

STUDY

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Independence and transparency policies of the European Food Safety Authority (EFSA)



Policy Department for Economic, Scientific and Quality of Life Policies
Directorate-General for Internal Policies
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Independence and transparency policies of the European Food Safety Authority (EFSA)

Abstract

This study has been commissioned by the European Parliament's Policy Department for Economic, Scientific and Quality of Life Policies, Directorate-General for Internal Policies at the request of the ENVI Committee. It analyses EFSA's independence and transparency policies and examines how legislative provisions have been implemented by EFSA and whether rules and practices adopted by EFSA can be improved.

This document was requested by the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI).

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LIST OF ABBREVIATIONS

ADoI	Annual Declaration of Interests
AI	Artificial Intelligence
ART	Architecture Transformation Programme
BEREC	Body of European Regulators for Electronic Communications
CEOS	Conditions for the Employment of Other Servants of the Union
CJEU	Court of Justice of the European Union
cnDAspe	Commission Nationale Déontologie et Alertes en santé et environnement
CoC	Code of Conduct of the Management Board of the European Food Safety Authority (2022)
CoI	Conflict of interests
DCIM	Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management (2018)
DG	Directorate-General
DoI	Declaration of interests
EBA	European Banking Authority
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EFCA	European Fisheries Control Agency
EFSA	European Food Safety Authority
EIGE	European Institute for Gender Equality
EIOPA	European Insurance and Occupational Pensions Authority
EMA	European Medicines Agency
ENISA	European Union Agency for Cybersecurity
EP	European Parliament

EPPO	European Public Prosecutor's Office
ESMA	European Securities and Markets Authority
ETF	European Training Foundation
EU	European Union
FRA	European Union Agency for Fundamental Rights
FRONTEX	European Border and Coast Guard Agency
GFL	General Food Law (Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002)
GMO	Genetically modified organisms
LA Unit	Legal and Assurance Unit
MoU	Memorandum of Understanding
NGO	Non-governmental organisation
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006)
RoP	Rules of Procedure of the Management Board of EFSA (2022)
SRB	Single Resolution Board
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union

EXECUTIVE SUMMARY

This study assesses EFSA's current approach to independence and transparency. It examines how the relevant legislative provisions have been implemented by EFSA and whether rules and practices adopted by EFSA can be improved.

EFSA's current approach to independence is embedded in its 2017 Policy on Independence and the 2018 Decision on Competing Interest Management. These policy documents are in turn implemented by further internal documents. Following up on the entry into force of the Transparency Regulation, the Management Board has adopted in 2022 new Rules of Procedure, a Code of Conduct and new Rules on the selection, appointment and operations of scientific experts.

Overall EFSA's independence policy is assessed positively. Some definitional inconsistencies are observed in relation to the use of experts and external experts in legislative provisions, EFSA's rules and practice, which is important to clarify in relation to the applicable rules on conflicts of interests. Moreover, EFSA's definition of conflicts of interests does not include 'national interests' or 'political pressure', but is broad enough to include within its scope not only personal interests but also interests deriving from other public duties/roles of the concerned individual. Potential conflicts are not expressly included in the definition.

EFSA screens declarations of interests against the mandate of the relevant scientific group and not against EFSA's overall remit. Such a choice, which narrows down the material scope of EFSA's independence policy, has raised concerns by the European Parliament. Broadening of the material scope of EFSA's independence policy may however conflict with the principle of scientific excellence. The temporal scope of EFSA's independence policy is five years and is in line with the Commission's orientation.

EFSA's CoI rules do not apply to Advisory Forum members and Network members who shall submit ADols but these ADols are not screened by EFSA. Here EFSA relies on the Advisory Forum's own Declaration of Intent, MoUs concluded with relevant Article 36 organisations and relevant national rules. There is a need for more clarity as regards the applicable independence rules to these members, which becomes more pressing in view of the strengthening of Article 36 organisations in the preparation of EFSA scientific opinions. Here problems as regards independence from national pressure are likely to increase. Hearing experts are required to submit ADols but these ADols are not subject to screening.

EFSA applies a cooling-off period of two years in cases where private research funding exceeds 25% of the expert's total budget. EFSA does not have a specific rule concerning the obligation for academic experts to declare the financial relationship between their university employers and their university employers' commercial partners. ECHA and EMA have more detailed rules on this issue in place.

EFSA requires its actors to submit their DoI through the dedicated IT tool, with the exception of declarations submitted by tenderers and participants in grant-awarding procedures. The IT tool is recognised as one of the most appreciated features of EFSA's independence policy. The malfunctioning of the new IT solution launched in 2021 negatively impacted the independence-related activities carried out by EFSA in 2021 and 2022.

Final decisions about conflicts of interests of members of the Management Board are taken by the Management Board itself, after receiving an assessment by the Executive Director. The discretion allowed to members of the Management Board is broader than in ECHA and EMA.

The enforcement of EFSA's independence policy was hindered by the reprioritisation of certain independence-related activities due to COVID-19. The criteria behind such reprioritisation were not made public by EFSA. The criteria for the granting of a waiver to members of EFSA's working groups and peer review meetings do not appear sufficiently clear and there is no obligation to communicate or publish the decisions granting a waiver.

Also EFSA's transparency policy is overall assessed positively. EFSA has implemented the legal provisions of this Regulation by means of the Management Board decision of 2020 for passive transparency and the Executive Director's decision of 2021 for active transparency.

The Management Board's 2020 decision lays down the practical arrangements for the access to documents requests. It contains the exceptions to access to documents, namely the protection of public interest, commercial interests, privacy and a 'space to think' in ongoing decision-making processes. These exceptions are to be interpreted narrowly and appear to be in line with the recent case law of the Court of Justice.

The operating procedure and the practical arrangements adopted by EFSA appear generally in line with the Access Regulation and the Aarhus Regulation, with the exception of the deadline for the extension of the time limit in case of complex or voluminous applications, which is not specified, whilst the Access Regulation requires a time limit of 15 working days and an extension of 15 working days in exceptional cases.

EFSA has not consistently complied with the obligation to report annually on access to documents requests, including on the number of requests and whether access was (or was not) granted, in particular in its 2022 Annual Activity Report.

Implementing the provisions of the Transparency regulation, EFSA's Executive Director's decision of 2021 specifies the moment of publication for each category of documents, and determines for which categories of documents it is possible to submit a confidentiality request. It has operationalised the provisions of the Transparency Regulation concerning the pre-submission advice and the notification of studies through the creation of the Connect.EFSA portal. The summaries of pre-submission advice and the notified information are published in the OpenEFSA portal.

EFSA publishes the non-confidential version of applications, scientific data, studies or other information part of, or supporting, the application on the OpenEFSA portal once a valid application has been received. EFSA is the only agency providing this systematic publication of studies and data supporting applications, representing the forerunner of proactive transparency of regulatory science. Moreover, EFSA's scientific outputs, the information on which EFSA's scientific outputs are based, and the scientific studies commissioned by EFSA, are published in the EFSA Journal. The comments received during public consultations are publicly available on the OpenEFSA portal. Also the annual reports of EFSA's activities are made public on its website immediately after their adoption. The EFSA's portals and website are operational, but since further enhancement of EFSA's IT tools is expected by July 2023 a critical assessment of their effectiveness appears premature.

EFSA publishes also the agendas, list of participants and minutes of the Management Board, the Advisory Forum, the EFSA's networks, the Scientific Committee, the Scientific Panels and their working groups. The participants' Dols and ADols are also made public. Some of the meetings of the Scientific Committee, the Scientific Panels and their working groups are open and can be joined by observers upon registration. Observers cannot take part in the discussion, but they can ask questions at the end of the meeting. Moreover, the meetings of the Management Board can be observed by the public upon registration. The recordings of these meetings are available online.

EFSA's rules on limiting transparency of EFSA's documents for the protection of personal data are in line with the recent case law of the Court of Justice. For confidentiality requests, EFSA's rules stipulate that the disclosure of certain information is presumed not to harm the applicant to a significant degree if the potential harm affects less than 5% of the gross annual turnover for legal persons, or the gross annual earnings for natural persons; if the document is publicly available; and if it was finalised more than 5 years before the confidentiality request. EFSA's practical arrangements do not clarify the relation between the disclosure for reasons of urgent action to protect human health, animal health or the environment and the 'overriding public interest' allowing access to documents.

The study gives various recommendations as to how rules and practices on independence and transparency adopted by EFSA can be further improved.

1. INTRODUCTION

The European Food Safety Authority (EFSA) is mandated to give scientific advice on most subjects related to food and feed safety, such as animal health, additives, chemical contaminants, food packaging, genetically modified organisms (GMOs) and pesticides. Established in 2002 by Regulation (EC) No 178/2002 (General Food Law or GFL)¹ in response to the Bovine spongiform encephalopathy (BSE) crisis, EFSA is designed as ‘an independent scientific source of advice, information and risk communication’.² Article 37 GFL, therefore, provides that the members of EFSA’s operational management (the Management Board, the Advisory Forum and the Executive Director) shall ‘act independently in the public interest’ and that EFSA’s scientific experts (members of the Scientific Committee and the Scientific Panels) shall ‘act independently of any external influence’. Similarly, pursuant to Article 38 GFL, EFSA ‘shall carry out its activities with a high level of transparency’.

Over its first decade of activity, EFSA faced criticism in relation to its independence and how it managed conflicts of interests. In particular, the ‘revolving doors’³ problématique negatively impacted public trust in the Authority, leading the European Ombudsman,⁴ the European Parliament⁵ and the European Court of Auditors⁶ to recommend EFSA to improve its independence and set up rules on the management of conflicts of interests. In addition, concerns arose regarding the transparency of EFSA’s operations, to which both the Court of Justice of the European Union⁷ and the Ombudsman⁸ turned their attention.

As of 2012, EFSA started implementing a Policy of Independence⁹ which replaced its 2007 Policy on Declarations of Interests.¹⁰ Moreover, in 2014 EFSA started implementing its OpenEFSA policy, a five year-plan aimed at transforming the Authority into an Open Science organisation through the strengthening of its transparency and openness.¹¹

These developments did however not put an end to the discussion about EFSA’s independence and transparency. The request for the re-approval of glyphosate in 2016 reinvigorated the debate about EFSA’s independence and transparency.¹² Moreover, the revelation of the ‘Monsanto papers’¹³ in 2017 increased the public attention on the relationship between industry and regulatory agencies like EFSA.

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.

² Recital 35 of Regulation (EC) No 178/2002.

³ Vos, E., 2016, *EU Agencies and Independence*, in Rittleng, D. (ed.), *Independence and Legitimacy in the Institutional System of the European Union*, Oxford University Press, p. 206, pp. 220–221.

⁴ European Ombudsman, 7 December 2011, *Draft recommendations of the European Ombudsman in his inquiry into complaint 775/2010/ANA against the European Food Safety Authority (EFSA)*.

⁵ European Parliament, 10 May 2012, *Decision of 10 May 2012 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2010*, C7-0286/2011 – 2011/2226(DEC).

⁶ European Court of Auditors, 2012, *Management of conflict of interest in selected EU Agencies*, Special Report, 15.

⁷ Case C-615/13 P *ClientEarth and PAN Europe v EFSA* [2015] ECLI:EU:C:2015:489, paras 57–60.

⁸ European Ombudsman, 18 June 2014, *Decision in case 952/2014/OV on the European Food Safety Authority’s (EFSA) public consultation procedure for the renewal of the approval of the herbicide glyphosate*.

⁹ EFSA, 15 December 2011, *Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority*, mb 15 12 11.

¹⁰ EFSA, 5 October 2007, *Policy on Declarations of Interests*, MB – 11.09.2007 – 5.4.

¹¹ EFSA, 2014, *Discussion Paper - Transformation to an ‘Open EFSA’*.

¹² Arcuri, A., Hendlin, Y.H., 2019, *The Chemical Anthropocene: Glyphosate as a Case Study of Pesticide Exposures*, King’s Law Journal, Vol. 30 No. 2, pp. 239–241; Arcuri, A., Hendlin, Y.H. (eds.), 2020, *Symposium on the Science and Politics of Glyphosate*, European Journal of Risk Regulation, Vol. 11 No. 3, pp. 411–682; Morvillo, M., 2020, *Glyphosate Effect: Has the Glyphosate Controversy Affected the EU’s Regulatory Epistemology?*, European Journal of Risk Regulation, Vol. 11 No. 3, pp. 422–423.

¹³ A series of documents, slowly released since March 2017 in a U.S. lawsuit by cancer victims against Monsanto concerning the industry’s influence over scientific studies. See Morvillo, M., 2020, *Glyphosate Effect: Has the Glyphosate Controversy Affected the EU’s Regulatory Epistemology?*, European Journal of Risk Regulation, Vol. 11 No. 3, p. 423.

In this context, the European Parliament adopted in 2016 and 2017 two resolutions leading to the establishment of the Special Committee on the Union's authorisation procedure for pesticides.¹⁴ The European Parliament more generally criticised EFSA's policies on independence and transparency.¹⁵ It expressed concerns about, among others, the scope of EFSA's independence policy,¹⁶ the lack of in-house scientific expertise and the high number of conflicts of interests problems.¹⁷ Discussions about EU agencies' independence and transparency have thus regained momentum.¹⁸

EFSA has therefore changed its approach towards the principles of independence and transparency over the last five years. As for independence, EFSA has adopted a new Policy on Independence in 2017¹⁹ and a corresponding Decision on Competing Interests Management in 2018.²⁰ These acts aim to improve the effectiveness of the screening of conflicts of interests by re-defining its scope, means and enforcement tools. The most important innovation as regards transparency has been brought by Regulation (EU) 2019/1381 (Transparency Regulation),²¹ which aims to improve the transparency and sustainability of EU risk assessment in the food chain. This Regulation amends the GFL and applies as of March 2021.²² The Transparency Regulation enshrines new rules concerning access to documents which strengthen the transparency of, inter alia, agendas, participant lists and minutes of the Management Board, the Advisory Forum, the Scientific Committee and the Scientific Panels and their

¹⁴ European Parliament, 13 April 2016, *Resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011*, D044281/01 – 2016/2624(RSP); European Parliament, 24 October 2017, *Resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011*, D053565-01 – 2017/2904(RSP); Special Committee on the Union's authorisation procedure for pesticides, 17 September 2018, *Draft Report on the Union's authorisation procedure for pesticides*, 2018/2153(INI). See also European Parliament, 2017, *Answer given by Mr Andriukaitis on behalf of the Commission to Parliamentary question E-004945/2017*. Moreover, the Court of Justice ruled in a number of cases relating to glyphosate, namely Case C-616/17 *Blaise and Others* [2019] ECLI:EU:C:2019:800, Case T-329/17 *Hautala and Others v EFSA* [2019] ECLI:EU:T:2019:142, Case T-716/14 *Tweeddale v EFSA* [2019] ECLI:EU:T:2019:141.

¹⁵ European Parliament, 18 April 2018, *Resolution of 18 April 2018 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2016*, 2017/2159(DEC); European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, 2019/2078(DEC); European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*, 2020/2162(DEC).

¹⁶ European Parliament, 18 April 2018, *Resolution of 18 April 2018 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2016*, para. 14.

¹⁷ European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, paras 18–19.

