TESTBIOTECH Briefing 26 - 11 - 2018

Voting recommendations on proposed changes of Regulation 178/2002 "transparency and sustainability of the EU risk assessment in the food chain"

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1. Introduction

Testbiotech's (www.testbiotech.org) activities includes the impact assessment of modern biotechnology, in particular from the perspective of health and environmental goals. We are a non-profit, science-based organisation and strictly independent of regulated industries. We have followed the work of EFSA for around ten years and provided input on public consultations, such as those in the context of GMO authorisation. Consequently, we are very familiar with many of the topics now being discussed in the context of Regulation 178/2002. Further, to ensure the quality of our input, we also commissioned and published a legal dossier written by the well-known EU legal expert, Professor Ludwig Kraemer (http://www.testbiotech.org/node/2248).

2. General Comments

It is important to improve access to information and transparency, to provide more independent research and to strengthen the precautionary principle. Testbiotech cannot agree with the proposal of the EU Commission in so far as it would exclude some important data from becoming accessible. We also are concerned about amendments made by Members of Parliament, which would substantially delay access to the relevant information. Therefore, we hope the Parliament will support in particular those amendments that aim to strengthen the protection of health and the environment. In this regard, it will be necessary to support several amendments currently not covered by the Compromise Amendments. An overview of those amendments is given in our briefing.

3. Comments on Compromise Amendments

Many of the Compromise Amendments are a step in the right direction and can substantially improve the proposal of the Commission. However, we are concerned about Compromise Amendment 5, which would allow several representatives of regulated industry to become members of the Board of EFSA. The applicants (industry) are in continuous contact with EFSA during the process of risk assessment while the public is not. Further, industry can participate in all public consultations and hearings. Parliament should not allow regulated industry to increase its influence on the work of EFSA since this might endanger the credibility and trust in the work of the authority.

4. Important issues not sufficiently taken on board by the Compromise Amendments

Access to information and transparency

Amendments such as 440-442 are important to prevent industry from claiming confidential business information in regard to documents that are highly relevant for risk assessment. More specifically, amendments such as 443-446 ensure that information on inserted or technically engineered DNA can also be accessed by independent experts (please see below for detailed argumentation).

Protection goals

Based on the reasoning presented in the legal dossier, we support the idea of integrating environmental protection on a wider basis and giving more weight to the precautionary principle. Therefore, we believe that in particular amendments e.g. 64, 65 and 183-185 are very important (please see below for detailed argumentation).

More risk research and better data

We support the idea that additional studies can be commissioned to investigate specific areas of risk assessment in more detail. In addition, we think it is important that the EU Parliament and interested public can also have their say on the selection of topics and projects. Therefore, amendments such as 139 and 305 are very relevant. Further, we appreciate that the issue of combinatorial effects, which up until now are not taken into account by EFSA, is reflected in some amendments e.g. 176 and 315 (please see below for detailed argumentation).

Amendments that should be rejected

There are a few amendments which we are concerned about because they might unduly restrict access:

- For example, if data are made public at a late stage of the process this could create a huge problem for those experts wanting to analyse and comment on it within the short time lines given for public consultations.
- Further, if criteria such as GLP standards are used to restrict data being taken into account, this can substantially damage risk assessment. It is very important that all relevant data and publications are duly taken into account.
- Finally, we do not think that a new process for appeal should be established for regulated industries. The applicants (industry) are continuously in contact with EFSA during the process of risk assessment, while the public is not. Thus, industry should not be allowed to put even more pressure on EFSA during and after the risk assessment. We should not forget that industry has access to EU courts if they do not agree with the outcome of risk analysis and decision-making.

Some relevant recommendations for voting on the amendments are tabled below.

Please **support**	Topic	Amendment Number
	Give more weight to the protection goals such as human and animal health as well as the environment.	64, 65, 73, 75, 77, 78, 79, 100, 111, 148, 161, 183, 184, 185.
	Improve transparency and access to data	122, 144, 145,148, 150, 154, 155, 161, 165, 167, 169, 328, 329, 331, 338, 342-345; 347, 348, 351, 353, 355-360, 362-369, 371-375, 377-384, 385-387, 389-393, 394, 396-399, 406-410, 412; 415-417, 419-424, 426, 427, 439, 440-442, 443-446, 450, 452-457, 458-461, 464, 465, 468-473, 475, 477-480, 483-489, 491-495, 496-497, 499-501, 502-506, 511-514, 516-523, 524, 526, 529, 530, 532-535, 537.
	Improve public communication	171, 172, 186.
	Improve the work of EFSA and strengthen its independence	95, 103, 107, 240, 241.
	Improve science and risk research	132, 139, 176, 232, 233, 305, 307, 308, 315.

