To Dr. Viola Peter, Study team leader Technopolis

CC Mr Klaus Berend European Commission DG SANTE



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EU Transparency Register ID 151554816791-61

28 July 2022

Dear Dr. Peter

Thank you for the invitation to participate in the targeted consultation on New GE (NGT). However, after carefully studying the questions in the targeted consultation, Testbiotech has decided not to participate.

As far as we can see from our analysis, the consultation appears to be largely based on imagination and speculation: it makes comparisons between several scenarios, but lacks the necessary data to compare the potential future impacts of NGTs. Moreover, the lack of data and reliable findings are not made clear. Instead, the potential benefits of NGTs are presented as a given fact with no mechanisms in place to assess or scrutinize their potential. However, unless such assumptions can be looked at more carefully, no comparisons can be made in regard to the expected positive or negative impacts compared to existing methods of production.

In general, reliable instruments and criteria are needed to distinguish traits with 'real benefits' from those which are just 'empty promises'. In addition to mandatory risk assessment, complementary prospective technology assessment (TA) should be made a priority for the political decision-makers – it should include the development of robust criteria to assess potential benefits.

Every effort should be made to avoid creating the impression that the hypothetical benefits of NGT plants are a given fact. As yet, there is no established regulatory system to provide sufficiently clear and transparent standards or criteria needed to make evidence-based decisions on sustainability and potential benefits. Therefore, no incentives can be issued and labelling cannot be used to inform consumers. There is a high risk that, given the current situation, misinformation and market

distraction will result from the proposed initiatives. In this context, the experience gained from the first generation of transgenic crops should be taken into account; these were at the time not subject to adequate technology assessment. Despite many of the expected benefits never actually materializing, none of the products, such as herbicide resistant plants, were sanctioned or removed from the market.

In addition to the mandatory case-by-case risk assessment, the priority for political decision-makers should be a complementary regulatory framework for prospective technology assessment. It should take into account the systemic NGT risks which reach beyond the distinct applications, such as those emanating from unintended interactions of several NGT organisms within a shared environment. It should also include robust criteria to assess potential benefits of NGTs for production systems and the environment. In this way, TA would represent a second level of scrutiny (additional to case-specific risk assessment) to evaluate whether these technologies are really needed and suitable to solve the problems at hand. While TA cannot replace the risk assessment of the specific organisms (events), it can nevertheless help political decision-making in seeking a balance between potential benefits and the need to reduce the overall risk of adverse effects on biodiversity and human health. However, in the context of NGTs, the methodology for comprehensive TA still needs to be developed. As it stands, your targeted consultation would only bring up possible relevant findings if a regulatory system with reliable instruments and criteria were in place to allow 'real benefits' to be distinguished from those which are just 'empty promises'.

In particular, if any incentives are discussed, these would require clear, transparent, reliable and enforceable assessments, standards and criteria, thus allowing evidence-based decisions to be made on sustainability and potential benefits predicated on a comprehensive technology assessment. The criteria should take into account alternatives which are based on conventional breeding, agroecology or other sectors within the food production systems. In future, the regulator should aim to prevent releases of any NGT plants based on non-justified claims and empty promises. Otherwise, the planned EU Commission initiatives will cause market distraction and disruption and, in addition, damage both health and the environment.

With kind regards

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