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Reform of the General Food Law
Analysis of the new provisions on transparency

The European Commission proposed on 11 April 2018 to reform the overarching piece of EU law that governs food, Regulation 172/2002 (the "General Food Law"), and the functioning of European Food Safety Agency (EFSA)[1], (the "Proposal").

The wording of the reform proposed by the Commission is highly problematic. It needs to be fixed through significant amendments to avoid that the new regime while promising more transparency leads to the contrary.

Amendments are indispensable to prevent that:

1) The changes proposed in the rules on proactive publication lead to a restriction of the right of citizens to obtain access to documents upon request;

2) In application of the new rules, the information necessary to enable meaningful public consultation and the restoration of public trust is still not published and its publication made even more difficult than before.

Sections 1 and 2 address these two essential points. They explain why the current wording adopted by the Proposal is highly likely to lead to a decrease in transparency by giving more legal tools to industry to keep information secret while depriving citizens of proper transparency safeguards. Section 3 highlights a few other issues and Section 4 gives a non-exhaustive list of positive elements that need to be maintained in the Proposal.

Contents

[1] Commission Proposal COM(2018)179 for a Regulation of the European Parliament and the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods].

1) The need to protect the right to access to document upon request from the reform

The existing EU rules on transparency consist of two regimes:

(i) The regime applicable **to triggered disclosure, upon access to document requests** by a private or public person. This regime is set by Regulation 1049/2001 and Regulation 1367/2006, as interpreted by the Court.

(ii) The regime applicable to **proactive disclosure (or 'publication'**) of the information held by the EU authorities. This regime is grounded in the general obligation to actively disseminate and is set by Article 11 and 15 TEU and by Article 4(1) of Regulation 1367/2006[2]. Its implications for Food Law are laid out by the specific provisions on proactive disclosure set in the General Food Law and its related sectoral legislations.

Proactive disclosure and access upon request both contribute to ensuring the transparency of the decision-making process in the EU, but their specific aims are different. Proactive disclosure aims at providing the same information to all citizens, in order to improve the legitimacy of the institutions and the capacity of all citizens to actively contribute to the decision-making process.

The right to access documents upon request is the last resort for individuals when the EU institutions, or the Member States, have decided to not proactively disclose the information they hold.

In the best-case scenario, the rules that govern proactive disclosure and access to documents upon request are fully aligned: public authorities publish proactively what they would have to disclose anyway if a person requests it. A full alignment avoids confusion between the regimes, increases trust and saves resources for the public authorities who will not have to manage the flux of requests.

As they are today, the rules on proactive dissemination and access upon request are mostly aligned, and are generally clearly distinguished from one another.

The General Food Law reform proposed by the Commission changes this situation in two ways:

- The Proposal restricts the current 'transparency safeguards' (current Article 39 compared to new Article 39(4)) which are now much stricter than the ones applicable to

[2] Regulation (EC) No 1367/2006 of the European Parliament and of the Council 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, OJ L 264, 25.9.2006, p. 13–19 'Community institutions and bodies shall organise the environmental information which is relevant to their functions and which is held by them, with a view to its active and systematic dissemination to the public, in particular by means of computer telecommunication and/or electronic technology in accordance with Articles 11(1) and (2), and 12 of Regulation (EC) No 1049/2001. They shall make this environmental information progressively available in electronic databases that are easily accessible to the public through public telecommunication networks. To that end, they shall place the environmental information that they hold on databases and equip these with search aids and other forms of software designed to assist the public in locating the information they require'.

access to document requests. This means that even if there is an overriding public interest in disclosure, the information would not be published.

- The unfortunate wording of Recitals 27 and 36 of the Proposal and to some extent Article 38(1) and Article 41(1) of the General Food Law could lead to the misinterpretation of the new provisions on dissemination as a new set of rules applicable to both proactive dissemination and access to documents upon request.

Any restriction of the right to access information upon request is inacceptable. Not only is this right clearly defined by International and EU law, but the Court has also affirmed many times that it gives to natural and legal persons the widest possible right to access information[3]. The right to access needs to be wider or equivalent to the obligation to disclose proactively.

However, the combination of the two changes described above creates a very high risk of restricting the right to access documents upon request. The result would be that EFSA could decide to not publish an information because it falls under Article 39, and then refuse to disclose it upon request even if a clear overriding public interest, as set by Regulation 1049/2001, exists. **In no way would it make sense to restrict the access to documents rules specifically for food law, and even less so in a Proposal supposed to increase transparency**.

It is therefore indispensable to amend the Proposal in order to avoid that the new provisions on proactive disclosure restrict in any way the rules on access to documents upon request.