¹⁸ Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, *Common Market Law Review*, Vol. 59 No. 3, p. 677; Leone, L., 2020, *EFSA under Revision: Transparency and Sustainability in the Food Chain*, *Yearbook of European Law*, Vol. 39, pp. 545–546; Löfstedt, R., Boudier, F., 2021, *Evidence-based uncertainty analysis: What should we now do in Europe? A view point*, *Journal of Risk Research*, Vol. 24 No. 5, pp. 521–540; Morvillo, M., 2021, *Why Should Citizens Trust EU Regulatory Expertise? Legal Warrants, Science and Politics in EU Food Governance*, in Barradas de Freitas, R., Lo Iacono, S. (eds.), *Trust matters: cross-disciplinary essays*, Hart Publishing, p. 229; Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, Publication for the committee on Petitions, Policy Department for Citizens' Rights and Constitutional Affairs, available at [https://www.europarl.europa.eu/RegData/etudes/STUD/2020/621934/IPOL_STU\(2020\)621934_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2020/621934/IPOL_STU(2020)621934_EN.pdf), p. 13.

¹⁹ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, mb170621-a2.

²⁰ EFSA, 2018, *Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management*, REF. EFSA/LA/DEC/19568050/2018.

²¹ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC PE/41/2019/REV/1 [2019] OJ L 231.

²² Pursuant to its Article 11, the rules of Regulation (EU) 2019/1381 concerning the composition of the Management Board and the appointment of scientific experts came into force in July 2022.

working groups.²³ The Regulation also aims at enhancing confidentiality²⁴ and risk communication²⁵ in line with a new 'proactive approach'²⁶ to transparency.²⁷

The purpose of this study is to assess EFSA's current approach to independence and transparency and examine how the relevant legislative provisions have been implemented by EFSA and whether rules and practices adopted by EFSA can be improved.

To this end, firstly, the study will analyse how EFSA has implemented its 2017 Policy on Independence and 2018 Decision on Competing Interest Management (Chapter 2). Secondly, the study will examine EFSA's transparency policy and its most recent measures adopted to enhance transparency (Chapter 3). Based on these findings, the study will identify potential needs, if any, for revision of rules and policies on the independence and transparency of EFSA and make recommendations for their improvement (Chapter 4).

The study will assess the relevant rules and policies against the main concerns and recommendations made by EU institutions and bodies and the academic literature with regard to EFSA's independence and transparency. This will be done on the basis of desk research which encompasses the analysis of relevant legislation, case-law, policy documents and literature. Where appropriate, the study will also provide some examples from the rules and practice of two other EU agencies that are active in risk regulation, namely the European Chemicals Agency (ECHA) and the European Medicines Agency (EMA).

²³ Article 38 of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381. See Section 3.3.3(iv).

²⁴ Articles 39-39g of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

²⁵ Articles 8a-8c of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

²⁶ Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, Common Market Law Review, Vol. 59 No. 3.

²⁷ Chearnaigh, B.N., 2021, *Piecemeal Transparency: An Appraisal of Regulation (EU) No. 2019/1381 on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain*, European Journal of Risk Regulation, Vol. 12 No. 3, pp. 704–708.

2. EFSA'S INDEPENDENCE

2.1. Framing the Notion of 'Independence' within EU Law

There is no general and uniform definition of 'independence' within the EU law framework. The concept has instead a relative nature, which may vary depending on the specific features of the legal instrument which refers to the notion of 'independence'.²⁸ Therefore, several provisions of both primary and secondary law envisage different types and degrees of independence.²⁹ In general terms, the independence of a public body can be defined as 'a status which ensures that the body concerned can act completely freely, without taking any instructions or being put under any pressure'.³⁰

While it is in principle possible to distinguish between institutional, organisational, budgetary, staffing, financial and functional independence, all these facets can be captured in the notions of 'institutional' and 'functional' independence. The concept of *institutional* independence refers to a separate legal entity and encompasses elements of organisational, budgetary, staffing and financial independence. *Functional* independence implies that an entity is shielded from any instruction given by external actors that might influence the entity's activities in the performance of its tasks.³¹

The EU Treaties refer to the independence of the members of the Commission,³² the members of the EU Courts and Advocates-General³³ and the European Central Bank.³⁴ With regard to the Commission, the TEU requires its members not to seek nor take instructions from any government or other institution, body, office or entity. In respect of members of judicial bodies, the TFEU states that their independence must be 'beyond doubt'. As for the European Central Bank, the TFEU further provides that EU institutions and agencies and the Member States' governments shall fully respect the independence of the ECB and national central banks.

Finally, Article 298 TFEU stipulates that, 'In carrying out their missions, the institutions, bodies, offices and agencies of the Union shall have the support of an open, efficient and *independent* European administration' (emphasis added). Independence is an essential element to ensure that administrative affairs are handled impartially and fairly. Therefore, the independence of institutions and bodies of the Union is a fundamental element of the right to good administration enshrined in Article 41 of the Charter of Fundamental Rights of the EU.³⁵

²⁸ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 14.

²⁹ See for instance Article 17(3) TEU and Article 245 TFEU on the independence of the European Commission; Article 19(2) TEU and Articles 252-254 TFEU on the independence of CJEU Judges and Advocates-General; Article 39 TEU, Article 16 TFEU and Article 8 EU Charter on the independence of national data protection authorities; Article 228 TFEU on the independence of the Ombudsman. For the use of the term 'independence' in secondary law in relation to national regulatory or supervisory authorities, see in the energy sector (Article 39 of Directive 2009/73/EC), the telecommunications sector (Article 6 of Directive (EU) 2018/1972), the railway sector (Articles 55-57 of Directive 2012/34/EU), the audiovisual media services (Article 30 of Directive 2010/13/EU as amended by Directive (EU) 2018/1808), the aircraft services (Article 11 of Directive 2009/12/EC), competition law (Article 35 of Council Regulation (EC) No 1/2003 and Articles 4-5 of Directive (EU) 2019/1) and in the field of data protection (Articles 51-54 of the General Data Protection Regulation (EU) No 2016/679 (GDPR)).

³⁰ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 14.

³¹ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 14.

³² Article 17(3) TEU.

³³ Articles 253-254 TFEU.

³⁴ Article 130 TFEU.

³⁵ Vos, E., 2016, *EU Agencies and Independence*, in Ritleng, D. (ed.), *Independence and Legitimacy in the Institutional System of the European Union*, Oxford University Press, p. 214.

2.2. EU agencies, independence and conflicts of interests

The independence of EU agencies rests on the autonomy of their internal organisation and functioning.³⁶ To achieve their main purpose, namely to offer non-political and objective input to the political decision-making process,³⁷ decentralised agencies,³⁸ like EFSA, must be isolated from the potential influence of political or contingent considerations.³⁹ As decentralised agencies have been established through different founding Regulations,⁴⁰ the way in which such Regulations design agencies' independence is not homogeneous.⁴¹ Some founding Regulations require the independence of the agency as a whole.⁴² Other founding Regulations, like the General Food Law for EFSA, focus on the independence of the persons managing the agency.⁴³

With regard to institutional independence, decentralised agencies have their own legal personality⁴⁴ and must be provided with the financial means, technical resources and expertise that they need for the performance of their tasks.⁴⁵ Such features of agencies' structural separation are coupled with additional guarantees regarding the personal independence of the managers (Executive Directors) and members of the Management Boards. Directors and members of the Management Boards of EU agencies must be selected through procedures based on merits and their mandate must be sufficiently long and susceptible of interruption only on predefined grounds.⁴⁶ In addition, the independence of the staff of EU decentralised agencies falls within the scope of the Staff Regulations and Conditions for the Employment of Other Servants of the Union (CEOS).⁴⁷

As set forth above, functional independence refers to the requirement neither to seek nor to take instructions from any external actor. Since EU agencies act in between EU institutions and the Member States,⁴⁸ this requirement applies to actors both at the European and national level. The hybrid

³⁶ European Commission, 11 December 2002, *The operating framework for the European Regulatory Agencies*, COM(2002) 718 final, p. 5.

³⁷ Vos, E., 2016, *EU Agencies and Independence*, in Ritleng, D. (ed.), *Independence and Legitimacy in the Institutional System of the European Union*, Oxford University Press, p. 212.

³⁸ Within the EU institutional framework, it is possible to distinguish between executive and decentralised agencies. Executive agencies are entities entrusted by the Commission with any task required to implement a Union programme. As such, they directly depend on the Commission, to whom they are exclusively accountable. The analysis of executive agencies falls outside the scope of this study. Decentralised agencies such as EFSA, instead, have been established to provide the implementation of certain EU policies with the necessary technical expertise.

³⁹ Busuic, M., 2013, *Rule-Making by the European Financial Supervisory Authorities: Walking a Tight Rope: Rule-Making by the European Financial Supervisory Authorities*, *European Law Journal*, Vol. 19 No. 1, p. 114.

⁴⁰ Chamon, M., 2019, *Transparency and Accountability of EU Decentralised Agencies and Agencification in Light of the Common Approach on EU Decentralised Agencies*, in Garben, S., Govaere, I., Nemitz, P. (eds.), *Critical Reflections on Constitutional Democracy in the European Union*, Hart Publishing, p. 245, p. 251.

⁴¹ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 17.

⁴² Article 4(2) of Regulation (EC) No 1211/2009 on BERECA; Article 1 of Regulation (EC) No 1093/2010 on EBA; Article 6 of Regulation (EC) No 1922/2006 on EIGE; Article 1 of Regulation (EU) No 1094/2010 on EIOPA; Article 3(4) of Regulation (EU) No 526/2013 on ENISA; Article 6 of Regulation (EU) No 2017/1939 on EPPO; Article 1 of Regulation (EU) No 1095/2010 on ESMA; Article 1 of Council Regulation (EC) No 168/2007 on FRA; Article 56(3) of Regulation (EU) No 2016/1624 on FRONTEX; Article 47(1) of Regulation (EU) No 806/2014 on SRB.

⁴³ Article 37 of Regulation (EC) No 178/2002 on EFSA; Article 12(7) of Regulation (EC) No 713/2009 on ACER; Article 19(2) of Regulation (EC) No 851/2004 on ECDC, Articles 83 and 88(2) of Regulation (EC) No 1907/2006 on ECHA, Article 37 of Regulation (EU) No 2019/473 on EFCA, Article 37 of Regulation (EC) No 178/2002 on EFSA; Article 63 of Regulation (EC) No 726/2004 on EMA; Article 11 of Regulation (EC) No 1339/2008 on ETF.

⁴⁴ European Parliament, Council of the EU, European Commission, 19 July 2012, *Joint Statement on decentralised agencies*, p. 1, referring to 'independent legal entities'.

⁴⁵ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 18.

⁴⁶ See European Parliament, Council of the EU, European Commission, 19 July 2012, *Common Approach*, Annex to the Joint Statement on decentralised agencies, para. 10 (for members of the Management Board) and 16 (for Directors). See also Athanasiadou, N., 2019, *Independent regulatory authorities at the EU and Member State level: towards different notions of 'independence'?*, in Auby, J.-B., Chevalier, E., Slautsky, E. (eds.), *The future of administrative law/Le futur du droit administratif*, LexisNexis, Paris, p. 199, p. 206.

⁴⁷ Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community [1962] OJ 45.

⁴⁸ Everson, M., Monda, C., Vos, E. (eds.), 2014, *European Agencies in between Institutions and Member States*, Kluwer Law International.

character of agencies is reflected in agencies' institutional design, finances and operational activities, which are often not shielded from the influence of the Commission, Parliament or the Member States.⁴⁹ In particular, with regard to the relationship between EU agencies and the Commission, the latter can issue formal advice on agencies' work programmes and be represented in their Management Boards,⁵⁰ thereby exercising some degree of influence on the functioning of agencies in the performance of their duties. It follows that EU agencies do not enjoy full functional independence.⁵¹ Importantly, also individual actors, such as scientific experts involved in day-to-day operations, participate in the activities of EU agencies.

The complex role and institutional features of EU agencies therefore require the adoption of clear rules governing conflicts of interests (Cols). In the absence of a uniform definition of 'conflicts of interests', different definitions are provided in a number of binding (Staff Regulations,⁵² Financial Regulation,⁵³ Framework Financial Regulation)⁵⁴ and non-binding (policy documents⁵⁵ and codes of conduct)⁵⁶ EU acts.

In 2013, the Commission issued general Guidelines aimed at facilitating the harmonisation of the policies on Cols across EU decentralised agencies.⁵⁷ These Guidelines set the core principles for the development of those policies but leave the specific design of its own Cols policy to the responsibility of each agency alone.⁵⁸ Therefore, each agency adopts its own independence policy on the basis of the framework provided by the Commission.⁵⁹

According to the Guidelines, the prevention and management of risks of conflicts and actual conflicts is carried out throughout a cycle of three phases (Cols management cycle): (i) the declaration phase, (ii) the screening/assessment phase, and (iii) the enforcement phase in case of breach of the rules.⁶⁰ The Guidelines set out general principles which underpin every stage of the Cols management cycle. First, internal rules must be transparent, clear, precise and effectively communicated to all persons concerned.⁶¹ Second, agencies should constantly work for the improvement of their practices by

⁴⁹ Vos, E., 2016, *EU Agencies and Independence*, in Rittleng, D. (ed.), *Independence and Legitimacy in the Institutional System of the European Union*, Oxford University Press, p. 212.

⁵⁰ European Parliament, Council of the EU, European Commission, 19 July 2012, *Common Approach*, Annex to the Joint Statement on decentralised agencies, paras 10 and 29.

⁵¹ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 21.

⁵² Article 11 of the Staff Regulations.

⁵³ Article 61 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union [2018] OJ L 193.

⁵⁴ Article 42(2) of Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.

⁵⁵ European Commission, 2021, *Guidance on the avoidance and management of conflicts of interest under the Financial Regulation*, 2021/C 121/01, para. 3.2.1.

⁵⁶ Article 8 of the Ombudsman's Code of Good Administrative behaviour; Section 2 of the Code of Good Administrative Behaviour for Staff of the European Commission in their Relations with the Public; Article 2(6) of the Code of Conduct for members of the European Commission.

⁵⁷ European Commission, 10 December 2013, *Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies*.

⁵⁸ European Commission, 24 April 2015, *Progress report on the implementation of the Common Approach on EU decentralised agencies*, COM(2015) 179 final, p. 5.

⁵⁹ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, pp. 32–33.

⁶⁰ European Commission, 10 December 2013, *Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies*, pp. 4–12.

⁶¹ European Commission, 10 December 2013, *Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies*, pp. 7 and 9.

providing awareness-raising and training sessions, collecting statistics, monitoring and reviewing independence policies and sharing best practices through the Agencies' Network.⁶²

All agencies are required to prevent and manage Cols already throughout the selection and appointment procedures.⁶³ Preventive and remedial measures are envisaged when a potential or actual conflict arises during the mandate or employment of a person.⁶⁴ When an interest has not been declared, the Guidelines recommend the introduction of a breach of trust procedure which attaches consequences to the failure to declare.⁶⁵

2.3. EFSA's Independence Policies

2.3.1. EFSA's 2017 Policy on Independence

Since its establishment, EFSA has adopted internal policies aimed at implementing the principle of independence enshrined in Article 37 of the General Food Law. The 2004 Code of Conduct on Declarations of Interests⁶⁶ was followed, in 2007, by the introduction of EFSA's Policy on Declarations of Interests.⁶⁷ In 2011, EFSA adopted its first Policy on Independence,⁶⁸ which was more detailed than the 2007 Policy on Declaration of Interests. The 'development of streamlined management of competing interests, and a revised Independence policy' was later part of the Implementation plan of EFSA's 2020 Strategy⁶⁹ and brought to the adoption of EFSA's current Policy on Independence on 21 June 2017. Designed to come into effect with the adoption of the corresponding Decision on Competing Interest Management,⁷⁰ it replaced the 2011 Policy on Independence.