Please **reject**	Topic	Amendment Number
	Timely access to data should not be disabled	291, 334, 354, 404, 413, 414, 449, 451, 463, 466, 474, 476, 481, 482, 498, 525, 527, 528, 531.
	Industry should not be allowed to increase pressure on EFSA	146, 400, 407.
	Usage of relevant data and / or access to it should not be restricted by too narrowly defined criteria	112, 118, 124, 135, 299, 311, 335, 349, 350, 352, 361, 370, 376, 395, 401, 411, 515, 536.

5. Further arguments and considerations:

Give more weight to the protection of the environment

It has been suggested that Article 192(1) TFEU is added as a supplementary legal basis, as the proposal directly concerns (EU) environmental law. Indeed, Directive 2001/18 on the deliberate release into the environment of GMOs, Regulation 1829/2003 of GM food and feed, and Regulation 1107/2009 on plant protection products (pesticides), which are all to be amended by the future Regulation, directly concern the cultivation of plants, the use of pesticides on land and in agricultural activities, and the authorisation for putting GM products into circulation. Furthermore, EFSA not only assesses risks to health but also environmental risk, for example, the import and cultivation of GMOs.

Strengthen the precautionary principle

The provisional character of measures on the basis of the precautionary principle contradicts very clearly the basic approach adopted by Regulation 178/2002 that the Commission itself formulated as follows (Commission, Proposal (fn.1, above), p.2 and 3, and Recitals 16 and 22.): "Current procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This principle is based on the premise that public health is better protected when the burden is on the applicant to prove that a particular food of feed is safe prior to its placing on the market, instead of the public authorities having to prove that it is unsafe".

Following this basic approach, in cases of technical, scientific or other uncertainty, the EU institutions not only have an obligation to take provisional measures, they should also protect the environment - which includes the protection of human health - by not authorising the substance or product in question. It is then up to the applicant to dissipate any doubt by introducing new information. This is the only procedure in line with the precautionary principle.

Transparency

The Commission proposes that it may be acceptable to treat the following information confidentially:

(a) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,
(b) breeding patterns and strategies.

There are good reasons not to follow this proposal:

- The DNA sequences are highly relevant for risk assessment:

The DNA sequences have direct implications for the biological quality of the *intended gene products*, such as Bt toxins. These toxins as expressed in the plants are not produced from a DNA

that is identical to the native variants as found in soil bacteria. In most cases, the DNA is truncated or changed in its structure to render it more efficient. These changes in the structure of the DNA are highly relevant for environmental risk assessment as well as food safety. If the sequences are not disclosed, experts cannot assess the risks independently from industry and authorities. Thus, the public would not have access to information that is highly relevant for risk assessment. There is no need to treat this information as confidential since the relevant sequences are eligible for patent protection in Europe.

Furthermore, the DNA sequences of the gene constructs and the structure of the DNA at the site of insertion is also highly relevant for risk assessment of *unintended gene products* e.g. natural genes can be interrupted by the insertion of the additional DNA. Further, open reading frames can emerge unintentionally and give rise to unintended gene products. Currently, EFSA does not fully assess these gene products. For example, gene products that are not translated into proteins are completely ignored.

If the relevant DNA sequences are not disclosed, the public will have no access to information that is highly relevant for risk assessment.

- Breeding patterns are relevant for risk assessment for the following reasons:

EU regulation requests that the comparator for GMO risk assessment is chosen from a similar genetic background. For example, plant varieties can largely differ in this respect, therefore the "isogenic line" is the best comparator. To get a proper understanding of why a plant / organism is chosen as comparator or reference line, the breeding pattern has to be known. The breeding pattern is further highly relevant for risk assessment of stacked events. In this case, it is not only relevant to know how the stacked event was created from parental plants, but also why and how the comparator was chosen. This information is highly relevant for the so-called comparative approach in risk assessment. Interestingly, this information is currently available to the public. Refusing access to this information in future would contradict EU regulation and decrease transparency.

<u>Combinatorial effects</u>

Where in regard to risk assessment of specific products the expertise of several expert panels and units is involved, the EFSA and the Commission have to ensure sufficient interface between the relevant sectors to close potential gaps between those sectors, and establish the overall safety of the products before they are placed on the market. This is especially relevant for the interface of GMO and Pesticide Legislation and the assessment of combinatorial effects of residues from spraying with the complementary herbicide.

Further, the gaps between the tasks of the national authorities and those of EFSA have to be taken into account. Whereas (as long as) risk assessment of additives being used in commercial formulations of herbicides is the task of the Member States, the risks of residues from those additives is the task of EFSA if they are present in imported food from outside of the EU. To support EFSA in their task, Member States have to make fully available all relevant information about the formulations and additives used in the Member States without any restrictions on confidentiality.

In general, where specific patterns of residues from spraying and / or other stressors, such as potentially toxic substances, are supposed to be present in specific products, these residues and stressors must not only be assessed in isolation, but also in combination.