European Crop Protection

ECPA LEGAL OPINION
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LAEG analysis of EFSA working document on practical arrangements for confidentiality requests

I. BACKGROUND

The European Commission ("**Commission**") recently published a staff working document ("**Working Document**")[1] providing EFSA's provisional position on the implementation of the new rules included by Regulation 2019/1381 ("**Transparency Regulation**")[2] in Regulation 178/2002 ("**Revised GFL**")[3].

We are particularly concerned about some contradictory statements related to the disclosure of confidential information and potential requirements which might be considered to assess confidentiality requests. LAEG therefore feels the need to urge EFSA and the Commission to stick to the legal framework applicable to this subject and calls EFSA to reconsider its position on this important subject.

We are only one year away from the application of the key provision of the Revised GFL and LAEG is deeply concerned that the new system will not be ready by the ambitious deadline set out in the Revised GFL. Therefore, we consider that EFSA and the Commission should focus on the correct and realistic implementation of the new provisions, avoiding unnecessary discussions on unreasonable requirements to protect confidential information.

II. LAEG VIEW ON THE CONFIDENTIALITY REQUIREMENTS OUTLINED IN THE WORKING DOCUMENT

1.1. The reference to the Aarhus Regulation and the applicable legal framework

Point 6 of the Working Document states that, according to articles 2 and 4 of Regulation 2006/1367 ("**Aarhus Regulation**")[4], "*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*".

Article 2 of the Aarhus Regulation (Title I, General provisions) widely defines environmental information. Article 4 (within Title II of the regulation, entitled "Access to environmental information") provides for a proactive dissemination of certain environmental information. It is of utmost importance to clarify that this disclosure cannot adversely affect the confidentiality of commercial or industrial information (with an exception for information on emissions).

Article 6(1) of the Aarhus Regulation refers to Article 4(2) of Regulation 1049/2001 ("**Regulation on Access to Documents**")[5] to introduce some exceptions to general access and disclosure of environmental information. Article 4(2) of the Regulation on Access to Documents provides that "*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*". The exception clearly

[1] The document can be found in the Commission page dedicated to the implementation of the Revised GFL (also here).
[2] Regulation (EU) 2019/1381 of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.
[3] Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. So-called "General Food Law".
[4] Regulation (EC) No 1367/2006 of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies.
[5] Regulation (EC) No 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

applies to the whole Title II of the Aarhus Regulation (including Article 4) and this can be easily deduced from the structure and provisions of that Title but also from the wide Aarhus framework.

In fact, the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters ("**Aarhus Convention**") provides further evidence that EFSA's claim lacks any legal basis and justification. Likewise the Aarhus Regulation, Article 2 of the Convention defines environmental information. Article 4 of the Convention requires the contracting parties to make such information available in response to an explicit request with the exception of, *inter alia*: (i) confidential information protected by law, excluding information on emissions relevant for the protection of the environment, which must be disclosed[6]; (ii) intellectual property rights[7].

In light of the above, and differently from what is claimed by EFSA, only confidential information on emissions "may always be disclosed"[8]. And this information, if considered confidential under the Revised GFL, would be reactively disclosed in response to an official request for information. Article 5 of the Aarhus Convention covers the categories of environmental information which instead should be proactively made available to the general public, including, *inter alia*: (i) reports on the state of the environment; (ii) environment-related legislation; and (iii) environment-related policy information. Article 5(10) is also clear in restating that the Parties of the Convention always have the right to refuse to disclose confidential information and IP rights.

In any case, the proactive publication of non-confidential environmental information contained in regulatory dossiers is already provided by Article 38 of the Revised GFL. The obligation under Article 4 of the Aarhus Regulation is less stringent than the GFL one, because it implies a progressive publication of non-confidential environmental information in electronic databases. And EU authorities/institutions may also replace publication of relevant studies or risk assessments with a reference to the place where the information can be requested[9]. The Regulation on Access to Document and the Aarhus Regulation will certainly apply to requests to access to all documents held by EFSA which are not proactively disclosed by the authority. As evidence of the fact that the legislator had access to those documents in mind, the Revised GFL (which is also EFSA's founding act) makes a reference to the Aarhus and Access To Documents regulations in Article 41 (entitled "Access to documents") and not in its confidentiality provisions, Article 39 to 39d.

Finally, 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**")[10]. According to Article 216 of the TFEU, international agreements such as the TRIPS Agreement and the Aarhus Convention have a legal force superior to EU Regulations, which must therefore comply with them[11]. With regard to the Aarhus framework, this is confirmed by the recently published report on the implementation of the Convention[12].

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[6] Article 4(4)(d) of the Aarhus Convention. Information on emissions was defined by the ECJ in para. 103 of C-442/14 *(Bayer CropScience SA-NV and Stichting De Bijenstichtig)* as "*information concerning the nature, composition, quantity, date and place of the 'emissions into the environment' of those products or substances, and data concerning the medium to long-term consequences of those emissions on the environment".*

[7] Article 4(4)(e) of the Aarhus Convention.

