

Transparency and Openness in Food Safety: insights about new Data Confidentiality rules

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Abstract

This short study discusses the potential implications of an ownership-based approach to the debate on data transparency and openness in the context of food safety legislation. Measures enshrined in the draft EU reform of the General Food Law Regulation give more power to the European Food Safety Authority to disclose scientific data submitted by commercial entities when requesting an authorisation to place food products on the EU market. This originates a conflict between the public interest in the disclosure of data for the cross-check of the evidence supporting the safety of foods and the commercial interest of the industry in keeping the data confidential. Possibly due to some divergence in the conceptualisation of the goals of transparency and openness, the rationale underlying the publication remains unclear. Departing from the proposed reform, this study looks at how it determines a shift of the ownership when scientific data is transferred from food business operators to the Authority and then published for transparency and openness reasons. Findings from this paper also suggest that the issues pertaining to data ownership shall be taken into account when legislative initiatives or decisions concerning the disclosure of data take place.

Keywords— Food Safety; Transparency; Openness; Data Ownership; EFSA.

1 Introduction

The General Food Law Regulation (GFLR, Regulation 178/2002¹) plays a crucial role in European Union (EU) food policy for its twofold goal: on the one hand, it aims to

protect human health by ensuring that safe and wholesome foodstuffs circulate within the EU; on the other hand, it stimulates the free movement of foods in the internal market, which is beneficial both for the industry and for consumers.

As regards the first goal, the GFLR defines food safety risk analysis as an activity that consists of three main competences. The European Food Safety Authority (EFSA) is in charge of risk assessment, which consists of a scientific evaluation intended to find evidence about the safety of foods in order to support decision-making processes. Then, the EU Commission is responsible for risk management, i.e. the political decisions - informed by the risk assessors - which may include food banning, food recalls, and authorizations. Finally, both institutions are competent for risk communication, which primarily consists of informing consumers about policy-making, foodborne outbreaks and EU initiatives regarding food safety. The three areas are widely interconnected and several policy tools ensure dialogue between the two institutions.

In the modern food safety system and, in particular, among EU institutions involved in the risk analysis, the interest towards data usage is growing (Cappè et al., 2019). The impact of an ongoing reform at the EU level, revolving around the use and publication of scientific data, has raised a considerable amount of question concerning the use of data within the risk assessment.

In the centralised EU food safety system regulated by the GFLR, food business operators willing of placing certain products on the market (including plant protection products, GMOs, and additives) or marketing other foodstuffs (e.g. novel foods) are required to seek authorisation from the European Commission. Its decision is informed by EFSA, to which food business operators have to submit scientific data and documents supporting their request for an authorisation.

The Authority publishes its opinions in an open access journal (EFSA, 2003). Transparency and openness of data

¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council 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 [2002] OJ L 31/1

represents one of the most controversial fields of debate. While scientists and NGOs advocate for a wide availability of scientific data in order to review evidence about the safe use and composition of foodstuffs, applicants seeking authorisation need to protect their investment in research and development of their products, thus claiming a confidential treatment over their most valuable data.

This paper attempts to clarify how the ongoing EU reform addresses this peculiar conflict of interest and how the solutions provided by the draft reform interfere with data ownership. For the purposes of this analysis, the "black letter" of the law - including the existing legislation and the proposed reform - and the academic literature discussing transparency and openness in the context of food safety constitute the main source of analysis. Moreover, recent rulings by the Court of Justice of the European Union (CJEU) have been taken into account to analyse how the balance between the public interest in the disclosure of data held by public authorities and the possible interference with private interests has been settled in the case law.

Following this introduction, this paper departs from the differences regarding the remit of the concepts of transparency and openness in the academic literature, in CJEU ruling, and in the current legislative framework (Section 2). Section 3 summarises the provisions contained in the Proposal for a Regulation on the Transparency and Sustainability of the EU risk assessment in the food chain² in the areas of transparency and openness. Since Section 2 and Section 3 demonstrate that a certain degree of ambiguity can be found in the definition of the goals and scopes of transparency and openness, Section 4 provides food for thought on the concept of data ownership. On the basis of the analysis of the measures contained in the Proposal regarding the publication of scientific data, this Section proposes two alternative ownership-based interpretations of the provisions enshrined in the Proposal and discusses their implications for policy-making. Final remarks summarise the study and pose questions for further research.