The 2017 Policy on Independence acknowledges that independence is one of EFSA's main corporate values.⁷¹ To ensure the impartiality of professionals participating in EFSA's operations and in line with the 2013 Guidelines, the approach followed by the Policy rests on two pillars:

- the management of existing Cols; and
- the prevention of Cols and other ethics and integrity issues.⁷²

Mirroring the Commission Decision establishing horizontal rules on the creation and operation of Commission expert groups,⁷³ the Policy defines a 'conflict of interest' as:

⁶² European Commission, 10 December 2013, *Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies*, pp. 7 and 11–12.

⁶³ European Commission, 10 December 2013, *Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies*, p. 7.

⁶⁴ European Commission, 10 December 2013, *Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies*, p. 9.

⁶⁵ European Commission, 10 December 2013, *Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies*, p. 10.

⁶⁶ EFSA, 10 March 2004, *Code of Conduct on Declarations of Interests*, MB-10.03.2004-5. See also EFSA, 16 December 2004, *Guidance on declarations of interests*, MB 16.12.2004.

⁶⁷ EFSA, 5 October 2007, *Policy on Declarations of Interests*. See also EFSA, 5 October 2007, *Guidance Document on Declarations of Interests*, MB – 11.09.2007 – 5.3; 5 October 2007, *Procedure for identifying and handling potential conflict of interests*, MB – 11.09.2007 – 5.2.

⁶⁸ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*.

⁶⁹ See EFSA, 2016, *EFSA Strategy 2020 - Trusted science for safe food*, p. 28. Conversely, no revision of the independence policy is envisaged in EFSA, 2021, *EFSA Strategy 2027*, mb210624-a2.

⁷⁰ EFSA, 2018, *Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management (DCIM)*.

⁷¹ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 3.

⁷² EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 4.

⁷³ Article 2(4) of European Commission, 2016, *Commission Decision of 30.05.2016 establishing horizontal rules on the creation and operation of Commission expert groups*.

‘any situation where an individual has an interest that may compromise or be reasonably perceived as compromising his or her capacity to act independently and in the public interest in relation to the subject of the work performed at EFSA’.⁷⁴

This definition covers actual and perceived CoIs but does not clarify the exact meaning of these terms nor provides specific examples to distinguish among them. Moreover, potential conflicts are not expressly included in the definition, whereas they are mentioned in several points of the Policy. Furthermore, the Policy refers to conflicts of *interest* and not to conflicts of *interests*. Although, unlike the European Ombudsman Code of Conduct,⁷⁵ this definition does not mention ‘national interests’ or ‘political pressure’, its broad wording allows to include within its scope not only personal interests but also interests deriving from other public duties/roles of the concerned individual.⁷⁶ Article 28 (5d) GFL now explicitly requires Member States and employers of the members of the Scientific Committee and of the Scientific Panels to refrain from giving any instruction which is incompatible with the individual tasks of these members and experts, or with the tasks, responsibilities and independence of EFSA. The 2022 rules on the selection, appointment and operations of the Scientific Committee, Scientific panels and of their Working groups of experts explicitly recognise this.⁷⁷

To strike a balance between the principles of independence and scientific excellence,⁷⁸ the Policy provides that CoIs are relevant when they pertain to matters discussed in the working group(s) where the person concerned is serving or is expected to serve.⁷⁹ In line with the principle of proportionality, the aim of this limitation is to ensure that an unnecessarily broad understanding of CoIs may hinder the availability of expertise. In the same vein, proportionality demands stricter rules and procedures for areas where CoIs are more likely to occur.⁸⁰

The Policy identifies the main sources of CoIs for EFSA’s experts, namely:

- their economic and financial sphere;
- the creations of the mind; and
- affiliations or other involvements.⁸¹

Building on these three categories, the Policy requires persons involved in EFSA’s operations to declare all interests, falling under EFSA’s remit, held by them, their partners or dependent family members over the five years preceding the declaration. All participants in EFSA’s operations are required to declare

⁷⁴ EFSA, 2017, *EFSA’s policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 4.

⁷⁵ Article 8(2) of the Ombudsman’s Code of Good Administrative behaviour stipulates: ‘The conduct of the official shall never be guided by personal, family, or national interest or by political pressure. The official shall not take part in a decision in which he or she, or any close member of his or her family, has a financial interest’.

⁷⁶ See the recommendations of Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 75.

⁷⁷ Article 37(2) of EFSA, 6 October 2022, *Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups*, mb221006-a5.

⁷⁸ In Case T-13/99 *Pfizer Animal Health v Council* [2002] ECLI:EU:T:2002:209, para 159, the Court held that scientific advice must be based on the principles of excellence, independence and transparency.

⁷⁹ EFSA, 2017, *EFSA’s policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 5.

⁸⁰ EFSA, 2017, *EFSA’s policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 5.

⁸¹ EFSA, 2017, *EFSA’s policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 4.

the percentage of their annual earnings deriving from entities which have an interest in EFSA's activities.⁸²

The Policy further sets out the main principles governing the independence of various actors involved in EFSA's work.

First, all EFSA's employees, including the Executive Director, are subject to the requirements enshrined in the EU Staff Regulations. Accordingly, they are subject to COLS screening before their recruitment and must annually declare their interests.⁸³ Moreover, they must obtain preliminary clearance for 'outside activities' while working for EFSA and for all gainful activities they intend to carry out within two years following the end of their employment for EFSA.⁸⁴

Second, with regard to scientific experts, interests concerning financial investments with 'business actors' affected by EFSA's operations and current employment engagements in this field are absolutely incompatible with EFSA's mandate and therefore cannot be held by persons who wish to participate in EFSA's activities.⁸⁵ The Policy, moreover, provides for a two-year cooling-off period for persons who have held managerial roles, employment and consultancies, membership in a scientific advisory body and research funding from legal entities pursuing private or commercial interests and falling under the mandate of the relevant EFSA scientific group.⁸⁶ Lastly, the Policy sets at 25% the acceptable share of research funding from the private sector from which EFSA's experts can benefit.⁸⁷

Third, where EFSA recruits experts cooperating with, advising or employed by national or international academies, academic institutions, public authorities and research institutes to participate in EFSA's Scientific Committee, scientific panels, working groups and peer review meetings, it implements a thorough screening of activities unrelated to public interest duties to these experts participating to these meetings and will place their ADOLs on the website. However, the Authority does not directly check the independence of external experts representing the views of the Member States or international organisations in EFSA's network or networking meetings, as this is a duty of each appointing authority in accordance with the applicable legislative and regulatory framework.⁸⁸

Fourth, the rules applicable to members of EFSA's Scientific Committee and scientific panels are also extended to tenderers.⁸⁹

⁸² EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 5.

⁸³ Article 11 of the Staff Regulations and EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 5.

⁸⁴ Articles 11a and 16 of the Staff Regulations and EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 6.

⁸⁵ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 6.

⁸⁶ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, pp. 6–7.

⁸⁷ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 8.

⁸⁸ The independence standards of these experts are governed by specific memoranda of understanding. See EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 7. The example of EFSA's network or networking meetings provided by EFSA are EFSA Focal Points in Member States. EFSA's network is composed, according to Article 36 of Regulation (EC) No 178/2002, by 'legal entities that pursue public interest objectives, have technical and scientific capacity and are active in one or more of the fields of work of EFSA, which could undertake tasks assigned by EFSA and perform them with independence and integrity'. Every year EFSA classifies organisations in order to update the list of public institutions falling within the meaning of Article 36 of Regulation (EC) No 178/2002.

⁸⁹ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 5.

Fifth, members of the Management Board are subject to specific requirements which include a mandatory annual declaration of interests.⁹⁰

EFSA's Policy on Independence also concerns transparency and enforcement. As for transparency, EFSA publishes on its website⁹¹ all of its experts' declaration of interests.⁹² Moreover, EFSA has committed itself to make publicly available:

- decisions concerning its cooperation with other authorities and institutions;⁹³
- decisions confirming breaches of the rules on independence;⁹⁴
- the register of activities carried out by its former Management Board members for the two years following the cessation of their work for EFSA,⁹⁵ and,
- following the positive conclusion of technical and feasibility considerations, decisions concerning the *ex-ante* scrutiny of declarations of interests.⁹⁶

With regard to enforcement, the Policy provides for the combination of compliance checks and sanctions which range from a reprimand letter to dismissal.⁹⁷ Moreover, it stipulates to have an *ex post* evaluation of the policy not later than five years after its entry into force.⁹⁸

2.3.2. EFSA's 2018 Decision on Competing Interest Management

The 2018 Decision on Competing Interest Management (DCIM) was adopted on 29 June 2018 to implement EFSA's 2017 Policy on Independence.⁹⁹ The DCIM reproduces the definition of Col provided by the Policy on Independence.¹⁰⁰ In line with the latter, the DCIM requires concerned individuals¹⁰¹ to declare past activities which have taken place within the five years preceding their declaration of interests (Dol).¹⁰²

⁹⁰ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 5. See Article 13(1) RoP.

⁹¹ See <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

⁹² EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 8.

⁹³ See <https://www.efsa.europa.eu/en/about/corporatedocs#institutional-agreements>.

⁹⁴ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 8. We have however not found these decisions on the website under the heading relating to independence ('trusted science').

⁹⁵ See <https://www.efsa.europa.eu/en/people/mbmembers>.

⁹⁶ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 8. We have however not found these decisions on the website under the heading relating to independence ('trusted science'). See <https://www.efsa.europa.eu/en/howwework/independentscience>.

⁹⁷ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 9.

⁹⁸ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 9. The *ex post* evaluation is planned to be carried out in 2023. See EFSA, 2023, *Annual Report on the implementation of EFSA's policy on independence 2022*, mb230323-a2, p. 132.

⁹⁹ EFSA, 2018, *Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management* (DCIM).

¹⁰⁰ Article 2(1)(e) DCIM.

¹⁰¹ According to Article 2(1)(k), 'concerned individuals' are experts, networks members, members of EFSA's governance bodies, hearing experts, staff of European Union institutions, bodies or other agencies participating in EFSA's meetings in their private capacity and without prejudice to the Staff Regulations of the European Union, tenderers and participants to grant-awarding procedures.

¹⁰² Article 3(2) DCIM.

Whereas the European Parliament¹⁰³ and, at least for agencies' key actors, academics¹⁰⁴ recommend the use of positive Dols,¹⁰⁵ EFSA adopts an 'intermediary' approach: the Dol form is divided in different areas, such as financial investments, employment etc., but it is for the concerned individuals to identify whether they have any relevant interest in those areas. This is based on a self-assessment - and not on an assessment of the agency - of which interests of the concerned individual could be relevant for each area.¹⁰⁶

Since the Policy on Independence makes clear that compliance with Col rules is a shared responsibility between EFSA and persons working for EFSA,¹⁰⁷ the DCIM explicitly requires individuals to submit true, accurate, up to date, complete, clear and precise Dols.¹⁰⁸ Concerned individuals must submit an annual declaration of interest (ADoI) through the dedicated IT tool and update their ADoI within 45 days in case a change in their interests occur.¹⁰⁹ No update is required upon change of tasks.¹¹⁰

EFSA requires relevant actors to declare only the interests which fall within the regulatory field of the Authority, thereby adopting a narrower approach when compared to other agencies that require Dols also in fields linked with the one of the agency.¹¹¹

In setting the rules governing Cols, the DCIM designs a mixed system¹¹² which provides for both automaticity and discretion.¹¹³ The automaticity lays in the blacklists policy governing experts' Cols.¹¹⁴ Discretion is envisaged in the rules applicable to members of EFSA's Management Board.¹¹⁵

a. Scientific experts

As for scientific experts, the 'zero tolerance approach' envisaged in the Policy on Independence is reiterated in Article 7(4) DCIM. This provision confirms the absolute incompatibility with EFSA's mandate of:

- current industry employment by¹¹⁶ and/or
- industry financial investments in¹¹⁷ business actors affected by EFSA's operations with EFSA's mandate.

¹⁰³ European Parliament, 26 March 2019, *Resolution of 26 March 2019 on discharge in respect of the implementation of the budget of the European Union agencies for the financial year 2017: performance, financial management and control*, 2018/2210(DEC), para. 38.

¹⁰⁴ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, pp. 37–38.

¹⁰⁵ A positive Dol includes the mention of all occupational activities, memberships, financial interests of the person and of his/her close family members within a specified timeframe, irrespective of their relevance with the mission of the agency the person works for. A negative Dol consists of the declaration of absence of certain interests related to the domain of activity of the agency.

¹⁰⁶ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 37.

¹⁰⁷ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 9.

¹⁰⁸ Article 3(1) and (3) DCIM.

¹⁰⁹ Articles 4 and 6(1) DCIM. Moreover, according to Article 5 DCIM, concerned individuals must declare orally at the beginning of each meeting any interest that they have not declared yet.

¹¹⁰ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 40.

¹¹¹ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, pp. 38–39.

¹¹² Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 52.

¹¹³ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 61.

¹¹⁴ 'Experts' are defined by Article 2(1)(f) DCIM as 'the members of EFSA's Scientific Committee, Scientific Panels, Working Groups, candidates having applied to the call for expression of interest published by EFSA pursuant to Article 28(5) of Regulation (EC) No 178/2002, and participants in peer review meetings also when appointed by, or representing, Member States' authorities, and excluding Hearing Experts and Observers'.

¹¹⁵ Article 13 DCIM.

¹¹⁶ Defined in Article 2(2)(IV) DCIM as 'any form of occupation or business, part-time or full-time, paid or unpaid, including self-employment, with an employer or client directly or indirectly concerned with EFSA's remit'.

¹¹⁷ Defined in Article 2(2)(I) DCIM as 'any economic stake or share in an entity with a direct or indirect interest falling within EFSA's remit'.

These are *unconditional* restrictions, meaning that persons holding these interests cannot be involved in any EFSA scientific activity.¹¹⁸

A more nuanced approach is adopted towards the assessment of the compatibility of certain activities, if carried out within the past two years ('cooling-off period'),¹¹⁹ with the mandate of a specific body. Managerial roles, employment, occasional consultancy and membership of scientific advisory bodies with private institutions are incompatible with membership of the relevant Scientific Committee, scientific panel(s), working group(s) and peer review meeting(s). The same applies to research funding from the private sector exceeding 25% of the expert's research budget.¹²⁰ These are *qualified* restrictions, meaning that these interests may be compatible with the task assigned to an expert if they do not overlap with the mandate of the relevant scientific group or panel.¹²¹ For the screening of qualified restrictions, close family members¹²² are subject to the same rules of the concerned individual.¹²³

Actual or potential Cols falling outside the scope of unconditional and qualified restrictions are assessed by EFSA on a case-by-case basis pursuant to Article 7(11) DCIM.

No Col can arise from the performance of a task for EFSA.¹²⁴ Similarly, activities performed for public institutions¹²⁵ in the exercise of public interest duties¹²⁶ do not constitute Cols, except for the exercise of risk management functions.¹²⁷ Conversely, experts cannot engage with the assessment of their own work, unless it constitutes only a part of the publications, opinions, paper, study, test or protocol which the mandate requires to review. In the latter case, experts can be members of the relevant scientific group or panel but cannot participate in the meeting(s) where their own work is discussed.¹²⁸ In specific cases an expert can become a member of a scientific group or panel but cannot be appointed as chair or vice-chair: in the case of employment in the food or feed industry or an industry which overlaps with the mandate of the specific group in the past two to five years, or in the case of IP rights linked to the group's mandate where the review is part of a broader scientific mandate.¹²⁹

Importantly the rules stipulate that members of the Scientific Committee, Scientific Panels and Working Groups shall not represent the opinion of a Member State, of their employers or of any other organisation.¹³⁰

Experts' Dols are assessed by the secretariat responsible for each scientific group or panel and validated by the Legal and Assurance (LA) Unit.¹³¹

¹¹⁸ Annex 1 DCIM.

¹¹⁹ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 42.