[8] In para. 88 of C-673/13 P *(Commission v Stichting Greenpeace Nederland and PAN Europe)* the ECJ clarified that information on emissions *"may not, in any event, include information containing any kind of link, even direct, to emissions into the environment. If that concept were interpreted as covering such information, it would to a large extent deprive the concept of 'environmental information' as defined in Article 2(1)(d) of Regulation No 1367/2006 of any meaning. Such an interpretation would deprive of any practical effect the possibility, laid down in the first indent of Article 4(2) of Regulation No 1049/2001, for the institutions to refuse to disclose environmental information on the ground, inter alia, that such disclosure would have an adverse effect on the protection of the commercial interests of a particular natural or legal person and would jeopardise the balance which the EU legislature intended to maintain between the objective of transparency and the protection of those interests. It would also constitute a disproportionate interference with the protection of business secrecy ensured by Article 339 TFEU."*

[9] Article 4(2)(g) of the Aarhus Regulation.

[10] Article 39(3) TRIPS reads: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

[11] The official explanation of Article 261 of the TFEU can be found on Eurlex (here).

[12] Page 4 of the Report (available here) reads: "*the Aarhus Convention concluded by the Union binds its institutions and prevails over acts of secondary Union legislation".*

1.2. Legal assessment of the Working Document reference to the Aarhus Convention

In view of the above, LAEG believes that in the context of publication of non-confidential environmental information included in regulatory dossiers, the Revised GFL provides for stricter requirements than the Aarhus framework and, in its quality of *lex specialis*, prevails over the Aarhus provisions governing this specific aspect. As regards confidentiality, Article 4(4)(d) of the Aarhus Convention, Article 6 of the Aarhus Regulation, Article 4(2) of the Regulation on Access to Document and Article 39 *et seq.* of the Revised GFL confirm that confidential information must not be disclosed.

The Aarhus Regulation would complement the Revised GFL with regard to access to all unpublished documents held by EFSA and disclosure of confidential information on emissions contained in regulatory dossiers. In this case, the information on emissions may be made available in a reactive manner to a specific applicant (avoiding, therefore, dissemination of data) and extracting relevant data from the main piece of information.

The arbitrary disclosure described in the Working Document would also infringe Article 339 TFEU, Article 39(3) TRIPS and interfere with the EU Charter of Fundamental Rights (freedom to conduct a business and right to property enshrined in the Charter)[13]. Moving away from a strict legal analysis, it is well known that protection of confidential regulatory information is the real foundation of investments and innovation. Without the promise of returns guaranteed by such protection, companies would have no reasons to invest in innovative products and billions of euro would be lost. Confidential information and business secrets will ultimately be used by competitors to gain accelerated market access and save investment for any own research. Access to this information would favor competitors rather than the general public.

Therefore, stating that under Articles 2 and 4 of the Aarhus Regulation all environmental information should not be treated as confidential and always be made available to the public is incorrect and lacks any legal basis.

2.1. Minimum content of confidentiality requests

Point 8 of the Working Document states that applicants, when submitting confidentiality requests, should provide a text explaining why the following cumulative requirements are satisfied:

a. the document, information or data for which confidentiality status is requested is not publicly available or is known only to a limited number of persons;
b. the public disclosure of the document, information or data for which confidentiality status is requested may potentially harm the interests of the applicant to a significant degree;
c. 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;
d. the document, information or data for which confidentiality treatment is requested is worthy of legal protection in the form of the award of the confidentiality status;
e. 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;
f. 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.

Before assessing these conditions, it is worth recalling that, under the Revised GFL, EFSA may grant confidential treatment to specific items of information, where “*verifiable justification*” has been

[13] Article 16 and 17 of the EU Charter of Fundamental Rights.

demonstrated by the applicant that disclosure would "*potentially harm its interests to a significant degree*"[14].

2.2. Legal assessment of the potential requirements for confidentiality requests

i. *Requirement a. – information shall not be publicly available*

This requirement should be considered in the confidentiality assessment. LAEG agrees that, if information is already in the public domain (through lawful disclosure, rather than theft or unauthorized misuse) a confidentiality claim should not be substantiated.

ii. *Requirement b. – potential harm to a significant degree*

LAEG agrees that this requirement should be considered in the confidentiality assessment and correctly reflects the meaning of Article 39(2) of the Revised GFL.

iii. *Potential requirement c. – damage concerning at least at least to 5% of the total turnover of a legal persons*

As stated above, Article 39(2) requires applicants to demonstrate that disclosure would "*potentially harm its interests to a significant degree.*"

The nature of such potential damage includes (but is not limited to):

- adverse effects to the competitive position of the applicant (e.g. facilitating reverse engineering of the technical specifications of an active substance or of a product formulation);
- competitive advantage to competitors (e.g. accelerated market access through disclosure of trade secrets or know how); and/or
- financial loss which can result from the disclosure of the information (reduced sales of current products and losses in revenue for investment in new products).