2 Openness and Transparency in EU Food regulation

In line with EU law principles, openness and transparency are two core values of EU food safety legislation and of risk assessment activities carried out by EFSA. This section

summarises the most relevant conceptual approaches to openness and transparency proposed by regulators, the Court of Justice of the European Union (CJEU) and academic commentators. These attempts to conceptualise these two concepts primarily focus on their goals.

Openness and transparency are commonly used interchangeably (Lodge, 2003), when describing "good governance" measures indented to promote the de-construction of layers of opaqueness and secrecy in EU decision-making, in order to support democracy (Alemanno, 2014). Therefore, a first interpretation claims that there is no major difference between the two concepts, as they share a common goal. The CJEU has interpreted these two concepts as synonyms when discussing Article 15 of the Treaty of Functioning of the European Union³. In *Turco*⁴, the CJEU stated that "openness [...] contributes to strengthening democracy by allowing citizens to scrutinize all the information which has formed the basis of a legislative act"⁵. However, in *Bavarian Lager*⁶, the CJEU pointed out that Regulation 1049/2001⁷ (the Regulation granting EU citizens' access to documents held by EU institutions) "is designed to ensure the greatest possible transparency of the decision-making process of the public authorities and the information on which they base their decisions"⁸.

A second theory, at the other extreme, suggests that, at least in food safety policy, transparency and openness differ profoundly. While the former only concerns all the activities of the EU institutions (thus, including EFSA) and access to documents, the latter deals with the release of information (and data) concerning private parties (Conte-Salinas and Wallau, 2016, p.582).

A third approach claims that openness is a general principle discouraging secrecy and enabling the EU institutions to have greater legitimacy and to be more effective and more accountable to EU citizens. In *Hautala*⁹, the CJEU stated that the disclosure of scientific

² (COM (2018) 179 Final)

³ Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (TFEU) [2016] OJ C202/1

⁴ Joined cases C-39/05 P and C-52/05 *Kingdom of Sweden and Maurizio Turco v Council of the European Union* [2008] ECR I-04723

⁵ *ibid*, para 46

⁶ Case T-194/04 *Bavarian Lager v Commission* [2007] ECR II-3201

⁷ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ L 145

⁸ *Bavarian Lager* para 49

⁹ Case T-329/17 *Heidi Hautala and Others v European Food Safety Authority* [2019] ECLI:EU:T:2019:142, para 60

data contributes to an open discussion, especially towards areas of scientific uncertainty and divergence, and fosters trust in EU institution. Therefore, openness encompasses transparency, which, in turn, inspires practical measures that facilitate citizens' access to information held by EU institutions (Alemanno, 2014). In food policy, as EFSA Programming Document 2019 - 2021 suggests (EFSA, 2019, p.11), openness is deemed to be a general principle aimed at fostering trust, while transparency is a necessary corollary that inspires data disclosure measures.

By looking at the centrality of these measures in food safety law, a fourth approach may argue that transparency is the key principle in this sector and, therefore, it encompasses openness. This is due to multiple mentions to transparency (including the whole section II of the GFLR) in the provisions which mandate publications of data. Openness, instead, is used as synonymous for "inclusiveness" and plays a role only in scientific consultation, with no direct effect over information disclosure. This theory has not been fully analysed by the literature, but should nonetheless deserve some attention.

3 Evidence from the Proposal

The Fitness Check of the GFLR published by the EU Commission in 2018¹⁰ highlighted the lack of transparency perceived by EU consumers in food safety risk assessment activities. Following "Monsanto Paper" scandal (Foucart and Horel, 2018), the European Citizens' initiative "Ban glyphosate and protect people and the environment from toxic pesticides"¹¹ generated debate all over Europe, with more than 1 million citizens signing the initiative, thus raising attention on the use of pesticides and, more broadly, safe innovation in food and feedstuffs.