2) The need to ensure that the Proposal increases transparency as promised

The General Food Law and the other sectoral legislations covered by the Proposal already contain provisions obliging the EU institutions to proactively publish the information they receive in the context of risk assessments.

In order to keep the promise of the Proposal, which is to increase transparency, the new rules need to reinforce and broaden this obligation. Analysing whether the Commission actually delivers on its promise requires keeping in mind the difference between document and information when it comes to transparency regimes. ‘Documents’ or sums of documents are, for example, the dossier submitted by a company to apply for an authorisation to sell pesticides. ‘Information’ is the data found in the document.

The Proposal without doubt increases the **number of documents** concerned by EFSA’s obligation to disseminate, either by detailing the content of what was previously a general obligation or by broadening pre-existing obligations (see Article 38(1) as amended in the Proposal). This part of the reform is a welcome attempt to force EFSA to change its culture on dissemination, and better align with other EU Agencies such as the European Medicines Agency (EMA) and the European Chemicals Agency’s (ECHA) practices, by proactively publishing more documents.

[3] See e.g. C-280/11 P Council v. Access Info Europa, para 30.

The relevance of a proactive publication, however, depends as much – and often more – on whether or to what extent the information contained in those documents is redacted before release.

Unfortunately, **the Proposal, as it stands today, is very likely to result in even more restrictive access than before** to important information contained in the documents that do need to be public to enable a meaningful public consultation and restore trust.

Two aspects of the Proposal have to be significantly reworked:

- The wording and scope of the definition of 'confidential information' that opens the door to information being kept secret well beyond what is commonly considered as commercially sensitive;
- The 'transparency safeguards' that have been considerably cut in the Proposal.

These changes are even more crucial in case the Proposal is not amended to explicitly state that the new rules applying to proactive publication do not affect in any way the scope of the right to access information upon requests (see Section 1 above) and if the 'transparency safeguard' (see section 2.2) remains as strict as it is in the current version of the Proposal.

2.1. The need to re-work carefully the wording on the definition of confidential information

a) The need to maintain clarity on information that can never be confidential

All the sectoral legislations covered by the Proposal – besides the General Food Law and the Pesticides Regulation – contain today a list of information that can never be confidential.[4] The Proposal deletes all of them, without proper justification.

Those lists provide clarity to citizens and ease the work of EFSA by allowing an automatic rejection of the confidentiality requests directed to the information concerned. The current lists have therefore to be maintained. Such lists should also be adopted for the Pesticides Regulation, considering the obligation to release information related to emissions into the environment under Regulation 1049/2001 and 1367/2006, as confirmed by the Court.[5]

b) The protection of personal data needs to be reworded

In the sectoral legislations covered by the Proposal, only Regulation 1107/2009 [on plant protection product] contains a provision on the protection of personal data – Article 63g. The

[4] Regulation 1935/2004 [on food contact materials], Article 20(2).
Directive 2001/18 [on the deliberate release into the environment of GMOs], Article 25(4)
Regulation 1829/2003 [on GM food and feed], Article 30(3)
Regulation 1831/2003 [on feed additives], Article 18(3)
Regulation 2065/2003 [on smoke flavourings], Article 15(3)
Regulation 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Article 12(1)
Regulation 2015/2283 [on novel foods], Article 23(4)
[5] C-442/14 and C-673/13 P

Proposal widens the provision to persons involved in obtaining toxicological information. There is no rationale behind protecting the identity of the persons involved in toxicological research in general; on the contrary, a transparent and excellent research undertaking requires ownership from the authors of the studies involved. There is therefore no reason to keep this undue addition proposed by the Commission.

c) The lists of commercial information that may be considered for confidential treatment must be clearly exhaustive

The Commission clarified in bilateral meetings that it intends the lists of information for which disclosure may be considered as significantly harming commercial interests to be exhaustive.

The current wording of Article 39(2) in the Proposal should be improved to ensure that the final text will be implemented with such results. The current wording is indeed unduly complex and could bring confusion.

For the same reason, it is indispensable to amend the list set out for Regulation 1935/2004 [on food contact materials], as it opens the door to too many other potential additions to the list, without any criteria limiting their potential scope or nature.

Further, the Commission made clear in bilateral meetings that its intention was not to create a presumption of confidentiality of the information listed in Article 39(2). For each category of information listed, the applicant would have to provide verifiable justifications and explanations why the information covered would significantly undermine its commercial interest. The current wording of this provision needs to be clarified along those lines.

d) Some categories need to be deleted from the lists of 'confidential information' or amended

Currently, only the Pesticides Regulation contains today a list of information which may be considered of commercial interest. For all the other sectoral regulations covered by the Proposal, the Commission has created new categories of 'confidential information'.