Among these examples, only damages related to financial loss may be calculated by companies; still, it would be extremely difficult to precisely quantify the damage prior to disclosure. Article 39a of the Regulation requests a general justification of the causal link between publication of a few specific items of information which in other contexts are always qualified as confidential data and potential harmful effects; no reference to certain turnover thresholds is made in the legal text.

The Revised GFL sets out strict requirements for granting confidentiality and it will be already very hard to demonstrate a clear causal link between publication of data and harmful effects prior to such disclosure. An additional requirement based on arbitrary thresholds, besides lacking any legal grounds, would make this operation nearly impossible.

iv. *Requirement d. - confidentiality is worthy of legal protection*

LAEG agrees that this requirement should be considered in the confidentiality assessment. As regards PPPs, the GFL list of eligible items and requirements to obtain protection of confidentiality is complemented by the revised Article 63 of Regulation 1107/2009, as amended by Article 7 of the Transparency Regulation. As specified in Article 39(e) of the Revised GFL, protection of personal data will be guaranteed by regulations 2016/679 and 2018/1725.

v. *Potential requirement e. – the information does not fall under the definition of "environmental information" pursuant to Article 2 of the Aarhus Regulation*

As explained in greater detail above, this cannot be a requirement to assess confidentiality requests under the Revised GFL. EFSA should consider the Aarhus framework only if certain confidential data qualifies as "information on emissions relevant for the protection of the environment" and may reactively disclose to a specific applicant only data concerning emissions (which should be extracted from the confidential source of information).

[14] Article 39(2) of the Revised GFL.

vi. *Potential condition f. – the document concerned shall not be older than 5 years*

The Revised GFL does not provide a predetermined threshold when data becomes old enough not to harm applicants' interests. Whether data becomes "harmless" depends on its specific characteristics and should be evaluated on a case-by-case scenario. Disclosure of most items of information included in the categories indicated in Article 39(2) of the Revised GFL, regardless to their age, will harm applicants' interests to a significant degree.

As an example, disclosure of certain information (such as number of process steps, manufacturing efficiencies, innovative production methods, identity and quantity of non-relevant impurities, degree of purity etc.) reveals details about the determination of which production process has been applied. This information, would always allow competitors to gain accelerated market access through acquisition of business secrets/know how which is not protected by patents.

Moreover, disclosure of supply chain information, regardless to its age, facilitates the replacement of actors in that supply chain by third parties and the identification of more cost-efficient routes to market. It also undermines an applicant's bargaining power vis-à-vis a producer or importer since it will no longer be the sole customer for that service in that market.

Therefore, no legal basis justifies this potential requirement and its introduction would be extremely damaging for companies, since it would provide an unreasonable safe harbour to disclose trade secrets to competitors.

III. CONCLUSIONS

We understand that these requirements are still under discussion but we are concerned about the alarming picture emerging from the GFL Expert Group debate over the implementation of the confidentiality provisions of the Revised GFL.

As clarified above, stating that under Articles 2 and 4 of the Aarhus Regulation confidential information on environmental aspects shall always be made public is incorrect and would contradict: (i) the actual provisions of the Aarhus framework (articles 4(2) and 6(1) of the Regulation; articles 4(4) and 5(10) of the Convention); (ii) the whole transparency system set up by the Revised GFL (articles 38 to 39d and Article 41); (iii) Article 339 of the TFEU, Article 39(3) of the TRIPS Agreement and the EU Charter of fundamental rights. In fact, in the context of publication of non-confidential environmental information included in regulatory dossiers, the Revised GFL provides for stricter requirements than the Aarhus framework and, in its quality of *lex specialis*, prevails over the Aarhus Regulation provisions governing this specific aspect. Only information on emissions "may always" be disclosed to specific requestors.

Moreover, the potential requirements for confidentiality outlined in letters c), e) and f) of point 8(2) of the Working Document are manifestly inapplicable and lack any reference in the text of the Revised GFL.

This is an issue of direct concern for all sectors affected by the Revised GFL and we would very much appreciate clear and practical guidance from EFSA/Commission on the description and demonstration of: (i) the damage that would be caused by disclosure; (ii) the competitive advantage for competitors that have access to confidential information; and (iii) the causal link between disclosure and harmful effects.

In conclusion, we believe that without immediate and coordinated action by EFSA and the Commission to implement the new provisions, the GFL system will not be ready by 27 March 2021. Discussing the overall feasibility of additional requirements that are not provided in the adopted text would not help to speed up the implementation process and meet the ambitious deadline set out in the Revised GFL.