As a reply, the EU Commission proposed a new Regulation on the Transparency and Sustainability of the EU risk assessment in the food chain¹² (hereinafter, the

Proposal) to amend confidentiality rules that prevent the disclosure of highly valuable scientific data submitted by commercial food business operators to EFSA.

The Proposal contains data transparency measures that amend the GFLR¹³. Article 38 sets a general obligation on EFSA to make public, without delay, scientific data supporting any application for placing regulated products on the market and transmitted to the Authority accordingly. Four different kinds of measures aims at protecting the commercial interests of private entities when proprietary data is disclosed to the public. These measures can be summarised as confidentiality, technical, licensing, and exclusivity rules.

Firstly, EFSA's disclosure is limited by the exceptions detailed in the Proposal which refer to "confidential data"¹⁴, i.e. information whose disclosure may harm the commercial interest of the applicants. Article 39a defines 1) the procedure to submit the confidential and the non-confidential versions of the application for an authorisation (which include scientific data), 2) the request of confidential treatment and 3) the rules to seek redress for EFSA's decision in case the applicant alleges harm to its commercial interests that results from the rejection of the request.

Secondly, technical measures will be implemented to prevent the commercial exploitation of data made public, even when it is used in a third country. This includes a watermark for traceability when the information is printed¹⁵.

Thirdly, it is clearly pointed out that the disclosure of data shall not be considered "an explicit or implicit permission or license" for the commercial use, reproduction or exploitation¹⁶. Using the data is limited to "the purpose of public scrutiny of the results, including a better understanding of the potential adverse effects on health and the environment". Moreover, the Proposal sets a refutable presumption that the public interest in the disclosure prevails over private interests.

Lastly, data exclusivity rules prescribe that scientific data attached to an application request cannot be used for the benefit of a subsequent applicant for a certain period of time. These rules are common in sectoral food legislation, e.g. in the case of Article 26 of Novel Foods Regulation¹⁷. These

¹⁰ Commission, 'Refit Evaluation of the General Food law (Regulation (EC) No 178/2002' SWD(2018) 38 final

¹¹ Commission, 'Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides"

¹² This paper will discuss the version of the Proposal adopted by the European Parliament in its first reading of the draft GFLR reform. The Proposal contains amendment of other sectoral food legislation that out of the scope of the paper. The comparison between the original proposal and the Parliament version is available at [http://www.europarl.europa.eu/RegData/seance_pleniere/textes_deposes/rapports/2018/0417/P8_A\(2018\)0417_EN.pdf](http://www.europarl.europa.eu/RegData/seance_pleniere/textes_deposes/rapports/2018/0417/P8_A(2018)0417_EN.pdf)

¹³ Article 38 of the draft GFLR reform

¹⁴ Article 39 of the draft GFLR reform

¹⁵ Article 38.1 subparagraph 1 of the draft GFLR reform

¹⁶ Article 39.1a subparagraph 2 of the draft GFLR reform

¹⁷ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation

measures, however, do not concern transparency or openness since they are independent from the confidentiality claim and only serve for protecting the competitive position of applicants vis-à-vis their competitors.

The Proposal also explicitly mentions the need for ensuring openness¹⁸. Remarkably, this reference only relates to risk communication and it would not perfectly serve as a rationale for data transparency measures. However, this consideration seems to be in contrast with EFSA Programming Document 2019 - 2021, that seeks to enhance openness (rather than transparency) by automatically making available to the public non-confidential versions of dossier data supporting applications (EFSA, 2019, p.106).

The section has shown that, in the Proposal, transparency is mainly intended to grant the general public the right to access the data to promote the cross-validation of scientific evidence, while openness operates in the area of risk communication¹⁹. However, the Authority prefers the latter term to describe the policy objectives related to the disclosure of information. Considering the relevance of the data at stake, both for consumers' health and applicants' investments in research and development, more clarity is needed to predict on which basis EFSA is going to assess future confidentiality claims.

A different approach might take into account how the ownership of data is handled when the information is transferred across the entities involved in the risk assessment, rather than focusing on the unclear and confusing rationales underlying transparency and openness. This different perspective and its implications are proposed in the next section.