¹²⁰ Article 7(5) DCIM. The method of calculation is outlined in Annex 1 DCIM. See also Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 42.

¹²¹ Annex 1 DCIM.

¹²² Article 2(1)(n) DCIM defines 'Close Family Members' as the spouse, the partner with whom the concerned individual has contracted a registered partnership and the direct descendants and ascendants who are financially dependent on the concerned individual.

¹²³ Article 7(9) DCIM.

¹²⁴ Article 7(10) DCIM.

¹²⁵ Public institutions are defined in Article 2(1)(m) DCIM.

¹²⁶ Public interest duties are defined in Article 2(1)(r) DCIM.

¹²⁷ Article 7(6) and (7) DCIM.

¹²⁸ Article 7(3) and Annex 1 DCIM.

¹²⁹ Annex 1 DCIM.

¹³⁰ Article 37(2) of EFSA, 6 October 2022, *Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups*.

¹³¹ Article 8 DCIM. See also Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 43.

b. Members of the Management Board

In 2022, the new Management Board adopted its own Rules of Procedure (RoP)¹³² and Code of Conduct (CoC)¹³³ that both implement rules on independence. Importantly, Article 37(1) GFL requires that the members of the Management Board, whilst being representatives of the Member States, ‘undertake to act independently in the public interest’.¹³⁴ This requirement is taken over in both the Rules of procedure and the Code of Conduct.¹³⁵

Like scientific experts, Management Board members shall present an ADol through the dedicated IT tool.¹³⁶ To enhance transparency, the ADols of Management Board members and their assessments are published on EFSA’s website and kept by EFSA for a maximum period of ten years from the date of their submission.¹³⁷ Every update of ADols of Management Board members is assessed by the Executive Director. Upon request, the members of the Management Board are required to produce supporting information, data or documents relevant for the screening of their ADols.¹³⁸ The Director’s assessment is subsequently submitted to the Management Board itself which must reach a conclusion on each ADol and, if necessary, recommend a follow-up action.¹³⁹ If the Management Board identifies a Col which is affecting the work of the Management Board or EFSA’s reputation and is not resolved by the follow-up action, the Management Board, acting on a two-thirds majority, may ask for the replacement of the member concerned.¹⁴⁰

Management Board members cannot be part of any other EFSA’s body and cannot influence EFSA’s scientific output.¹⁴¹ In particular, should they also engage, in their professional or personal capacity, in risk management activities concerning food safety, they are required to guarantee the utmost level of independence.¹⁴² Moreover, Management Board members are forbidden from engaging in projects or activities funded by EFSA and, if holding managerial positions in entities funded by EFSA, cannot manage contractual relationships with EFSA.¹⁴³ In addition, when participating in external activities, they should make sure that such activities do not result in actual, potential or perceived Cols.¹⁴⁴

Finally, Management Board members must inform the Board of any professional activity overlapping with EFSA’s remit that they carry out in the two years following the expiry of their mandate.¹⁴⁵ This information will be made publicly available.

c. Members of the Advisory Forum and Network Members

Like scientific experts and the members of the Management Board, members of the Advisory Forum shall submit ADols.¹⁴⁶ However, no screening of such ADols is carried out. According to the Declaration

¹³² EFSA, 6 October 2022, *Rules of Procedure of the Management Board of the European Food Safety Authority*, mb221006-a2.

¹³³ EFSA, 6 October 2022, *Code of Conduct of the Management Board of the European Food Safety Authority*, mb221006-a3.

¹³⁴ Similarly, for EMA, Article 63(2) of Regulation (EC) No 726/2004 provides that members of EMA’s Management Board ‘shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality [and] shall undertake to act in the public interest and in an independent manner’.

¹³⁵ Article 13 RoP; Article 5(1) CoC.

¹³⁶ Article 13(1) DCIM, Article 13(2) RoP and Article 5(1) CoC.

¹³⁷ Articles 13(4) and 15(1) RoP. See for instance EFSA, 15 December 2022, *Assessment of the interests declared pursuant to Article 37(1) of the Regulation (EC) No 178/2002 of the European Parliament and of the Council*, mb221215-d1.

¹³⁸ Article 5(6) CoC.

¹³⁹ Article 13(3) RoP.

¹⁴⁰ Article 13(5) DCIM; Articles 13(3) and 17 RoP.

¹⁴¹ Article 5(8) and (9) CoC.

¹⁴² Article 5(7) CoC.

¹⁴³ Article 5(4) CoC.

¹⁴⁴ Articles 5(10) and 8(1)(a) CoC.

¹⁴⁵ Article 13(6) RoP.

¹⁴⁶ Article 14(1) DCIM.

of Intent, members of the Advisory Forum acknowledge each other's commitment to promote the implementation of measures aimed at pursuing the impartiality of their respective food risk assessment systems. The Declaration explicitly includes in the definition of independence the absence of instructions deriving from State authorities and experts' employing organisations. Members may apply their own impartiality framework when engaging with experts from other Member States, whilst national rules and legislation regarding independence and transparency of the scientific opinions delivered in the field of public health, food chain safety and the environment and regarding public access to data and documents remain applicable.¹⁴⁷

Also network members (members of EFSA's networks, focal points or other networking activities carried out pursuant to Article 36 GFL) have to submit an ADol, and no screening, assessment or validation is performed by EFSA.¹⁴⁸ Memoranda of Understanding (MoUs) between EFSA and Public Institutions specify the applicable standards.¹⁴⁹ Independence of the experts who represent the views of Member States or international organisations in EFSA's network or network meetings is to be ensured by each appointing authority in accordance with the relevant national rules.¹⁵⁰

EFSA commits to follow-up on serious and well-documented cases of Col concerning members of the Advisory Forum and network members. In particular, in these cases the Executive Director may submit the issue to the Management Board. In turn, the Management Board can ask the competent Member State (for members of the Advisory Forum) or the national competent authority (for network members) to replace the concerned individual.¹⁵¹

d. Hearing Experts

Hearing experts are required to submit an ADol in advance of a meeting to which they are invited. No screening, assessment or validation is performed by EFSA.¹⁵²

e. Observers

Observers are not required to submit Dols.¹⁵³ Nevertheless, individuals who register to attend open plenary meetings¹⁵⁴ as observers must declare their specific interest in attending the meeting.¹⁵⁵ Observers must comply with specific rules. They must not hinder the work of the Scientific Committee and scientific panels, take part in the discussion, drafting, and deliberation of the scientific output, attempt to influence the meetings, distribute or request the circulation of any documents or record the meetings. Observers who do not comply with these rules may be asked to leave the meeting.¹⁵⁶ Finally, observers may be authorised to ask questions at the end of a specific discussion or at the end of the open plenary meetings. While priority is given to questions submitted at the time of registration, further questions can be asked if time allows.¹⁵⁷

¹⁴⁷ See EFSA, 3 July 2019, *Declaration of Intent of the EFSA Advisory Forum - Principles governing the impartiality of risk assessment in the areas of food, feed, plant health and animal health & welfare*.

¹⁴⁸ Article 12 DCIM

¹⁴⁹ EFSA's website does not report on these MoUs.

¹⁵⁰ EFSA, 2017, *EFSA's policy on independence: How the European Food Safety Authority assures the impartiality of professionals contributing to its operations*, p. 7.

¹⁵¹ Articles 14(2) and 12(3) DCIM.

¹⁵² Article 9 DCIM.

¹⁵³ Articles 10 and 11 DCIM.

¹⁵⁴ See Section 3.3.3(iv).

¹⁵⁵ EFSA, 21 September 2018, *Guidelines for Observers for open plenary meetings*, p. 2.

¹⁵⁶ EFSA, 21 September 2018, *Guidelines for Observers for open plenary meetings*, p. 4.

¹⁵⁷ EFSA, 21 September 2018, *Guidelines for Observers for open plenary meetings*, p. 4.

Staff of EU institutions, bodies or agencies attending the meetings of EFSA's scientific groups as observers are also not required to submit Dols.¹⁵⁸

f. Tenderers

Tenderers and participants in grant-awarding procedures must submit a Dol using the form provided by EFSA.¹⁵⁹ The screening of such Dols is carried out by the responsible authorising officer in accordance with the criteria set out in Annex 2 DCIM.¹⁶⁰ The responsible authorising officer can ask the tenderer to adopt the measures necessary to prevent a Col and, if such measures are not adopted, exclude the tenderer from the procedure.¹⁶¹

g. Enforcement

The enforcement of the DCIM is based on compliance and veracity checks that are carried out twice a year on random samples of Dols.¹⁶² When EFSA acquires information that is inconsistent with or missing from a Dol, the individual concerned shall update the Dol with the relevant information.¹⁶³ If the declaration of the relevant information would have resulted in a Col, its omission is considered a breach of the rules.¹⁶⁴ In case of a breach of the rules, the Management Board or the Executive Director¹⁶⁵ may adopt one of the following measures:¹⁶⁶

- a reprimand letter;
- the suspension from participation in (and compensation from) any EFSA activity for a period between 6 months and 1 year; or
- dismissal from the relevant body or scientific group.¹⁶⁷

When the sanction of suspension or dismissal is applied, EFSA must review the scientific output to which the expert has contributed.¹⁶⁸ In line with the recommendations of the European Parliament,¹⁶⁹ the findings on compliance are validated by an internal Advisory Committee, which also advises EFSA on all matters regarding independence.¹⁷⁰

h. Waivers

Even when a Col is identified, the Executive Director, on request by the officer responsible for the Dol assessment, may grant a waiver to an expert to allow his/her participation in working groups and peer review meetings under the following conditions:

¹⁵⁸ Article 11 DCIM.

¹⁵⁹ Article 15 DCIM.

¹⁶⁰ Article 16(1) DCIM.

¹⁶¹ Article 16(2) and (3) DCIM.

¹⁶² Article 19(1) DCIM. See Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 70.

¹⁶³ Article 19(3) DCIM.

¹⁶⁴ Article 20(1) DCIM.

¹⁶⁵ The Management Board for breaches committed by members of the Scientific Committee or Scientific Panel; the Executive Director for breaches committed by members of Working Groups or of participants to peer review meetings. See Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 69.

¹⁶⁶ Pursuant to Article 20(3) DCIM, the choice concerning the measure to apply shall be based on subjective elements, the importance and the financial impact of the relevant interest, the role of the expert concerned and the time of the omission.

¹⁶⁷ According to Article 20(2)(c) DCIM, this may be combined with a prohibition on participating in further EFSA activities for a period of 1 year up to a maximum period of 10 years.

¹⁶⁸ Article 20(4) DCIM.

¹⁶⁹ European Parliament, 26 March 2019, *Resolution of 26 March 2019 on discharge in respect of the implementation of the budget of the European Union agencies for the financial year 2017: performance, financial management and control*, para. 40. See also Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, pp. 43–44.

¹⁷⁰ Article 22 DCIM. The DCIM however does not define or explain the composition of this Advisory Committee.

- the contribution of this expert is essential for the completeness of the draft output;
- the secretariat of the relevant working group could not find a suitable alternative expert; and
- the expert's contribution could not be handled through his or her participation as hearing expert.¹⁷¹

If a waiver is granted, the expert is invited to take part in the discussions and in the drafting phase of the scientific output.¹⁷² In line with the 2013 Commission's Guidelines and the 2017 Policy on Independence, waivers, therefore, aim at striking a balance between the need for scientific expertise on the one hand and the need for independence on the other hand.¹⁷³ Waivers do not entail eligibility for chairship and vice-chairship and cannot be granted in respect of unconditional restrictions.¹⁷⁴ In this manner, no waivers shall be granted to experts with a current industrial employment or with a current financial investment in an entity impacted by EFSA's outputs.

i. Training and transparency

In implementing the 2017 Policy on Independence, the DCIM also provides for the organisation of training sessions for staff members and scientific experts¹⁷⁵ and the publication of independence-related information.¹⁷⁶ However, there are no rules in place concerning the publicity of meetings between EFSA's Management Board members and senior staff with interest representatives.¹⁷⁷

2.3.3. ADols and Cols reported between 2018 and 2022

In line with the Commission's 2013 Guidelines, EFSA has committed to continuously work for the improvement of its independence policy. Its approach follows the 'Plan-Do-Act' cycle, based on the activities carried out along four phases: planning, doing, checking and acting.¹⁷⁸

Every year, pursuant to Article 24(1)(b) DCIM, these activities are reported and published in EFSA's Consolidated Annual Activity Report which includes the Annual Report on the implementation of EFSA's policy on independence. For the purposes of this study, the reports for the years 2018, 2019, 2020, 2021 and 2022¹⁷⁹ are taken into consideration to assess the implementation of the 2017 Policy on Independence and the 2018 Decision on Competing Interest Management.¹⁸⁰ A detailed overview of the main figures is provided for in Annexes 1 and 2.

a. Scientific experts

Over the period 2018-2022, the number of ADols screened every year by EFSA decreased from 4140 to 1690 (see *Table 1* and *Figure 1*). EFSA explains such a decrease by reference to the deprioritisation of some independence-related activities due to the impact of the COVID-19 pandemic¹⁸¹ and to technical

¹⁷¹ Article 21(1)-(3) DCIM.

¹⁷² Article 21(6) DCIM.

¹⁷³ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 68.

¹⁷⁴ Article 21(6) and (4) DCIM.

¹⁷⁵ Article 23 DCIM. See also European Commission, 2021, *Guidance on the avoidance and management of conflicts of interest under the Financial Regulation*, para. 6.1.

¹⁷⁶ Article 24 DCIM. See also Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, pp. 45–46.

¹⁷⁷ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 46. See Section 2.4.

¹⁷⁸ Deming, W.E., 1950, *Elementary Principles of the Statistical Control of Quality: A Series of Lectures*, JUSE; Ishikawa, K., 1985, *What is total quality control? The Japanese way*, Prentice-Hall, pp. 56–61.

¹⁷⁹ See EFSA, 2023, *Annual Report on the implementation of EFSA's policy on independence 2022*.

¹⁸⁰ EFSA, 2019, *Annual Report on the implementation of EFSA's policy on independence 2018*; EFSA, 2020, *Annual Report on the implementation of EFSA's policy on independence 2019*; EFSA, 2021, *Annual Report on the implementation of EFSA's policy on independence 2020*; EFSA, 2022, *Annual Report on the implementation of EFSA's policy on independence 2021*.

¹⁸¹ EFSA, 2021, *Annual Report on the implementation of EFSA's policy on independence 2020*, p. 170.

issues linked to the launch of a new IT tool for the implementation of EFSA’s independence activities.¹⁸² The percentage of Cols identified over the ADols screened was similar in 2018 (0.39%), 2021 (0.41%) and 2022 (0.41%), whereas it was higher in 2019 (1.10%) and 2020 (1.01%). In the same vein, the percentage of waivers granted over the total Cols identified was identical in 2018 and 2021 (100%), while being significantly lower in 2019 (51%), 2020 (42%) and 2022 (57%). The number of experts participating as hearing experts, whose ADols are not screened, remained instead stable throughout the period, with the exception of 2020, when it was 26% higher than the average.

