

POLLINIS

A NONPROFIT AND INDEPENDENT ORGANIZATION THAT CAMPAIGNS FOR SUSTAINABLE FARMING IN EUROPE. POLLINIS FIGHTS AGAINST THE SYSTEMATIC USE OF PESTICIDES, FOR THE PROTECTION OF POLLINATORS AND PROMOTES ALTERNATIVE AGRICULTURAL PRACTICES. WE ARE SUPPORTED EXCLUSIVELY BY DONATIONS FROM PRIVATE INDIVIDUALS.

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POLLINIS comments on the public consultation of “Evaluation of existing guidelines for their adequacy for the food and feed risk assessment of microorganisms obtained through synthetic biology”

General comment:

EFSA should ensure all the needed guidelines are developed before any release, as the role of EFSA is to ensure that risks are fully evaluated. Those applications of synthetic biology to micro-organisms, including yeast, viruses, protists, bacteria, fungi account for the majority of life on earth and form the basis of life and connections to all existing species. Microorganisms have the possibility to put into danger or change existing relationships within the biosphere. Moreover, the rise of zoonotic diseases raises more concern to the already complicated relationships between microorganisms, plants and other organisms, including humans. We urge EFSA to apply the precautionary principle on applications of synthetic biology to microorganisms.

Below are comments relevant to sections in the guidelines:

2.5 Selection of case studies

EFSA states: “There is no distinct borderline between the microorganisms obtained using existing genetic modification techniques and those derived from synthetic biology” [1].

We would suggest to add two issues to be included into the guidelines:

1. Understanding that this is not ERA, still, we think that there needs to special attention on a focus on more larger scales and long-term studies to understand the effects of applications of synthetic biology on microorganisms. Also understanding better concepts of invasion ecology: introduction of new organisms that many come from other continents. One of the lessons learned from invasion ecology is an increased transfer (intended and unintended) between organisms. Proponents argue that if there a large number of introductions, as in microorganisms, there will be a definitive impact on the environment and could have disastrous effects on the environment [2].
2. We also think it is a good idea that case studies include microorganisms that are used for organisms that influence food-affected animals, especially the honey bee (see below for comments on gut microbiome – 3.8). The idea of paratransgenesis [3-7] should be included in these guidelines as these issues go beyond just the microorganism, but the organism and overall environment, including human health (e.g. plant protection products, pest control) [4].

3.8 Gut microbiome and horizontal gene transfer

Current work on the microbiota and in the honey bee gut is advancing quickly [5-10]. Borum (2021) states: “the microbiota has important functions in metabolism, immune system, growth and development... Microbiota species can alter both the volatile profiles and olfactory behaviours of the host”. Thus, the microbiota affects the honey bee’s memory and learning capacity – and therefore its neurophysiological development via foraging, mating and chemical communication.

It is important for EFSA to consider the microbiota in a more broader way to include not only the microbiota itself but the organism as a whole and the context of the organism in which it is surrounded. This idea is emphasised in notion of holobiont. As Rosenberg & Zilber-Rosenberg states: “Microbiotas and their hosts interact in a manner that affects the fitness of the holobiont in many ways, including its morphology, development, behavior, physiology, and resistance to disease. Taken together, these interactions characterize the holobiont as a single and unique biological entity” (pg. 1) [11]. The effects of microorganism to the rest of the organism in which it is inserted, or its surrounding environment must be considered in any risk assessment. Without such consideration might weaken the risk assessment.

Moreover, we urge EFSA to include in its guidance a recent article by Xia et al. (2021) who demonstrated the first example of a natural gene transfer from a plant to an insect [12]. Considering the importance of current and potential work of the microbiota and the honey bee, and a real possibility of horizontal gene transfer between plant and insect push forward the relevance for need to broaden this risk assessment.

4. Evaluation

Based on the current guidelines, it seems that EFSA is planning to introduce microorganisms obtained through synthetic biology, especially through food and feed, food for humans (e.g. additives, decontaminants) going outside previous methods. Not only do some of these introductions have a history of safe use, many of the considerations of unintended or intended effects have not been adequately considered. We think it is a good idea that EFSA prioritise the precautionary principle developing international guidelines that take into account:

- To better understand the unintended and intended effects of applications of synthetic biology
- Investigate how to develop a technological assessment and horizon screening
- Incorporate a better and more holistic understanding of microorganism, its host and its environment

5.2 New hazards/risks

We think it is a good idea to include the concept of paratransgenesis (see 2.5 above) as it is a rapidly growing field including microorganisms and food-affected organisms (i.e. the honey bee).

6. Recommendations

EFSA should include

- The concept of holobiont – must look at the risks not just for the microorganism but the organism as a whole and the context in which it lives
- Develop technology assessment and horizon screening
- Develop a better understanding of how to limit and understand the possibility of limitations of any release of microorganisms obtained by synthetic biology because of the possible unintended and intended risks
- Respect and apply the precautionary principle

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