4 An ownership-based approach to data transparency and openness

The literature on the topic has suggested that, in food safety legislation, the rationale underlying the grant of data ownership rights to an entity is to protect an

investment in information gathering and to preserve a competitive position. Hence, this doctrine has suggested that data ownership remains with the originator despite the transmission to EFSA, which is only granted the right to store and process the data for its needs (Kocharov, 2009; Holle, 2014; Simpson, 2016).

This section aims to critically discuss this approach, despite recognising the validity of one of its preliminary assumptions: if the literature (as well as the Proposal) has specified which prerogatives are granted to the Authority, it follows that transferring data may also imply the transfer of rights.

Ownership has been defined as "an exclusive right to use, possess, and dispose of property, subject only to the rights of persons having a superior interest and to any restrictions on the owner's rights imposed by agreement with or by act of third parties or by operation of law"; moreover, "any transaction may confer specific rights to use, possess, or deal with property without conferring ownership of it (Martin, 2009, s. Ownership)". Consistently with the assumption mentioned above, transfer of data - which consists of a transfer of ownership-related rights - does not necessarily imply the granting of full ownership over the transferred information.

In the Proposal, the mechanism for making the data available to the public implies two transfers of ownership rights: first, the applicants has to grant EFSA the right to use both the non-confidential and the confidential versions of the data supporting an application; then, the Authority has to make available to the public the approved, non-confidential documentation (according to the limitations set by the first three measures already discussed).

It may be argued that there is only one mechanism of data transfer (from the applicants directly to the general public) as both EFSA and the general public share the same rights to use submitted data for cross-check of scientific evidence. However, this approach does not consider that the content of the data transmitted to EFSA and the non-confidential information made available to the general public might differ significantly due to the acceptance of confidentiality requests. Therefore, it may be suggested that the legal framework provides two separate transfers of data ownership rights.

Following this ownership-based approach, two arguments may be adduced. On the one hand, EFSA can be deemed to enjoy a limited amount of data ownership due to its active role in data-related decisions as a "gatekeeper" for transparency and democratic scrutiny of scientific evidence.

(EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2015] OJ L 327/1

¹⁸ Article 8b(a) of the draft GFLR reform

¹⁹ Although the name might suggest a link to the publication of data, risk communication is primarily focused on conveying information and advice regarding the safety of foods. For instance, social media activity and campaigns can be subsumed within this category

On the other hand, one can conclude that applicants enjoy a full ownership over the data despite its submission, in continuity with the previous literature, since the disclosure is interpreted as a way to collaborate with the Authority in the risk assessment rather than a democracy tool. The following discussion illustrates the benefits and the drawbacks of both approaches.

The first argument claims that transparency necessarily implies the grant of data ownership on the Authority. This perspective looks at the difference in the quality and quantity between the data available to the Authority and the information delivered to the general public. Once the data has been submitted, EFSA makes available to the public the version that it finds the most appropriate to guarantee public scrutiny of the risks for human health or the environment. Its decision is determined by the fact that the Authority has to take into account the possible confidentiality requests and the prevalence of the public interest in the disclosure of data stated by the Proposal.

If EFSA divulges data that are submitted by applicants, it is implicitly acting "as if" it was the data owner. Remarkably, the greater freedom that the Authority enjoys in deciding "if" and "what" data has to be published, as well as "how" such disclosure should occur (i.e. technical conditions and licensing terms) in a way that can be subsumed under a *quasi*-ownership framework. Moreover, by considering the limited remit of confidentiality exceptions, it may be argued that the Legislator has purposely granted EFSA more power to legitimately dispose of the data.

This "harder" approach would be consistent with the wording of the Proposal, since the legitimacy of such ownership would be attributed by the rationale underlying disclosure measures, i.e. the principle of transparency. In turn, transparency is grounded on a democratic cross-validation of evidence claiming the safety of foodstuffs and, in order to make this data available to the public scrutiny, EFSA has to enjoy some degree of ownership. This does imply that the Authority is the only owner of the information at stake. Its rights and duties co-exist with the ones attributed to the applicant. However, the condition that EFSA enjoys can be compared to a *quasi*-ownership status due to its prerogatives and its democratic legitimisation.