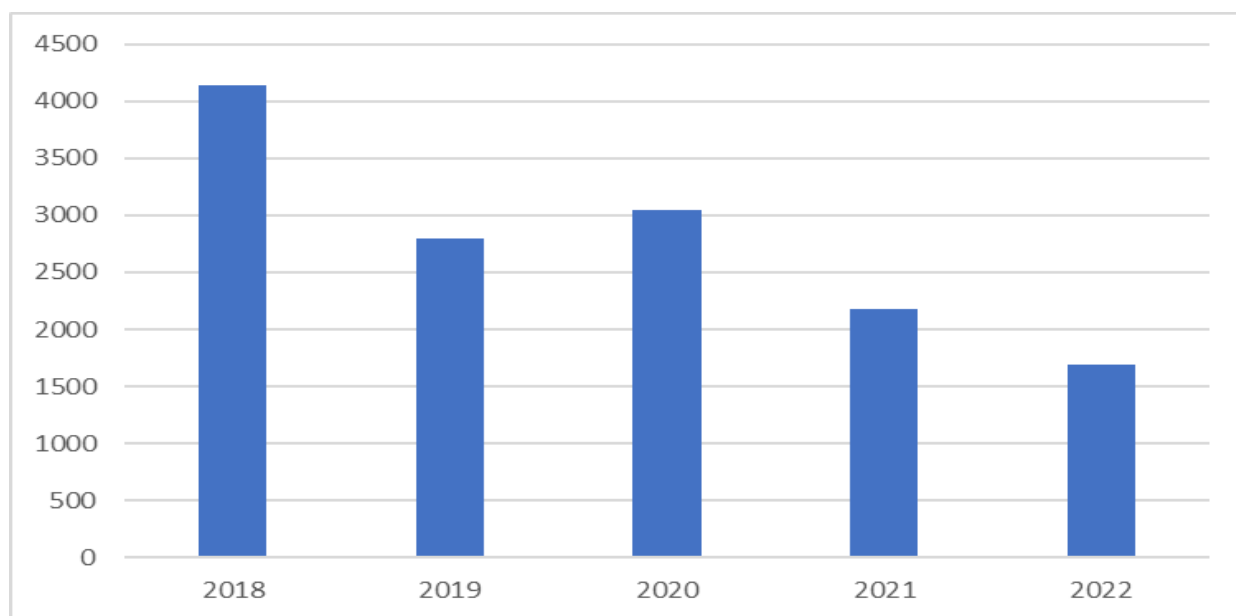
The sectors where Cols occurred most frequently were ‘Animal Health and Welfare’ (36 Cols identified over four years) and ‘Pesticides’ (28 Cols identified over four years) (Figure 2). Among the 14 sectors considered over the period 2018-2022, ‘Animal Health and Welfare’ and ‘Pesticides’ alone amounted to 56% of the total Cols identified.¹⁸³

Table 1: EFSA’s scientific experts’ Dols

	ADols screened	Cols identified and prevented	Waivers granted	Hearing experts
2022	1690	7	4	312
2021	2183	9	9	312
2020	3042	31	13	432
2019	2796	31	16	319
2018	4140	16	16	308

Source: Authors’ own elaboration on the basis of the data available in EFSA’s consolidated annual reports.

Figure 1: ADols screened over the period 2018-2022.

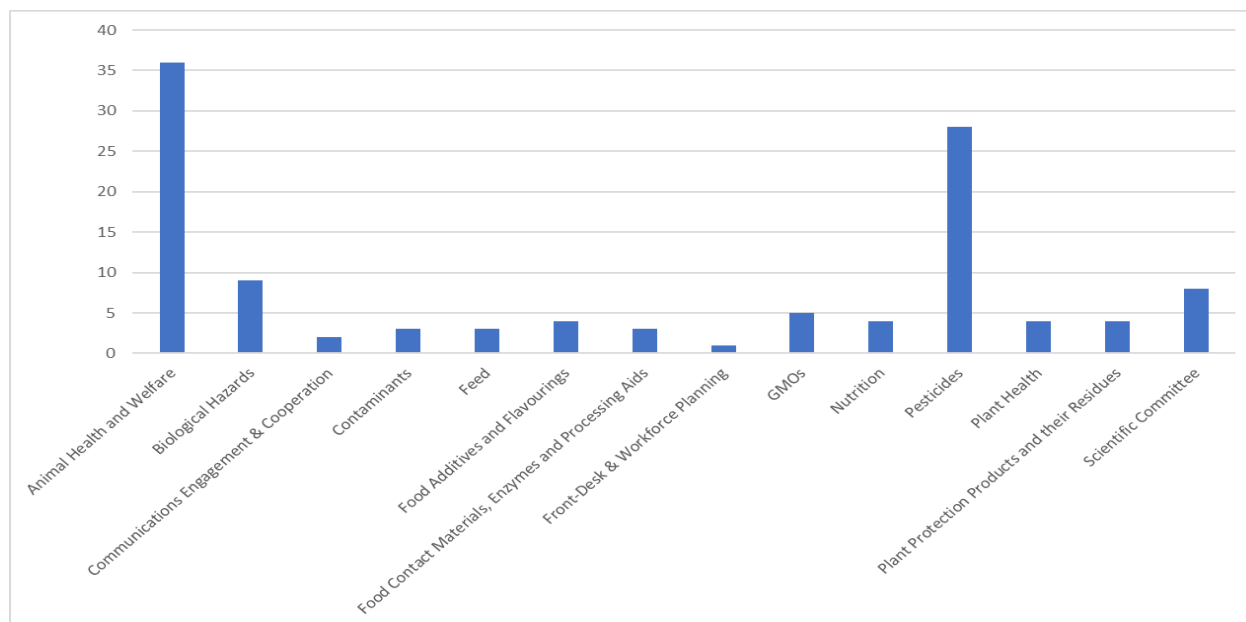


Source: Authors’ own elaboration on the basis of the data available in EFSA’s consolidated annual reports.

¹⁸² EFSA, 2021, *Annual Report on the implementation of EFSA’s policy on independence 2020*, p. 154; EFSA, 2023, *Annual Report on the implementation of EFSA’s policy on independence 2022*, p. 137.

¹⁸³ Annex 2 Tables 10-11.

Figure 2: Total Cols per sector over the period 2018-2022.



Source: Authors' own elaboration on the basis of the data available in EFSA's consolidated annual reports.

b. Members of the Management Board

During the concerned period, EFSA made publicly available the Dols submitted by former Management Board members as part of the corresponding registry of activities pursuant to Article 13(6) DCIM and Article 13(6) RoP.¹⁸⁴

c. Staff members

Cols are rare among Staff members, who are subject to the Staff Regulations. Over the period 2018-2022, only two Cols were identified in total.¹⁸⁵ In both cases EFSA adopted ordinary mitigating measures,¹⁸⁶ but the content of such measures is not published in the Annual Reports.¹⁸⁷ In 2021, only 67 staff members managed to submit their ADols due to the said IT tool deficiencies.¹⁸⁸ Therefore, a non-conformity report was filed to record the deviation from the applicable regulatory framework.¹⁸⁹

Following up on the internal audit performed by the Commission's Internal Audit Service in May 2018, EFSA adopted in 2020 a new set of internal instructions concerning Cols of the members of the Selection Board involved in the recruitment procedures of EFSA's statutory staff.¹⁹⁰ EFSA also carries out the screening of pre-selected candidates' Dols in accordance with Article 11 of the Staff Regulations and following the procedure set out in the relevant Standard Operating Procedure.¹⁹¹ Over the period

¹⁸⁴ Annex 1 Table 3. See <https://www.efsa.europa.eu/en/people/mbmembers>.

¹⁸⁵ Annex 1 Table 2.

¹⁸⁶ See EFSA, 13 July 2018, *Standard Operating Procedure on the Management of competing interests*, SOP_039_A, pp. 2–3. Ordinary mitigating measures can consist of: selling, freezing or disposal of stocks and shares, stock options, equities, bonds and or partnerships interest in the capital of a company holding an interest in EFSA's activities; or resigning from, or suspending, an activity, membership or affiliation with an entity holding an interest in EFSA's activities; or establishing short term limitations during the probationary phase of their contract with respect to the handling of dossiers for which the potential Col has been identified.

¹⁸⁷ EFSA, 2020, *Annual Report on the implementation of EFSA's policy on independence 2019*, p. 134; EFSA, 2021, *Annual Report on the implementation of EFSA's policy on independence 2020*, p. 172.

¹⁸⁸ EFSA, 2022, *Annual Report on the implementation of EFSA's policy on independence 2021*, pp. 150–151.

¹⁸⁹ Article 20(3) of EFSA, 31 July 2014, *Decision of the Executive Director on Declarations of Interest*, EFSA/LRA/DEC/02/2014.

¹⁹⁰ EFSA, 2020, *Standard Operating Procedure on the Recruitment and Selection of statutory staff*, SOP_043_A, p. 5; EFSA, 2021, *Annual Report on the implementation of EFSA's policy on independence 2020*, p. 171.

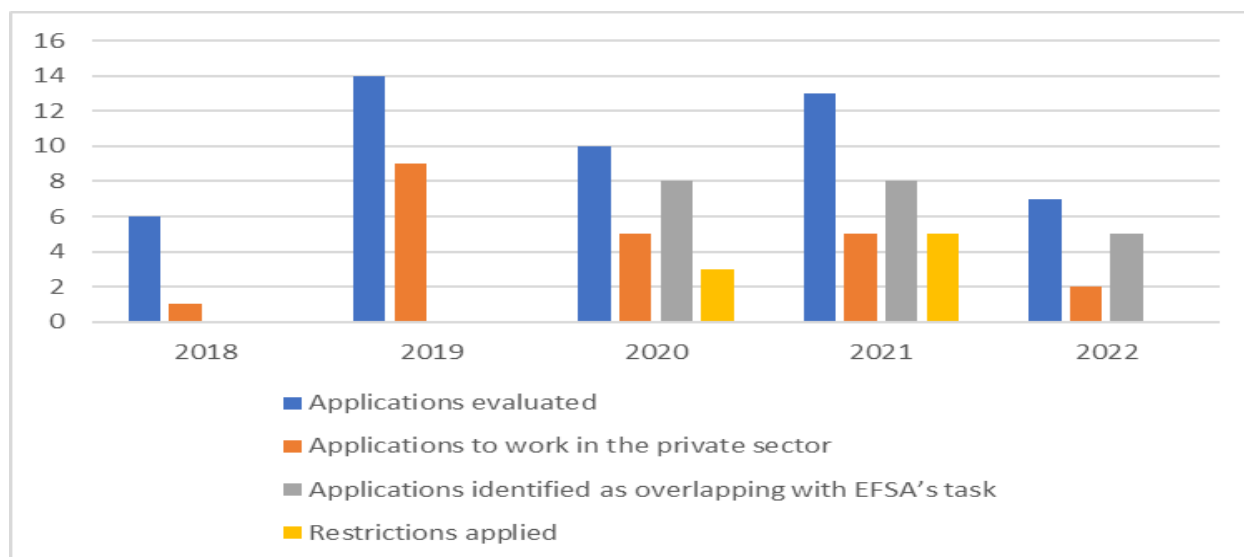
¹⁹¹ EFSA, 2020, *Standard Operating Procedure on the Recruitment and Selection of statutory staff*, p. 9.

2018-2022, only one case of Col was identified and resulted in non-recruitment.¹⁹² Conversely, every year EFSA adopted ordinary mitigating measures, including the exclusion of the concerned individual from activities carried out for the previous employer, to prevent Cols of pre-selected candidates.

Pursuant to Article 16 Staff Regulations, EFSA processes the application of staff members leaving the authority and wishing to engage in an occupational activity. Out of 50 applications processed over the period 2018-2022, around half (22) concerned engagement in the private sector (Figure 3). Among all the applications, four concerned working for companies providing consultancy services and three concerned non-profit organisations active in food safety. 21 applications were identified as overlapping with EFSA’s remit, and only eight required EFSA to apply restrictions.¹⁹³ In 2020 and 2021 the restrictions included temporary bans from engaging in the concerned activities and the remainder to take into account Cols before accepting specific tasks involving EFSA. In 2021, the restrictions also included forbidding the engagement in the outside activity.¹⁹⁴

Lastly, EFSA has worked on the development of a regulatory framework for the implementation of Articles 11 and 11a Staff Regulations on the prevention of Cols of EFSA employees and candidates to vacant positions since 2018. The proposal for new rules was initially expected by 2019¹⁹⁵ and then postponed to 2020,¹⁹⁶ 2021¹⁹⁷ and 2022.¹⁹⁸ A draft decision was discussed with the Commission throughout 2021 and 2022 with a view to have it adopted in 2023.¹⁹⁹ However, the Management Board has not adopted it yet.

Figure 3: Applications by former staff members over the period 2018-2022.



Source: Authors’ own elaboration on the basis of the data available in EFSA’s consolidated annual reports.

¹⁹² Annex 1 Table 4.

¹⁹³ Annex 1 Table 6.

¹⁹⁴ EFSA, 2021, *Annual Report on the implementation of EFSA’s policy on independence 2020*, p. 174; EFSA, 2022, *Annual Report on the implementation of EFSA’s policy on independence 2021*, p. 153.

¹⁹⁵ EFSA, 2019, *Annual Report on the implementation of EFSA’s policy on independence 2018*, p. 5.

¹⁹⁶ EFSA, 2020, *Annual Report on the implementation of EFSA’s policy on independence 2019*, p. 133.

¹⁹⁷ EFSA, 2021, *Annual Report on the implementation of EFSA’s policy on independence 2020*, p. 171.

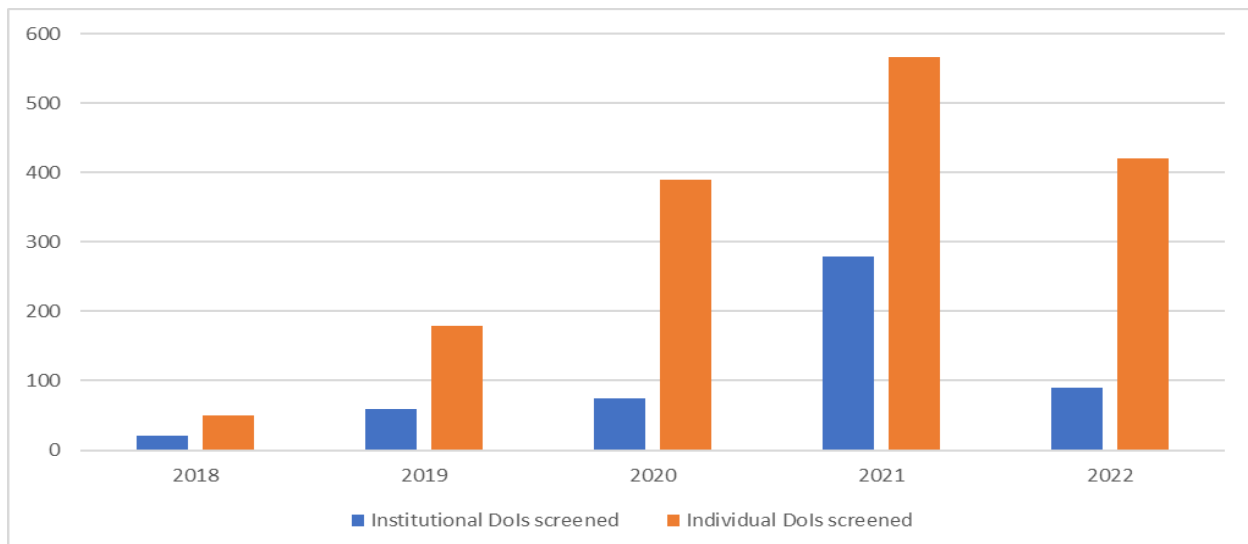
¹⁹⁸ EFSA, 2022, *Annual Report on the implementation of EFSA’s policy on independence 2021*, p. 150.

¹⁹⁹ EFSA, 2023, *Annual Report on the implementation of EFSA’s policy on independence 2022*, p. 132.

d. Tenderers

Between 2018 and 2021, in the context of procurement and grant awarding procedures, EFSA screened an increasing number of both ‘institutional’²⁰⁰ (20 in 2018 and 279 in 2021) and ‘individual’²⁰¹ (50 in 2018 and 566 in 2021) Dols (Figure 4).²⁰² In 2022, EFSA screened 90 institutional and 420 individual Dols. In 2019, five Cols were identified and prevented by rejecting the concerned experts.²⁰³ In 2021, three Cols were identified and prevented.²⁰⁴ The Report does not explain how this was done.

