies in the firm belief that EFSA is the most qualified and competent authority to conduct a comprehensive scientific risk assessment concerning cell-based food products.

4. **European Single Market:** As argued by the Italian Customs and Monopolies Agency during its hearing at the Italian Senate, we want to underline that the proposed ban would not prevent the import of cell-based products into Italy, thanks to the presence of the single market [6]. Therefore, we express our concerns about how the proposed law would limit and pose threats to the free trade of goods within the Schengen area once a cell-based product is approved by the EU Commission.

We respectfully implore you to consider the validity of the criticism and the gravity of the concerns that we have expressed in this letter and their potential implications for the future of cellular agriculture and food innovation within the European Union. We fervently hope that our points will be given the earnest consideration they merit, and we remain open to engaging in constructive dialogue to address how the proposed law is not aligned with EU principles and regulations.

Best regards,

Nike Schiavo

on behalf of Agricoltura Cellulare Italia APS

References

[1] TRIS Notification: 2023/0469/IT

[2] COM(2000) 1 final

[3] FAO & WHO. 2023. Food safety aspects of cell-based food. Rome.

[4] COM(2000) 1 final, Section 5.1.1.

[5] COM(2000) 1 final, Section 5.1.2.

[6] Article 26 and Articles 28 to 37 of the Treaty on the Functioning of the European Union (TFEU)