However, transparency measures intended to "democratise" the risk assessment by disclosing data fall off to be entirely satisfying for at least two reasons. On the one hand, such cross-check has only an indirect effect

over citizens' health since it is not directly correlated to risk management, that is the actual decision-making process. This partly contradicts what CJEU stated in *ClientEarth and Pan Europe*²⁰. The Court recognised that access to scientific dossiers, while preliminary and not constituting a decisive step in the decision-making process, is still relevant to "enhance the democratic nature of the European Union by enabling its citizens to scrutinise that information and to attempt to influence that process". However, it has to be reminded that the CJEU was referring to documents rather than data. On the other hand, the potential for an effective democratic participation seems quite limited, as only certain individuals would qualify to participate to the risk assessment due to the skill and the means required to process and interpret the data.

By contrast, a second approach may claim that, in order to avoid that even a limited amount of ownership is granted to EFSA, applicants should remain entitled to full ownership. This "softer" perspective implies that the disclosure of data is only justified by means other than "transparency". To maintain data ownership on applicants submitting data, a possible rationale underlying data disclosure could be the goal of ensuring openness, i.e. fostering trust among the citizens towards EFSA's activity by decentralising the risk assessment activity.

In this scenario, the idea of a democratic oversight over decision-making processes yields to the creation of intermediaries (including researchers and NGOs) that collaborate with the Authority to review scientific evidence. If this holds true, mere data disclosure could not be sufficient to achieve the goal of openness. In particular, due to the need for fostering the cross-validation of scientific evidence, it would be crucial to provide independent reviewers with licences that allow the re-use of disclosed information and data analysis.

This second approach is consistent with 1) the reference to openness in public consultation of the Proposal²¹, 2) with CJEU findings in *Hautala* and 3) with data exclusivity rules (the fourth kind of measure discussed in the previous Section aiming to protect the investment in creating the data). However, it contrasts with the wording of the Proposal, that explicitly endorses transparency and indiscriminate participation to the risk assessment when enshrining data disclosure measures.

²⁰ Case C-57/16 *ClientEarth v Commission* [2018] ECLI:EU:C:2018:660, para 92

²¹ Article 8b(a) of the draft GFLR reform

While preliminary, proposals from this paper suggest that an ownership-based approach can be used to discuss data openness and transparency in the debate on the ongoing reform and in the general discussion revolving around these two concepts. In particular, the impact of transparency and openness measures in terms of data ownership has to be taken into account both in the legislative discourse and when assessing confidentiality claims.

5 Final remarks

While the divergence among openness and transparency might look lexical or purely speculative, it raises questions about the rationale underlying EFSA's decisions on data confidentiality claims, be them justified with transparency to foster democracy, openness to improve trust or both.

This short study has discussed the new data transparency and confidentiality rules proposed within the context of the ongoing food safety legislation reform. While aiming to stimulate the debate towards the concepts of transparency and openness, this study has proposed an ownership-based approach to these concepts that focuses on the prerogatives granted to the Authority when disclosing data and then on the goals of such disclosure.

Rather than taking the side of one of the theories mentioned in Section 1, this study proposes three main preliminary findings. First, the debate on similarities and differences among the concepts of openness and transparency can be fruitfully enhanced by discussing the question of ownership. Transparency and openness should not be considered as mutually exclusive. Their co-existence, however, shall also be assessed in terms of data ownership. Secondly, if a choice has to be made in justifying the publication of private data either with transparency or openness, the criteria for this decision should also include the implications regarding data ownership. Thirdly, policy measures that aim to foster openness and transparency (in particular, those concerning the disclosure of commercial scientific data proposed in the ongoing reform) should take into account the issue of data ownership before their full deployment. Findings from this study should be taken as a contribution to an ongoing discussion and, possibly, as an incentive to debate data governance issues regarding "neighbour" fields such as chemical and pharmaceutical products.

Many questions have been purposely left open. Further research should investigate the new Regulation when it will be in force and test the conclusions of this study in the

"neighbour" areas mentioned above.

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