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Brussels, 18 May 2023

Cc: Irene Sacristan Sanchez (DG SANTE – E.3 Unit), Dirk Detken (EFSA, Legal Affairs Services Unit)

Subject: CropLife Europe's views on the relevance of information to be submitted to EFSA in support of the GM risk assessment

Dear Dr. Afonso,

Further to the meeting between EFSA and GM applicants on 18 April 2023, CropLife Europe would like to share its views on the relevance of information to be submitted to EFSA by applicants as part of the authorisation procedure for GM food and feed products.

During the above-mentioned meeting, the EFSA GMO Panel advised that: '*It is incumbent on all applicants to complete a comprehensive search of all relevant published literature and patents and guarantee the delivery of potentially relevant scientific information to EFSA to assist in the processing of applications.*'

In this regard, we believe that it is implicit in the relevant legal provisions that information submitted to EFSA by applicants, as part of the authorisation procedure for GM, must be relevant to the risk assessment. The terms of Articles 9(3) and 21(3) of Regulation (EC) No 1829/2003 on genetically modified food and feed ("Regulation 1829/2003") do not require all available information (irrespective of its significance) to be submitted.

The determination of what information is relevant for the safety assessment needs to be interpreted in light of the legislative context, considering the overriding purposes of Regulation 1829/2003and Commission Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed ("IR 503/2013"). The legal framework for what the applicant shall submit is determined by the purpose of Regulation 1829/2003 itself. All information must be necessary to satisfy the substantive requirements for GM food and feed, as respectively detailed in Articles 4(1) and 16 (1) of Regulation 1829/2003.

The same is true for the IR 503/2013 since its legal base is Regulation 1829/2003. Accordingly, it can only elaborate how dossiers under Regulation 1829/2003 should fulfil the substantive requirements of that Regulation. Its scope cannot legally go beyond what is required by Regulation 1829/2003 and this must shape the interpretation and application of its provisions.

It follows that the information requirements must only focus on satisfying these thresholds. Articles 5(3) and 17(3) of Regulation 1829/2003 list that what is required to be submitted for that purpose includes: "(e) *a copy of the studies, including, where available, independent, peer reviewed studies, which have been carried out and any other material which is available to demonstrate that the food* [or feed] *complies with the criteria referred to in Article 4(1)* [or 16(1)]."

Moreover, Article 9(3) and Article 21(3) of Regulation 1829/2003 similarly provide that the authorisation-holder shall inform the Commission of any new scientific or technical information which might influence

the evaluation of the safety used in the food or the feed in question, as applicable. Similarly, Article 6 of IR 503/2013 emphasises that safety concerns should be the only basis for determining the relevance of additional information to be submitted by applicants.

In determining what “any other” new information means, it is necessary to identify what information is already required by Regulation 1829/2003. The reference to “any other” information must be in addition to that which would otherwise be required. The next qualifier reflects the focus of Article 4 of Regulation 1829/2003 on “adverse effects on human health, animal health or the environment”. The focus is on identifying new information which questions the safety evaluation. This means that the authorisation holder should submit the "new” information linked to the evaluation of the safety.

To conclude, according to our interpretation of Article 6 of IR 503/2013, the applicant must make an objective assessment of what scientific information should be considered and included in the submission. The applicant must apply its professional judgement in an objective and independent manner. **The submission of every available study, including patent information, without having regard to whether it really is relevant to the risk assessment fails to distinguish between studies that are mandatory under the Regulation 1829/2003 and the IR 503/2013 and those which are merely confirmatory. In accordance with those legal acts, a test of relevancy is meant to be applied for the submission of information to EFSA (including of the literature search) and this test is subject to applicants’ objective judgment.**
With respect to patents, these might comprise scientific data generated for legal purposes. **In such cases, CropLife Europe applicants are committed to report any new additional scientific information that might influence the risk assessment conclusions in line with Regulation 1829/2003 and IR 503/2013 as described above.**

Finally, CropLife Europe would like to draw attention to the general EU principle of proportionality, which requires that measures must not exceed the limits of what is appropriate and necessary to attain the objectives legitimately pursued by the legislation concerned. Where there is a choice between several appropriate measures, recourse must be made to the least onerous one and the disadvantages caused by it must not be disproportionate to the aims pursued[1]. The provisions of Regulation 1829/2003 and IR 503/2013 must be read in that light. These are designed to be comprehensive but not impractical or incapable of being satisfied.

Therefore, CropLife Europe member applicants will continue applying their professional judgment in assessing which additional or new scientific information may impact the risk assessment conclusions and submit them to EFSA at any time during the authorisation procedure.

We remain at your disposal for any clarifications.

Best regards,

Laurent Oger

Deputy Director General
CropLife Europe

[1] Case T-96/10 *Rütgers Germany GmbH and Others v ECHA*, paragraph 135.