Figure 4: Dols screened for tenderers and participants in grant-awarding procedures over the period 2018-2022.



Source: Authors’ own elaboration on the basis of the data available in EFSA’s consolidated annual reports.

e. Enforcement

According to Article 19(1) DCIM, EFSA shall check twice a year the compliance and the veracity of a random sample of Dols submitted by scientific experts, tenderers and grant beneficiaries. While this obligation was respected in 2018 and 2019, in 2020 EFSA did not carry out compliance and veracity checks due to an internal reprioritisation exercise connected to the immediate impact of COVID-19.²⁰⁵ Moreover, only one check was carried out in 2021, due to ‘the strong IT deficiencies jeopardising the extraction of relevant data’.²⁰⁶ The minor non-compliances identified in 2021 were less than in 2018 and 2019. Conversely, the breaches of the applicable rules increased in 2021 compared to each of the preceding three years, resulting in two reprimand letters addressed to the concerned individuals (Figure 5).²⁰⁷

Finally, over the period 2018-2022 only one non-compliance led to the adoption of remedial measures. In particular, in 2018 EFSA failed to exclude an expert from a meeting in light of a Col identified in the

²⁰⁰ See Article 15(1) DCIM: ‘institutional Dols’ are the Dols submitted by legal persons taking part in EFSA’s public procurement procedures concerning EFSA’s scientific activities.

²⁰¹ See Article 15(2) DCIM: ‘individual Dols’ are the Dols submitted by each of the members of the team, the tenderer, or Grant applicant proposing to work on the project connected to the public procurement procedure or Grant.

²⁰² Annex 1 Table 5.

²⁰³ EFSA, 2020, *Annual Report on the implementation of EFSA’s policy on independence 2019*, p. 134.

²⁰⁴ EFSA, 2022, *Annual Report on the implementation of EFSA’s policy on independence 2021*, p. 150.

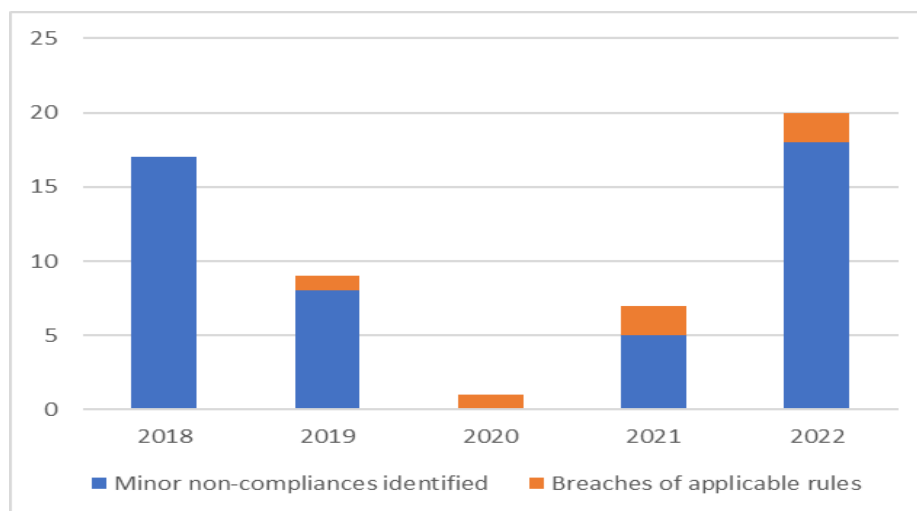
²⁰⁵ EFSA, 2021, *Annual Report on the implementation of EFSA’s policy on independence 2020*, p. 173.

²⁰⁶ EFSA, 2022, *Annual Report on the implementation of EFSA’s policy on independence 2021*, p. 151.

²⁰⁷ Annex 1 Table 7.

expert’s ADol. While the expert was sanctioned in 2019 for a breach of the applicable rules, the LA Unit found no indication of undue influence by the concerned expert in the preparation of a draft opinion. According to EFSA, an extra level of reassurance was given by the fact that the concerned expert ‘contributed to the preparatory work delivered by a working group, while the final scientific opinion was adopted by the EFSA Scientific Panel on Novel Foods and Food Allergens, whose members discussed, reviewed and endorsed the draft opinion submitted to their attention, thereby ensuring an additional level of scrutiny on the original proposal from the working group’.²⁰⁸

Figure 5: EFSA’s enforcement over the period 2018-2022.



Source: Authors’ own elaboration on the basis of the data available in EFSA’s consolidated annual reports.

f. Training

EFSA delivered four training sessions in 2018 and four training sessions (plus eleven individual awareness sections for each scientific panel) in 2019. However, the Covid-19 pandemic negatively impacted awareness-raising and training activities, with only one session being delivered (online) in 2020 and three sessions in 2021.²⁰⁹ In 2022, 13 training sessions were delivered.²¹⁰

g. Transparency

As set forth above, activities carried out for public institutions in the public interest do not constitute Cols. Therefore, Article 36 GFL and Commission Regulation (EC) No 2230/2004 require EFSA to draft and regularly update the list of public institutions included in the European network of organisations operating in the fields falling within EFSA’s remit.²¹¹ To that end, the Management Board, acting on proposal from the Executive Director, shall draw up and update the list of organisations, taking account of reviews or new designation proposals from the Member States.²¹² This list is published on EFSA’s website and currently contains 317 organisations.²¹³

²⁰⁸ EFSA, 2020, *Annual Report on the implementation of EFSA’s policy on independence 2019*, p. 135.

²⁰⁹ Annex 1 Table 8.

²¹⁰ EFSA, 2023, *Annual Report on the implementation of EFSA’s policy on independence 2022*, p. 136.

²¹¹ Article 2 of Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority’s mission [2004] OJ L 379.

²¹² Article 36(2) of Regulation (EC) No 178/2002 and Article 2(4) of Commission Regulation (EC) No 2230/2004.

²¹³ See https://efsa.force.com/competentorganisations/s/competentorganisation/CompetentOrganisation_c/00B1v000009LqfIEAS.

Moreover, all institutional fellows of EFSA are listed on its website and comprise a total of 762 public institutions.²¹⁴

2.3.4. Implementation of the Transparency Regulation

The Transparency Regulation, that will be discussed in more detail in section 3.3.1, is also relevant for EFSA's independence policy.²¹⁵ The Regulation, mainly aimed at enhancing EFSA's transparency, stresses that independence must be granted while enhancing risk communication.²¹⁶ Indeed, it underlines that strengthening independence also contributes to increase the trust of the general public in EU legislation, thereby 'ensur[ing] that the Authority is more accountable to the Union citizens in a democratic system'.²¹⁷

The Management Board was originally composed of 14 members plus a representative of the Commission with four of the members having their background in organisations representing consumers and other interests in the food chain. The Council in consultation with the European Parliament appointed the members from a list drawn up by the Commission.²¹⁸

As of July 2022, the Transparency Regulation has changed the composition of the Management Board. It is currently composed of one member for each Member State (appointed by the Council), two members appointed by the Commission as its representatives, two members appointed by the European Parliament and four representatives of civil society and food chain interests appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission.²¹⁹ The latter members representing civil society and food chain interests are drawn from four distinct areas: consumer, farmer and industry organisations and environmental NGOs.²²⁰ Following up on the entry into force of the Regulation, the Management Board has adopted new Rules of Procedure,²²¹ a Code of Conduct²²² and new Rules on the selection, appointment and operations of scientific experts.²²³ According to the Transparency Regulation, the new Management Board composition will not affect the independence of EFSA's scientific work, as the Management Board solely engages with administrative and financial aspects.²²⁴ Moreover, the literature does not show concerns about the impact of this

²¹⁴ See https://www.efsa.europa.eu/sites/default/files/documents/institutional_fellows_list.pdf. See Annex 1 Table 9.

²¹⁵ Independence has been granted throughout the implementation of the Regulation. As explained by EFSA, '[n]o undue influence has been allowed at any time during the implementation. DG SANTE and EFSA have informed stakeholders about the implementation of the Transparency Regulation in dedicated fora. No details regarding the implementation have been discussed with stakeholders, nor has any material been produced jointly with stakeholders. No substantive reply has been provided to individual stakeholder input outside the dedicated fora'. See <https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation>.

²¹⁶ Recital 8 of Regulation (EU) 2019/1381.

²¹⁷ Recital 12 of Regulation (EU) 2019/1381. In the literature, several authors suggest that there is no incompatibility between independence and accountability of agencies. See Busuioc, M., 2009, *Accountability, Control and Independence: The Case of European Agencies*, *European Law Journal*, Vol. 15 No. 5, pp. 599–615; Curtin, D., 2005, *Delegation to EU Non-Majoritarian Agencies and Emerging Practices of Public Accountability*, in Geradin, D., Muñoz, R., Petit, N. (eds.), *Regulation through agencies in the EU: a new paradigm of European governance*, Edward Elgar, p. 87; Gabbi, S., Wood, M., Strauss, B., 2020, *Controlling the European Food Safety Authority*, in Scholten, M., Brenninkmeijer, A.F.M. (eds.), *Controlling EU agencies: the rule of law in a multi-jurisdictional legal order*, Edward Elgar, p. 207; Morvillo, M., 2020, *Glyphosate Effect: Has the Glyphosate Controversy Affected the EU's Regulatory Epistemology?*, *European Journal of Risk Regulation*, Vol. 11 No. 3, p. 433; Vos, E., 2016, *EU Agencies and Independence*, in Ritleng, D. (ed.), *Independence and Legitimacy in the Institutional System of the European Union*, Oxford University Press, p. 227.

²¹⁸ Article 25 of Regulation (EC) No 178/2002, as adopted in 2002.

²¹⁹ Article 25 of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381.

²²⁰ Article 25(1a)(c) of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381.

²²¹ EFSA, 6 October 2022, *Rules of Procedure of the Management Board of the European Food Safety Authority*.

²²² EFSA, 6 October 2022, *Code of Conduct of the Management Board of the European Food Safety Authority*.

²²³ EFSA, 6 October 2022, *Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups*.

²²⁴ Recital 14 of Regulation (EU) 2019/1381. On this point, see also Gabbi, S., Wood, M., Strauss, B., 2020, *Controlling the European Food Safety Authority*, in Scholten, M., Brenninkmeijer, A.F.M. (eds.), *Controlling EU agencies: the rule of law in a multi-jurisdictional legal order*, Edward Elgar, p. 199.

reform on EFSA's independence; the guarantees provided by the strict appointment criteria²²⁵ are considered sufficient to ensure the independence of risk assessment.²²⁶

Furthermore, it is pointed out in the literature that, while the Regulation achieves its goal of ensuring some representation of stakeholders,²²⁷ their voice, and thus the impact of their interests, is significantly diluted in the increased Management Board.²²⁸ This may be an effective way of preventing the excessive influence of those interests on EFSA's operations. However, the literature also notices that such a dilution risks to render 'any attempt for enhanced participation and meaningful collaboration, arguably, moot'.²²⁹

Another change brought by the Transparency Regulation relates to the selection and appointment of the members of the Scientific Committee and the Scientific Panels.²³⁰

The scientific committee and panels were originally composed of independent scientific experts and appointed by the Management Board, acting upon a proposal from the Executive Director, for a three-year term of office, following publication of a vacancy in the Official Journal of the European Communities, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.²³¹ The GFL as amended by the Transparency Regulation first changes the office term of the members of the committee and panels into five years. Furthermore, it gives a role to the Member States in the announcement and distribution of the calls for the expression of interest.²³² In particular, the GFL includes independence and the absence of conflicts of interests among the criteria for the selection and appointment of the members of the scientific committee and the panels.²³³ Hereby it explicitly refers to the requirement that the members of the Scientific Committee and the Scientific Panels must act independently of any external influence and EFSA's independence policy. This is clearly reflected in Articles 3(1)(b), 24(5), and 37(1) of the 2022 Rules on selection, appointment and operations. The Regulation stresses, moreover, the importance of the financial independence of scientific experts.²³⁴ Furthermore, the Regulation requires EFSA and the Member States not to prejudice scientific experts' independence while supporting them in their operational activity.²³⁵ It states that Member States (as well as employers) must refrain from giving instructions to scientific and external experts which may undermine the independence of EFSA's work.²³⁶ Accordingly, Article 37(2) of the

²²⁵ See also Articles 1, 13, 14 and 15 RoP; Articles 2, 3, 5 and 10 CoC.

²²⁶ Chernaigh, B.N., 2021, *Piecemeal Transparency: An Appraisal of Regulation (EU) No. 2019/1381 on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain*, European Journal of Risk Regulation, Vol. 12 No. 3, p. 709; Morvillo, M., 2020, *Glyphosate Effect: Has the Glyphosate Controversy Affected the EU's Regulatory Epistemology?*, European Journal of Risk Regulation, Vol. 11 No. 3, p. 433.

²²⁷ In this respect, see also European Parliament, 4 May 2022, *Resolution of 4 May 2022 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority (EFSA) for the financial year 2020*, para. 20.

²²⁸ Chernaigh, B.N., 2021, *Piecemeal Transparency: An Appraisal of Regulation (EU) No. 2019/1381 on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain*, European Journal of Risk Regulation, Vol. 12 No. 3, pp. 708–709. However, the same author also observes that '[a]n immediate concern arising from this relates to purposive participation and the practical realities of overcrowded committees'.

²²⁹ Chernaigh, B.N., 2021, *Piecemeal Transparency: An Appraisal of Regulation (EU) No. 2019/1381 on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain*, European Journal of Risk Regulation, Vol. 12 No. 3, p. 709.

²³⁰ Recital 17 of Regulation (EU) 2019/1381.

²³¹ Article 28(5) of Regulation (EC) No 178/2002, as adopted in 2002.

²³² Article 28(5) of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381.

²³³ Article 28(5a)(c)(ii) of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381.

²³⁴ Recital 17 of Regulation (EU) 2019/1381.

²³⁵ Recital 18 of Regulation (EU) 2019/1381.

²³⁶ Article 28(5d) of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381. On this point, see Canfora, I., 2020, *L'evoluzione delle regole europee sulla trasparenza: verso un sistema di «Sicurezza Alimentare 2.0»*, Rivista di Diritto Alimentare, Vol. 14 No. 3, pp. 12–13.

2022 Rules on selection, appointment and operations provides that scientific experts ‘shall not represent the opinion of a Member State, of their employers or of any other organisation’.²³⁷

Notably, Article 28(5e) of the GFL as amended by the Transparency Regulation emphasises participation of the national scientific organisation referred to in Article 36 GFL in EFSA’s preparatory work, envisaging in particular the possibility for these organisations to prepare scientific opinions to be peer-reviewed by the scientific panels before adoption.

Finally, the Transparency Regulation contains a ‘Review clause’²³⁸ that requires the Commission to evaluate every five years the selection procedures for the Scientific Committee and Scientific Panels. In particular, the Commission must gauge their degree of, *inter alia*, transparency and suitability to ensure independence and prevent conflicts of interests.²³⁹

2.3.5. Main concerns of the Institutions/bodies about EFSA’s independence policies

Over the past few years EFSA, like other agencies,²⁴⁰ has been subject to pressure to improve Col management. In particular, the European Parliament has repeatedly expressed concerns about EFSA’s independence policies.²⁴¹

a. Scope of EFSA’s independence policy

In the context of discharge procedures,²⁴² the European Parliament has criticised the scope of the 2017 Policy on Independence and the corresponding DCIM.²⁴³ A particular point of concern has been that EFSA’s independence policy only covers interests on matters falling under the mandate within which the relevant scientific group or panel will carry out its assessment.²⁴⁴ This policy is in line with the 2013 Commission’s Guidelines discussed above.²⁴⁵ Conversely, according to the European Parliament, the independence policy should cover ‘all material interests related to the companies whose products are assessed by the Authority and to any organisations funded by them’.²⁴⁶ In other words, experts’

²³⁷ EFSA, 6 October 2022, *Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups*.