Some of the information listed at Article 39(2) of General Food Law such as the 'commercial information revealing business strategy of the applicant' has been repeatedly recognised as of commercial interest by the Court and can therefore be integrated in the list consensually.

The integration of other information is however much more contentious (e.g. Article 39(2)1. on the **method of manufacture** and Article 39(2)4. on the **quantitative composition**) as they have never been recognised as being of commercial interest by the Court, nor have a similar nature to the categories of information which have been recognised as being of commercial interest by the Court.

Amendments are required to make sure that the objective of the Proposal is achieved: ensure that the public has access to the information it needs to contribute to the decision-making process

involving a risk assessment, and to have the tools to better scrutinise the process – which will both lead to increased trust and legitimacy.

The information listed in Article 39(2) 1. and 4. can be crucial in the assessment and understanding of the risk. It is therefore logical to reserve to EFSA the right to publish when the information plays an essential role. This need was recognised in the Pesticides Regulation, when it listed 'the specification of impurity of the active substance' as potentially confidential 'except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant'.

Similarly, in **the sectoral legislation** covered by the Proposal, some information of direct relevance for the environmental or health risk assessment is now listed as "confidential information". This would lead to a decrease in transparency and therefore must be corrected. This includes, for example in Regulation 1935/2004 [on food contact materials] Article 20(2)(a) "any information provided in detailed descriptions of starting substances and preparations used to manufacture the substance subject to the authorisation, the composition of preparations, materials or articles in which the applicant intends to use this substance, the manufacturing methods of these preparations, materials or articles, impurities, and migration testing results".

It is important to note that amendments to this list would be particularly crucial if the Proposal is not amended to explicitly state that the new rules applying to proactive publication do not affect in any way the scope of the right to access information upon requests (see Section 1 above) and if the 'transparency safeguard' (see section 2.2) remains as strict as it is in the current version of the Proposal.

Listing such information as potentially confidential without guaranteeing that in case of overriding public interest (for example if it relates to emissions into the environment in the meaning of the Aarhus Convention) the information would be made public, would indeed be a significant reduction of the right to access documents upon request – and in the end of transparency.

Another information now included in the list of confidential information is not only new, but also runs contrary to the logic of the IP protection rules: in Food Contact Material law, the Proposal adds to the list of "confidential information", "the **trademark** under which the substance shall be marketed as well as the tradename of the preparations, material or articles in which it shall be used, where applicable"[6]. This has no legal basis. A trademark is meant to be public by definition. A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises. What it protects is the right to use the name registered, excluding others from using it.[7] It does not protect the name from being public. This provision defeats the purpose of a trademark registration.

Finally, information that is particularly important to understand the nature and potential impact of the emissions into the environment resulting from the use of **pesticides**, is still considered as potentially commercially sensitive information under the Proposal: "information on the **complete**

[6] Article 20(2)(b)
[7] http://www.wipo.int/trademarks/en/

composition" of the product.[8] The Proposal fails to improve transparency here by including this information in the list of information that can be claimed confidential.

e) The protection of intellectual property rights need to be reworded

The Commission proposes to have a new Article 38.1a (General Food Law) which reads as:

> "1a. The disclosure of the information mentioned in paragraph (1)(c) to the public shall be without prejudice:
> (a) to any intellectual property right which may exist over documents or their content; and,
> (b) any provisions set out in Union food law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations ('data exclusivity rules').
> The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited and its use by third parties shall not engage the responsibility of the European Union".

The term 'intellectual property rights' (IPR) is sometimes used to refer to two different notions:

- The first one concerns 'hard' IPRs: patents, trade mark, copyrights or design. Those rights do not oppose *disclosure*, they oppose the *commercial use* of the element protected by a third party. **They are already protected by Article 38.1a (b)**;

- The second one concerns 'soft' IPRs, which are more accurately called 'trade secrets'. Trade secrets are information (i) unknown and unavailable even by experts in the field (ii) that provides an economic benefit because of its secrecy and which would provide a competitive advantage to competitors (iii) that is the target of active efforts to maintain secrecy by the company.[9] The information that may be legitimately considered as trade secret (as per the jurisprudence of the EU Courts and as informed by the current practice of EMA) and that may be present in regulatory studies or other information covered by the Proposal **is already covered by the new Article 39(2) of the General Food Law.**

Article 38.1a raises, in that context, two issues:

First, the current formulation of Article 38.1a.(a) may lead to its misinterpretation as offering new ground to claim information as confidential because commercially sensitive, in addition to the ones already listed in Article 39. If it were the case, it would open the door to abusive claims considering the vagueness of the wording. As Article 39(2) is meant to be an exhaustive list of information which may be claimed confidential because it is commercially sensitive, **leaving Article 38 1a (a) in the text would defeat the purpose of Article 39**.

