

EuropaBio concerns regarding provisional practical arrangements on Articles 38 and 39 of Regulation (EU) 2019/1381

EuropaBio would like to express concerns over the recently published EFSA staff Working Document on the practical arrangements implementing Articles 38 and 39 of the Regulation (EU) 2019/1381 (“Transparency Regulation”)¹ which outlines the provisional position of EFSA.

1. Proactive disclosure of environmental information

According to point 6 of the Working Document *“any information falling under the definition of ‘environmental information’ should not be treated as confidential since the Authority is required to make such information available to the public”*, referring to Article 2 and 4 of the Regulation (EC) 1367/2006 (“Aarhus Regulation”)².

We believe this claim lacks any legal basis. The Aarhus Regulation indeed provides for a proactive dissemination of certain environmental information (Article 4). Nevertheless, exceptions to general access and disclosure of environmental information have been introduced in the Aarhus Regulation by referring to Article 4(2) of Regulation 1049/2001 (“Regulation on Access to Documents”) reads *“the institutions shall refuse access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property”*. This exception clearly applies to the whole Title II of the Aarhus Regulation, including Article 4. Furthermore, the Aarhus Regulation also contains rules where the information requested *“relates to emissions into the environment”*, meaning a subset of all potential information that could be considered “environmental”.

Similarly, Article 4 of the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (“Aarhus Convention”)³ obliges the contracting parties to make environmental information available in response to an explicit request with the exception of,

¹ EFSA staff Working Document on the practical arrangements implementing Articles 38 and 39 of the Regulation (EU) 2019/1381 of 26/02/2020; [accessible here](#).

² Regulation (EC) 1367/2006 of 6 September 2006, [accessible here](#).

³ Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters of 25 June 1998; [accessible here](#).

inter alia: (d) confidential information protected by law, excluding information on emissions relevant for the protection of the environment, which must be disclosed; (e) intellectual property rights. Hence, only confidential information on emissions must always be disclosed in a reactive manner upon request.

Regulatory confidential information submitted to authorities is also protected by Article 339 of the Treaty of Functioning of the European Union (“TFEU”) and Article 39(3) of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS Agreement”). International agreements such as the TRIPS Agreement and the Aarhus Convention are superior to EU Regulations as set out in Article 216 of the TFEU, and therefore EU Regulations must be compliant with their content.

2. Minimum requirements for confidentiality requests

Under the Transparency Regulation⁴, EFSA may grant confidential treatment to certain information if the applicant has demonstrated that disclosure would potentially harm its interests to a significant degree. Such requests need to be accompanied by verifiable justification that demonstrates how making public the information concerned significantly harms the interests concerned.⁵ Point 8 of the Working Document describes provisional minimum requirements for confidentiality requests. We view three of the requirements as problematic.

Requirement c. obliges applicants to provide “*explanation or evidence demonstrating to the satisfaction of the Authority that the harm that may be caused is of a significance corresponding at least to 5% of their total turnover for legal persons, or earnings for natural persons. If the harm is quantified as not reaching this percentage, the person shall provide a specific reason on why they considered that any public disclosure would potentially harm their interests to a significant degree*”. It would be extremely difficult if not impossible to quantify the damage prior to disclosure of the information claimed confidential. The legislator did not include any reference to specific turnover thresholds in the legal text. Article 39a of the Regulation requests only a general justification “*that demonstrates how making public the information concerned significantly harms the interests concerned*”. The new Regulation has already increased thresholds for granting confidentiality and the proposed additional requirement based on arbitrary thresholds without legal basis would make confidentiality treatment nearly impossible.

Per **requirement e.** the applicant should further provide “*the confirmation that the document, information or data for which confidentiality status is requested does not fall under the definition of “environmental information” pursuant to Article 2 of the Aarhus Regulation.*” As explained above, this

⁴ Regulation (EU) 2019/1381 of 20 June 2019; [accessible here](#).

⁵ Regulation (EU) 2019/1381, Article 39(2) and 39a.

requirement lacks any legal basis. With the exception of information on emissions that may be disclosed reactively, environmental information is not excluded from confidential treatment.

Finally, **requirement f.** demands “*the confirmation that the document, information or data for which confidentiality status is requested has not been finalised more than five years prior to the submission of the confidentiality request. If the document, information or data deemed to be awarded confidential status is older than five years, the applicant shall provide a specific reason on why public disclosure of that information would still potentially harm its interests to a significant degree.*” As with the requirement on turnover threshold, the Transparency Regulation does not provide a predefined threshold for data becoming obsolete and thus not harming applicants’ interests. This entirely depends on its specific characteristics and should be evaluated case by case.

Disclosure of most items of information included in the categories indicated in Article 39(2) and in sectorial legislation, regardless of their age, will harm applicants’ interests to a significant degree. As an example in the area of genetically modified plants, disclosure of DNA sequence information (if not available by a published patent) or breeding diagrams reveal details about the unique strategy which are at the heart of product development. This information would always allow competitors to gain accelerated market access through acquisition of business secrets and know-how.

There is no legal basis that would justify the introduction of the above-mentioned requirements that are currently being considered by EFSA. Their adoption would be extremely damaging for companies as competitors with access to confidential information would gain a competitive advantage. Protection of confidential information is a necessary tool to protect commercial interests of applicants in rapidly developing fields such as biotechnology and is therefore a crucial incentive for innovators to create new technologies. Failure to adequately protect confidential information discourages the research and development of innovative products and grant accelerated market access to competitors and save investment for their own research.

We call on EFSA to take these concerns into account and re-evaluate their provisional position to ensure the establishment of workable and proportionate practical arrangements which comply with EU legislation and international agreements such as the Aarhus Convention and the WTO TRIPS Agreement and do not jeopardise legitimate interests of applicants.