²³⁸ Article 61 of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381.

²³⁹ Recital 37 of Regulation (EU) 2019/1381.

²⁴⁰ Vos, E., 2016, *EU Agencies and Independence*, in Rittleng, D. (ed.), *Independence and Legitimacy in the Institutional System of the European Union*, Oxford University Press, p. 207; Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 71.

²⁴¹ European Parliament, 18 April 2018, *Resolution of 18 April 2018 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2016*; European Parliament, 26 March 2019, *Resolution of 26 March 2019 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2017, 2018/2190(DEC)*; European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*; European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*.

²⁴² Budget discharge procedures are described as ‘the most important tool available to the European Parliament to exercise its scrutiny over the operations of delegated bodies such as EFSA’ by Gabbi, S., Wood, M., Strauss, B., 2020, *Controlling the European Food Safety Authority*, in Scholten, M., Brenninkmeijer, A.F.M. (eds.), *Controlling EU agencies: the rule of law in a multi-jurisdictional legal order*, Edward Elgar, p. 212.

²⁴³ European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, para. 16; European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*, para. 22.

²⁴⁴ Article 7(2) DCIM.

²⁴⁵ European Commission, 10 December 2013, *Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies*, p. 9.

²⁴⁶ European Parliament, 18 April 2018, *Resolution of 18 April 2018 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2016*, para. 14; European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, para. 16.

interests should be assessed against the ‘the overall remit of the Authority’.²⁴⁷ Subsequent potential issues with the availability of scientific expertise are addressed by the European Parliament by reminding that EFSA can invite experts to participate in hearings without giving them the right to participate in deliberations and drafting conclusions.²⁴⁸

A further major concern for the European Parliament lies in the absence of CoIs screening for hearing experts and members of the Advisory Forum, focal points and scientific networks.²⁴⁹

b. Cooling-off periods and research funding

Following the repeated calls of the European Parliament for the incorporation of a two-year cooling-off period for CoIs deriving from research funding,²⁵⁰ EFSA introduced a cooling-off period for private funding exceeding 25% of each expert’s total research budget. In the view of the European Parliament, however, EFSA should include every research funding-related CoI within the scope of the cooling-off period, hence also below 25%.²⁵¹

c. Other relevant issues

In 2018, the European Parliament, following the European Ombudsman’s Decision of 2015,²⁵² expressed concerns about EFSA’s failure to require academic experts to ‘declare the details of the financial relationships between their university employers and their university employers’ industry partners’.²⁵³ Moreover, in 2020, the European Parliament recommended EFSA to reduce ‘as much as possible’ its dependence on external staff hired in IT consultancy roles.²⁵⁴ In 2022 it called upon EFSA to publish the CVs of its staff members online.²⁵⁵ The latter point was also recommended by academics for key managerial roles such as the Executive Director and the members of the Management Board.²⁵⁶

Furthermore, the European Parliament invited EFSA to align its policies with the recommendations of the European Court of Auditors and the Ombudsman regarding two topics:

i) Strengthening of the accounting officer’s independence

²⁴⁷ European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, para. 16. See also European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*, para. 22.

²⁴⁸ European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*, para. 22.

²⁴⁹ European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, para. 19.

²⁵⁰ European Parliament, 28 March 2017, *Report on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2015*, 2016/2174(DEC), paras 10–11; European Parliament, 18 April 2018, *Resolution of 18 April 2018 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2016*, para. 15; European Parliament, 26 March 2019, *Resolution of 26 March 2019 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2017*, para. 17.

²⁵¹ European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, para. 17; European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*, para. 23.

²⁵² European Ombudsman, 28 January 2015, *Decision of the European Ombudsman closing the inquiry into complaint 346/2013/SID against the European Food Safety Authority (‘EFSA’)*, paras 11–18.

²⁵³ European Parliament, 18 April 2018, *Resolution of 18 April 2018 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2016*, para. 16.

²⁵⁴ European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, para. 13.

²⁵⁵ European Parliament, 4 May 2022, *Resolution of 4 May 2022 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority (EFSA) for the financial year 2020*, para. 19.

²⁵⁶ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 38.

In 2017 the European Court of Auditors recommended to EFSA and other 12 agencies the strengthening of the accounting officer's independence by making this person 'directly responsible to the Agency's Director (administratively) and Board (functionally)'.²⁵⁷ However, EFSA replied that the independence of the accounting officer was 'beyond doubt'.²⁵⁸ The accounting officer reports to the Head of the Business Services Department²⁵⁹ who is responsible for the preparation of EFSA's Annual Activity Report.²⁶⁰ The Management Board can at any time suspend temporarily or definitely the accounting officer from his/her duties.²⁶¹

In 2021 the European Parliament invited EFSA to address the Court of Auditors' concern as soon as possible to seek confirmation that this organisational structure does indeed ensure the independence of the accounting officer.²⁶² In 2022 the Court of Auditors considered that EFSA sufficiently ensured the direct (functional) responsibility of the accounting officer to the Management Board, but not the direct (administrative) responsibility of the accounting officer to the Executive Director.²⁶³ EFSA did not address this issue in its reply to the Court of Auditors.²⁶⁴

ii) *Setting criteria to prohibit its senior staff from taking up specific positions after their term-office*

In 2020, the European Ombudsman recommended that the European Banking Authority (EBA) invoked, where necessary, the option of forbidding, for a limited period of time, its senior staff from taking up certain positions after their term-of-office. The Ombudsman recommended the setting out of the criteria for the adoption of such a measure, the preventive communication of these criteria to applicants for senior positions in the Authority and the adoption of internal procedures to restrict access to confidential information once a staff member moves to another job.²⁶⁵

Called upon by the European Parliament to align its rules to the Ombudsman's recommendations,²⁶⁶ EFSA started considering the adoption of the said internal procedure and is expected to report on the developments in that regard.²⁶⁷

2.3.6. External reviews of EFSA's independence policy

In compliance with Article 26(3) DCIM, which provides that 'The Executive Director shall review this decision by 1 December 2020, and at least every two years thereafter', EFSA launched the process of review of the DCIM in 2020. To this end, the Commission's DG SANTE commissioned a study to carry out a review of EFSA's 2017 Independence Policy. This review (the 2021 Review Report)²⁶⁸ was finalised

²⁵⁷ European Court of Auditors, 2017, *2017 audit of EU agencies in brief - Introducing the European Court of Auditors' 2017 annual report on EU agencies*, p. 20.

²⁵⁸ European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*, para. 21.

²⁵⁹ Now EMPOWER Department. See EFSA, 16 December 2021, *Programming document 2022-2024*, p. 120.

²⁶⁰ EFSA, 12 December 2017, *Internal Control Framework of the European Food Safety Authority*, mb171212-a5, p. 5.

²⁶¹ European Court of Auditors, 2020, *Report on the annual accounts of the European Food Safety Authority (EFSA) for the financial year 2019 together with the Authority's reply*.

²⁶² European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*, para. 21.

²⁶³ European Court of Auditors, 2022, *Annual report on EU agencies for the financial year 2021*, p. 161.

²⁶⁴ European Court of Auditors, 2022, *Annual report on EU agencies for the financial year 2021*, p. 162.

²⁶⁵ European Ombudsman, 7 May 2020, *Letter to the European Banking Authority (EBA) from the European Ombudsman on how the European Banking Authority handled the move of its former Executive Director to become CEO of a financial industry lobby group*.

²⁶⁶ European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*, para. 24.

²⁶⁷ European Parliament, 4 May 2022, *Resolution of 4 May 2022 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority (EFSA) for the financial year 2020*, para. 23.

²⁶⁸ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*.

in April 2021 and presented to EFSA's Management Board in June 2021.²⁶⁹ In addition, in February 2022 the French *Commission Nationale Déontologie et Alertes en santé publique et environnement* (cnDAspe) published its 'Critical Analysis of the EFSA's Rules for Managing Interests' (the 2022 Critical Analysis).²⁷⁰

Overall, both reports assess the DCIM positively. According to the 2021 Review Report, the DCIM has put EFSA 'at the forefront' with regard to Col management matters,²⁷¹ whereas the 2022 Critical Analysis praises the DCIM for having marked 'a significant and welcome change from the prevailing situation up until 2017'.²⁷²

a. The scope of EFSA's independence policy

The 2021 Review Report observes that EFSA's rules on Col result in a restricted access to expertise. The Report finds that, thanks to recourse to hearing experts and external contractors, this has not resulted in a worsened performance in terms of quality.²⁷³ However, the Report also points out that a revision of the 2017 Policy on Independence is necessary to ensure the long-term sustainability of EFSA's Col rules.²⁷⁴ The 2022 Critical Analysis proposes to adopt a more modulated approach that would allow experts with 'minor' interests to enjoy a 'simple participation regime' (i.e., without responsibility for chairship, vice-chairship or rapporteur).²⁷⁵

The Parliament already remarked that EFSA's independence policy covers only interests falling within the scope of the mandate of the relevant scientific group or panel. This approach results in a semi-centralised, two-layered system within which Dols are, firstly, assessed by the secretariat responsible for each scientific group or panel and, secondly, centrally validated by the LA Unit. The 2021 Review Report assesses whether this system could be simplified and fully centralised within the LA Unit. It concludes that the LA Unit would not have the necessary expertise to judge on key aspects related to the remit of the mandate of a specific group or panel.²⁷⁶ The Report suggests using AI tools and text mining facilities to refine the definition of EFSA's remit on the basis of consecutive iterations of examples for machine learning.²⁷⁷

b. Cooling-off periods and research funding

The 2022 Critical Analysis recommends the extension of cooling-off periods from two to four or five years.²⁷⁸ With specific regard to research funding, moreover, the 2022 Critical Analysis recommends the lowering of the relevant share from 25% to 15% and the inclusion within that share of all resources of private origin, including private sources that contribute to the budget of projects co-financed with public institutions.²⁷⁹ Conversely, the 2021 Review Report acknowledges current research funding rules among the main reasons for the improvement of EFSA's reputation. According to the Report, funding

²⁶⁹ EFSA, 2022, *Annual Report on the implementation of EFSA's policy on independence 2021*, p. 149.

²⁷⁰ cnDAspe, 18 February 2022, *Critical Analysis of the EFSA's Rules for Managing Interests*.

²⁷¹ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 10.

²⁷² cnDAspe, 18 February 2022, *Critical Analysis of the EFSA's Rules for Managing Interests*, p. 2.

²⁷³ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 6.

²⁷⁴ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, pp. 10–11.

²⁷⁵ cnDAspe, 18 February 2022, *Critical Analysis of the EFSA's Rules for Managing Interests*, p. 5.

²⁷⁶ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 6.

²⁷⁷ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 15.

²⁷⁸ cnDAspe, 18 February 2022, *Critical Analysis of the EFSA's Rules for Managing Interests*, p. 3.

²⁷⁹ cnDAspe, 18 February 2022, *Critical Analysis of the EFSA's Rules for Managing Interests*, p. 7.

from non-public operators constitutes a competing interest worth monitoring and EFSA's rules improve the overall credibility of its policy.²⁸⁰

c. Independence from national pressures and political agendas

The definition of Col provided in the 2017 Policy on Independence and 2018 DCIM does not refer to national interests.²⁸¹ The 2021 Review Report observes that, with the increased role played by Member States due to the changes brought by the Transparency Regulation, problems concerning independence from national pressure and Member States' political agendas will be more acutely perceived.²⁸² In particular, the Report refers to the increased role of the organisations listed in Article 36 GFL.²⁸³ In the respect, the Report suggests that EFSA should consider extend the scope of its cooling-off provisions to ensure consistency in the rules applicable to all experts involved in the preparation of EFSA's output.²⁸⁴

The 2022 Critical Analysis suggests that a common framework, based on the DCIM, of minimum requirements for the prevention of Cols should apply to members of national authorities involved in the preparation of EFSA opinions as rapporteur or co-rapporteur.²⁸⁵ The 2022 Critical Analysis observes moreover that the status of these authorities – in particular whether they should be considered as part of EFSA's scientific network - is not sufficiently clear under the present framework.²⁸⁶

d. Other relevant issues

The 2021 Review Report and the 2022 Critical Analysis include further points of attention:

1. Coherence between the 2017 Policy on Independence and the 2018 DCIM

The 2018 DCIM is overall coherent with the 2017 Independence Policy. However, there are some discrepancies between the definitions included in the 2017 Independence Policy and the corresponding implementing rules laid down by the 2018 DCIM. It would therefore be desirable to jointly evaluate and review the two documents.²⁸⁷

2. Clarity

While the tables included in the DCIM Annex are praised for their clarity,²⁸⁸ simpler language in the DCIM rules would allow a slightly smoother implementation of the DCIM itself.²⁸⁹ For instance, the conditions for the granting of waivers could be further clarified.²⁹⁰ In that respect,

²⁸⁰ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 10.

²⁸¹ See Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 37.

²⁸² Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 7.

²⁸³ Article 28(5e) of Regulation (EC) No 178/2002, as amended by Regulation (EU) No 2019/1381.

²⁸⁴ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 14.

²⁸⁵ cnDASpe, 18 February 2022, *Critical Analysis of the EFSA's Rules for Managing Interests*, pp. 2 and 4.

²⁸⁶ cnDASpe, 18 February 2022, *Critical Analysis of the EFSA's Rules for Managing Interests*, p. 3.

²⁸⁷ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 4.

²⁸⁸ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 5.

²⁸⁹ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, pp. 11–12.

²⁹⁰ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 13.

the 2022 Critical Analysis recommends the introduction of an obligation of information of the other members of the group in which the waived expert is involved.²⁹¹

3. *Screening of the Dols of hearing experts and network members*

The lack of screening of the Dols of hearing experts and network members has negatively impacted EFSA's reputation.²⁹² It is in particular not clear why ADols are required for hearing experts but they are not screened.²⁹³

4. *Sanctions and enforcement*

Enforcement rules are successful in bringing an high level of compliance with Col rules thanks to the clear sanctioning system.²⁹⁴ The clear sanctioning steps and the reduced room for discretion envisaged in the DCIM are considered to enhance EFSA's credibility.²⁹⁵ However, procedures concerning breaches of the applicable rules could be further streamlined by minimising involvement of high-level governance bodies for minor cases.²⁹⁶ Moreover, compliance and veracity checks could be expanded through the use of AI tools and text mining facilities.²⁹⁷

5. *Training*

Training activities are considered effective, albeit not decisive, in improving Col management.²⁹⁸ The 2022 Critical Analysis recommends to extend the training sessions to the Advisory Committee to further spread awareness about independence-related matters.²⁹⁹

6. *IT tool*

The management of Dols through the IT tool is acknowledged as one of the strengths of EFSA's Col management.³⁰⁰ However, the Report recommends EFSA to extend its use to procurement and grant procedures.³⁰¹

2.4. Key Findings and Recommendations

On the basis of the analysis carried out so far in this Study, this section aims at summarising the main findings concerning EFSA's policy on independence. This will be done by also including, where relevant, comparisons with ECHA and EMA.³⁰²

²⁹¹ cNDAspe, 18 February 2022, *Critical Analysis of the EFSA's Rules for Managing Interests*, p. 5.

²⁹² Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 10.