[8] Proposal to amend Regulation 1107/2009 [on plant protection product], new Article 63(2)(c) (current Article 63(2)(f))
[9] See Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 15 April 1994 (OJ 1994 L 336, p. 214; 'the TRIPS Agreement'), Article 39(2).

Second, (Hard) Intellectual Property Rights do not prevent independent scientists from evaluating industry studies and citing them in scientific publications. Only *use for commercial purposes* is prohibited under (Hard) Intellectual Property law. This distinction needs to be made clear in Article 38.1a.

EMA's policy makes this clear by requiring any person who would like to access the 'raw data' or studies commissioned or realised by the applicant in the context of the risk assessment to accept the 'Terms of Use', through a quick and simple procedure by which the person commits to not use the data for commercial purposes. Section 4.2.1 of EMA's policy (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf) could be used as an inspiration to fix Article 38.1a.

These changes are even more important in case the transparency safeguards are kept as narrow as proposed in the new rules (see Section 2.2 below), and if the Proposal does not explicitly state that the new rules do not affect in any way the scope of the right to access information upon requests (see Section 1 above). As a reminder, Regulation 1049/2001 provides for an exception to the right to request confidentiality on the grounds of Intellectual Property rights (Article 4(2)), i.e. if there is an overriding public interest in disclosure.

2.2 The need to keep 'transparency safeguards' at least as broad as before

All the sectoral legislations covered by the Proposal (with the exception of Directive 2001/18) contain in their current version a 'transparency safeguard': a provision setting the conditions under which information found to be commercially sensitive shall nevertheless be published by EFSA. The breadth of their transparency safeguards vary. Most contain a broad reference to the need to publish the information 'if circumstances so require in order to protect human health'[10]. The GM Food and Feed Regulation goes further 'if circumstances so require in order to protect human health, animal health or the environment' and the Pesticides Regulation beyond that, referring to the need to disclose confidential information if there is an overriding public interest in disclosure.

The Proposal aims at replacing those different approaches with Articles 39(4)(a) and (b) which would apply to all. Article 39(4) as worded today in the Proposal **would lead to a decreased level of transparency compared to the present situation**, contrary to the Commission's promise.

The addition of an 'emergency' component to the previous transparency safeguard in particular is a significant step back in the level of transparency offered. Indeed, circumstances can require the publication of certain information to protect human health or the environment without the existence of an emergency. The principle of prevention, which benefits from the highest legal value in the EU legal order, actually requires that information that is relevant for health or environmental protection to be disclosed far before an imminent danger appears.

[10] This is the case for the current version of the General Food Law, Regulation on Smoke flavouring, on Feed additives, on Food Contact Materials, on the common authorisation for Food additives, Enzymes etc. and the Novel Food Regulation.

The Pesticides Regulation has the broadest transparency safeguard, which takes into account the specificities of these substances, their impact and wide release. It is unacceptable that the harmonisation of sectoral food legislations leads to a decrease in transparency under Pesticides Law.

The Proposal, at the very least, has to be amended so that it does not weaken the current transparency safeguards. These safeguards must be preserved. If harmonisation is done, the reform should extend to all sectoral law the safeguards ensuring the most transparency (currently these are the safeguards set out in the Pesticides Regulation).

3) Other issues identified

- The reform ignores EFSA's current obligation to publish environmental information in application of Article 2 Aarhus Regulation. Article 38 listing which information must be now published by EFSA should refer to it.

- The notion of "scientific output" is not defined anywhere even though it is heavily used in the Proposal. A definition should be added, and should be made as broad as possible to be sure that all EFSA's activities are covered.

- Article 39a(2) does not clearly state *how* the Applicants must treat the information that they consider as confidential in the documents that they have to submit to EFSA and that EFSA has to publish. In its current form it just affirms that the document 'shall be without the information'. This practice differs from what ECHA and EFSA require from the Applicants, i.e. a redaction using black bars. The language of Article 39a is also not fully coherent with the procedure to handle confidentiality requests as set by the Proposal.

4) Positive elements to be maintained

- The immediate publication of the data upon receipt, as it essential to increase the legitimacy of the process by giving to civil society the tools it needs to scrutinize it, and exercise its new right to be consulted as set by Article 32c.

- The imposition of a standard and searchable format for the data (Article 39f)

- The greater precision in Article 38(1)(c) of what "the information on which its opinions are based" entails (i.e. scientific data, studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion)

- The publication of more than the summary of the dossier under the Pesticides Regulation (new Article 10 of Regulation 1107/2009)
- The register of studies (Article 32b)
- The organisation of a public consultation (Article 32c)
- The controls (Article 32d)
- The clarification of the process used to handle confidentiality requests (Article 39a & b)

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