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To
Mrs Sabine Jülicher
Director for food and feed safety, innovation, DG SANTE
Rue Breydel 4
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Belgium

cc Mr Claude Lambré, Chair of Food Contact Materials, Enzymes and Processing Aids at EFSA
cc Mr Jiri Sochor, Team Leader Food Improvement Agents, Unit E2, DG SANTE

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New guidance on the risk assessment of food enzymes

30 August 2021

Dear Mrs Jülicher, dear Mr Sochor, dear Mr Lambré,

We are writing to you in regard to EFSA's planned new 'Guidance for Submission of Dossiers on Food Enzymes'. Testbiotech is aware of the public consultation process and the workshop held at EFSA in June 2021.[1] However, we are sorry we did not participate in the process thus far.

Nevertheless, we have become aware of some open questions, which are also relevant in the debate on the risk assessment of SynBio micro-organisms[2] to which we gave our input during the period of consultation[3].

As you know, there have in the past been some cases of large-scale contamination with genetically engineered (GE) bacteria in the food chain.[4] These GE bacteria were used in the production of vitamin B2 but not authorized for use in the food chain. The general problem in this context is summarized by Deckers et al., 2020: they show the need for adequate detection methods and strategies to prevent similar cases in future.

Without publicly accessible information on detection and identification methods that can be used by independent control institutions, contamination with viable GE micro-organisms (MOs) or functional parts of their DNA might still go unnoticed, regardless of whether or not the GE MOs are used as enzymes in vitamin production (or for other purposes). As the case of the GE bacteria used in the production of vitamin B2 shows, these contaminations are associated with risks to human and animal health. Such accidents might also trigger environmental hazards, especially if viable forms of GE MOs can persist and propagate in the environment.

1 www.efsa.europa.eu/en/events/stakeholder-event-update-guidance-submission-dossiers-food-enzymes
2 https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.6263
3 www.testbiotech.org/content/testbiotech-input-efsa-consultation-synbio-microorganisms-june-2020
4 www.testbiotech.org/en/press-release/genetically-engineered-bacteria-animal-feed-products-are-spreading-resistance

We appreciate that EFSA requires whole genome sequencing (WGS) for all GE bacteria and GE yeast as well as information on specific DNA sequences. However, so far, these data are not available for the development of effective methods to detect and identify unintended contaminations. Therefore, we strongly recommend requesting applicants to provide adequate detection and identification methods that must be made freely available.

Two further questions arose during a review of the documents published online from the June 2021 workshop. We would therefore like to ask you to take the following issues into account in the ongoing process:

- As explained by Jose Barat and Holger Zorn from EFSA, the new guidance will require no data on the long-term stability of the food enzymes. Therefore, it is possible that the new guidance might become insufficient to prevent products entering the market with enzymes that are still active (for example, in bakery products, see Reichenberger et al., 2020) and which may, in addition, cause side effects at the stage of consumption. We strongly recommend exploring this issue to avoid major gaps in the risk assessment.

- If genetically engineered micro-organisms are considered to be QPS (qualified presumption of safety) strain, they are considered to be toxicologically safe and less data will be required. However, it is known that, for example, at least some GE bacteria can show a different genetic pattern and have a higher rate of spontaneous mutations compared to wild types (see, for example, Couto et al., 2018). Therefore, we strongly recommend that GE MO microorganisms are not categorized as QPS in the sense of being equivalent wild-type MOs. It should be acknowledged that the dynamic of genomic changes in GE MOs can be vastly different compared to wild-type MOs. These findings are closely related to specific risks regarding the genetic stability of the GE MOs and the safety of their products.

We would very much appreciate receiving your response before the new guidance is published. We also sincerely hope that our letter can contribute to safety standards that prevent adverse effects on health and the environment.

Thank you very much.

With kind regards

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References:

Couto J.M., McGarrity A., Russell J., Sloan W.T. (2018) The effect of metabolic stress on genome stability of a synthetic biology chassis Escherichia coli K12 strain. Microb Cell Fact, 17:8.

Deckers M., Deforce D., Fraiture M-A., Roosens, N.H.C (2020) Genetically Modified Micro-Organisms for Industrial Food Enzyme Production: An Overview, Foods 9, 326; doi:10.3390/foods9030326

Reichenberger K., Luz A., Seitl I., Fischer L. (2019) Determination of the Direct Activity of the Maltogenic Amylase from Geobacillus stearothermophilus in White Bread, Food Analytical Methods (2020) 13:496–502, https://doi.org/10.1007/s12161-019-01673-7