²⁹³ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, pp. 4–5.

²⁹⁴ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 5.

²⁹⁵ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, pp. 6 and 10.

²⁹⁶ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 14.

²⁹⁷ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 15.

²⁹⁸ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 5.

²⁹⁹ cNDAspe, 18 February 2022, *Critical Analysis of the EFSA's Rules for Managing Interests*, p. 5.

³⁰⁰ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 6.

³⁰¹ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 14.

³⁰² See Annex 3.

A. Definitions of conflict of interests, experts and external experts

1. *Conflicts of Interests*

The definition of Col provided in EFSA's 2017 Policy on Independence refers to conflicts of *interest* rather than conflicts of *interests*. The Policy does not contain sufficient descriptions and examples to clearly define the individual elements of the definition.³⁰³ Moreover, potential interests are not expressly mentioned in the definition although they are considered in the Policy. While the definition covers perceived interests, it does not mention 'national interests' and 'political pressure'. Its broad wording however allows to include within its scope not only personal interests but also interests deriving from other public duties/roles of the concerned individual. Art 28(5d) GFL and EFSA's 2022 rules on the selection of experts recognise this.

National interest or political pressure does neither appear in the definition of Col provided by ECHA.³⁰⁴ EMA's policy, instead, provides clear examples of 'direct' and 'indirect' interests.³⁰⁵ However, for the definition of Col, it relies on Article 107 of Regulation 2017/745,³⁰⁶ which does not mention 'national interests' and 'political pressure'.

Recommendations:

From a terminological perspective, the use of the word *interests* rather than *interest* is more accurate, since the notion of conflict requires at least two different interests which are incompatible with each other and thus conflict.³⁰⁷

The definition provided by EFSA should expressly cover potential conflicts.

Moreover, to improve clarity, it should provide precise definitions and examples to describe each of its elements (e.g., actual, potential and perceived interests).

Finally, especially in light of the amendments made by the Transparency Regulation, foreseeing a greater collaboration with national scientific organisations, the definition of Col should expressly include national interests and political pressure.

2. *'Experts' and 'external experts'*

'Experts' are defined by EFSA's DCIM as meaning 'members of EFSA's Scientific Committee, Scientific Panels, working groups, candidates who apply for membership of the Scientific Committee and Scientific panels, participants in peer review meetings, also when appointed by, or representing, Member States authorities. This definition excludes hearing experts and observers.'³⁰⁸

We note that there is unclarity as regards the definitions of 'experts' and 'external experts' in rules and practice. For example, some of the 'experts' defined above are considered in legislative provisions and EFSA's website as 'external experts'. We would like to make a few observations. First, Article 28(5d) GFL distinguishes members of the Scientific Committee and the scientific panels from the external experts participating in the working groups of the Committee and the panels. Such a distinction was clearly reflected in Article 11 of the 2014

³⁰³ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 10.

³⁰⁴ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, PRO-0067.07, pp. 17–18.

³⁰⁵ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts*, EMA/136875/2022, pp. 6–9.

³⁰⁶ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [2017] OJ L 117.

³⁰⁷ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 7.

³⁰⁸ Article 2(1)(f) DCIM.

Decision on the selection of experts, which provided, *inter alia*, that ‘External experts are subject to EFSA’s Independence policy and rules’.³⁰⁹ Second, the 2022 Rules on selection, appointment and operations do not contain a specific provision for external experts.³¹⁰ Third, while ‘external experts’ are not mentioned in EFSA’s 2017 Policy on Independence and 2018 DCIM, the members of the Scientific Committee and the scientific panels are listed in EFSA’s website under the heading ‘External experts’.³¹¹ Herewith EFSA seems to indicate a distinction between staff experts and experts external to the organisation, whilst surely the Scientific committee and panels and their members, make part of EFSA.

Looking at ECHA’s independence policy we observe that it considers as ‘external experts’ the scientific expert members of ECHA’s bodies. In ECHA, the term ‘external experts’ is used to indicate actors involved in ECHA’s scientific activity who are not staff members. Similar to EFSA, ECHA’s excludes networks and discussion fora from the scope of its independence policy.³¹²

EMA’s independence policy refers instead to the notion of ‘European experts’ to indicate members of the Agency’s scientific committees, working parties and other groups.³¹³ European experts, who can be nominated by Member States or by the Agency itself and are made available by the national competent authorities of the European Economic Area,³¹⁴ can only participate in EMA’s activities once EMA has assessed their DoIs.³¹⁵ Instead, staff and experts at national level participating in the evaluation, supervision and maintenance of medicinal products, the consultation on medical devices or the crisis preparedness and management for medicinal products and medical devices, for services provided to the Agency are not subject to EMA’s independence policy but fall within the scope of the MoU concluded between EMA and the national competent authorities.³¹⁶

More clarity of the definitions of the various kinds of ‘experts’ is needed in view of the applicability of different Col rules.

Recommendations:

To avoid confusion in relation to the application of the rules on the prevention and management of conflicts of interests to the various kinds of experts EFSA resorts to, EFSA should adopt a precise definition of ‘expert’ and ‘external expert’ and ensure the consistency of its internal documents and website.

³⁰⁹ EFSA, 31 March 2014, *Decision of the Executive Director concerning the selection of members of the Scientific Committee the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work*, REF. EFSA/SCISTRAT/DEC/01/2014.

³¹⁰ Although the preamble makes a distinction between the members of the scientific committee and panels and external experts. See EFSA, 6 October 2022, *Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups*, p. 5, recital 3.

³¹¹ See <https://www.efsa.europa.eu/en/science/scientific-committee-and-panels>.

³¹² ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, pp. 1–2.

³¹³ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees’ members and experts*, p. 14.

³¹⁴ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees’ members and experts*, pp. 14–15.

³¹⁵ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees’ members and experts*, pp. 2–3.

³¹⁶ EMA, 2010, *Memorandum of Understanding between the European Medicines Agency and the National Competent Authorities of the Member States on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authorities for services to be provided to the Agency*, EMA/150487/2010; EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees’ members and experts*, p. 3.

B. Scope of EFSA's independence policy

1. Temporal and material scope of EFSA's independence policy

EFSA's 2017 Policy on Independence and 2018 DCIM take into account current interests and interests that existed during the five years preceding the DoI. With regard to the material scope, Cols are screened against the specific mandate of each panel or working group and not against the overall remit of the Authority (as instead recommended by the EP).

Like EFSA, the temporal scope of ECHA's independence policy includes current interests and interests having existed within the preceding five years.³¹⁷ Concerning the material scope, interests not relevant to the work of the respective ECHA body are considered as 'cleared'.³¹⁸

The temporal scope of EMA's independence policy is instead narrower, as it covers current interests and interests having existed within the preceding three years.³¹⁹ When assessing declared interests, EMA considers the specific Agency's activity in which the experts will be involved.³²⁰

The five years temporal scope of EFSA's independence policy is in line with the Commission's 2021 Guidance on the avoidance and management of conflicts of interest under the Financial Regulation.³²¹

With regard to the material scope of the screening, on the one hand, assessing Cols against the overall remit of the Authority would strengthen EFSA's independence. Moreover, it would allow to fully centralise Col screening at the level of the LA Unit, as there would be no need for specific expertise to assess every DoI against the specific mandate of a certain working group or panel. This would save resources and allow for more streamlined procedures. On the other hand, the current rules are already not sustainable in the long-term in that there is a concrete risk of excessively reducing the availability of scientific expertise.³²² This would run counter to the principle of scientific excellence enshrined in the GFL.

Recommendations:

A potential solution could be to adopt a more nuanced approach, providing for 'intermediate' solutions that allow for regimes of reduced participation (e.g., participation as hearing experts or exclusion from chairship, vice-chairship, rapporteur, etc.) in presence of 'minor' Cols. This would require EFSA to adopt a clear and reasoned definition of what constitutes a 'minor' Col.

2. Personal scope of EFSA's independence policy: Advisory Forum members, Network Members and Hearing Experts

EFSA's Col rules do not apply to members of the Advisory Forum who shall submit ADols but these ADols are not screened by EFSA. In this EFSA relies on the Advisory Forum's own

³¹⁷ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, p. 5.

³¹⁸ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, p. 12.

³¹⁹ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts*, p. 12.

³²⁰ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts*, p. 12.

³²¹ European Commission, 2021, *Guidance on the avoidance and management of conflicts of interest under the Financial Regulation*, para. 6.3.

³²² Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, pp. 10–11. See also Gabbi, S., Wood, M., Strauss, B., 2020, *Controlling the European Food Safety Authority*, in Scholten, M., Brenninkmeijer, A.F.M. (eds.), *Controlling EU agencies: the rule of law in a multi-jurisdictional legal order*, Edward Elgar, p. 201; Jannarelli, A., 2019, *Trasparenza e sostenibilità nel sistema europeo della Food Law dopo il reg. 1381 del 2019*, *Rivista di Diritto Alimentare*, Vol. 13 No. 3, p. 28.

Declaration of Intent and relevant national rules. Network members also need to submit an ADol but these ADols are not screened, assessed or validated. Instead their independence is governed by MoUs between EFSA and the relevant Article 36 organisations. We note however that should these MoU exist they are not placed on EFSA's website.

Independence of the experts who represent the views of Member States or international organisations in EFSA's network or network meetings is to be ensured by each appointing authority in accordance with the relevant national rules.

Due to the amendment of the GFL brought by the Transparency Regulation emphasising the possibility for EFSA to ask the national organisation referred to in Article 36 GFL to participate in the preparation of EFSA's scientific opinions, clarification of the Col regime to experts of these organisations becomes even of more importance as this may increase problems with independence from national pressure and Member States' political agendas.³²³

Finally, hearing experts are required to submit ADols but these ADols are not subject to screening.

Recommendations:

EFSA should more clearly define the rules applicable to the experts of organisations listed in Article 36 GFL who participate in the preparation of EFSA's opinions. This would help ensuring the actual and perceived consistency of EFSA's independence policy

It also should more clearly define and publicise the rules and standards applicable to members of scientific networks.

Furthermore, EFSA should screen the Dols of hearing experts.

3. *Cooling-off periods for research funding*

EFSA applies a cooling-off period of two years in cases where private research funding exceeds 25% of the expert's total research budget.

The cooling-off period envisaged in ECHA's policy for research funding is different from the one applied by EFSA. First, ECHA's policy does not provide for the incompatibility between research funding and membership of scientific groups. Instead, ECHA's policy prevents staff and members of ECHA's bodies who receive research funding above 25% of the total research budget from a specific commercial entity from participating in any decision-making procedure which directly concerns that commercial entity. Second, the cooling-off period envisaged in ECHA's policy is five years.³²⁴

Conversely, no specific provision on research funding is envisaged in EMA's policy. A 'grant or other funding to the expert's organisation/institution'³²⁵ is considered over when such interest is no longer present, resulting in full involvement in the Agency's activities.³²⁶ In other words, no cooling-off period is provided for in the case of research funding.

³²³ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 7.

³²⁴ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, p. 10.

³²⁵ Defined as 'any funding received from a pharmaceutical company, a medical device company or the biotechnology sector by the organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work'.

³²⁶ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts*, pp. 10–11.

Recommendations:

The rationale behind the different approaches adopted by the three agencies is not clear. Further explanation and harmonisation would be desirable, especially considering that EFSA has opted for the shortest cooling-off period among the agencies which adopt cooling-off periods.³²⁷

4. *Declaration of financial relation university employers and their industry partners by academic experts*

EFSA's policy does not currently envisage a requirement for academic experts to declare the details of the financial relationships between their university employers and their university employers' industry partners.

ECHA's rules do not include such a requirement. However, they expressly forbid members of the Member State Committee, the Committee for Risk Assessment, the Committee for Socio-Economic Analysis and the Enforcement Forum who are also employees of universities from providing consultancy services to the chemical industry or downstream users associations, chemical companies, or other potential registrants or authorisation applicants, or other bodies which can be considered as an interest group in the context of the field dealt with by the respective committee.³²⁸

EMA requires experts to declare any grant or other funding received by the organisation or institution to which the expert belongs, but only if such funding is used to support an activity of the expert. Moreover, under EMA's independence policy, any unit, department, section or entity within universities, that manufactures medicinal products or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company. Furthermore, following the judgment of the General Court in the *Aplidin* case,³²⁹ EMA does not allow 'experts that are employed by universities or university hospitals performing development or manufacturing activities in respect of any medicinal products actually or potentially competing with the (candidate) product under review'³³⁰ to be involved in the procedure.

Recommendations:

EFSA should consider strengthening its policy and introduce specific rules for the declaration of financial relationships between their university employers and their university by academic experts. The policies adopted by ECHA and EMA can be of example.

C. Management of conflicts of interests

1. *Degree of centralisation and automaticity*

EFSA's Col management is semi-centralised. The screening of Dols occurs at the level of each working group or panel and then is validated by the LA Unit. The DCIM ensures some degree of automaticity ('blacklists') and discretion (Management Board members).

³²⁷ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 129.

³²⁸ Article 9(5) of ECHA, 26 June 2020, *Rules of Procedure for the Forum for Exchange of Information on Enforcement*, MB/34/2020 final; Article 9(6) of ECHA, October 2021, *Rules of Procedure for the Committee for Risk Assessment*, MB/10/2021 final; Article 9(6) of ECHA, November 2021, *Rules of Procedure for the Committee for Socio-Economic Analysis*, MB/10/2021 final; Article 9(4) of ECHA, September 2021, *Rules of Procedure for the Member State Committee*, MB/10/2021 final.

³²⁹ Case T-594/18 *Pharma Mar, SA v European Commission* [2020] ECLI:EU:T:2020:512.

³³⁰ EMA, 18 March 2022, 2021 - *European Medicines Agency Annual Report on Independence*, EMA/759921/2021, p. 6.

When compared with EFSA, ECHA adopts a different approach. It entrusts the chairperson of each of its own bodies with the screening of Dols. These persons are assisted by ECHA's secretariat.³³¹ ECHA adopts a 'semi-automatic'³³² system, where (non-)allowable interests are described in detail (and ordered in a 'interest levels' scale, ranging from A to C) but a certain degree of discretion is left to the chairperson of each ECHA body.³³³ In particular, for interests of risk-level B, the chairperson shall decide on the appropriate level of participation of the concerned person. The chairperson can decide among the several intermediate regimes of participation proposed in the policy but can also adopt further measures. In any case, the concerned person cannot participate in any voting nor transfer his/her voting right by proxy.³³⁴

EMA has the highest degree of automaticity, considering both scientific experts³³⁵ and members of the Management Board.³³⁶ For this reason, Col screening mainly occurs at the level of the scientific bodies concerned.³³⁷ Like ECHA, EMA's Col policy envisages various 'interest levels' (ranging from 1 to 3).

Recommendations:

On the one hand, a high degree of automaticity, as the one envisaged in EMA's policy, ensures greater objectivity in the implementation of Col policies. Moreover, it may allow for more streamlined and centralised procedures and more efficient allocation of administrative and financial resources. On the other hand, as such automaticity may appear to be rigid and in particular hindering the availability of experts, EFSA may combine it with a wider range of 'intermediate' forms of participation. This may benefit the availability of scientific expertise and the long-term sustainability of the independence policy.

2. *Waivers for experts with a Col*

Article 21 of EFSA's DCIM provides for the granting of waivers for an expert to allow his/her participation in EFSA's working groups and peer review meetings when the contribution of this expert is 'essential' for the completeness of the draft output but a conflicting interest other than a current industry employment or current financial investment in an entity impacted by EFSA's outputs has been identified. Under these conditions a waiver can be granted to the expert if the secretariat of the relevant working group could not find a suitable alternative expert and the expert's contribution could not be handled through his or her participation as hearing expert.

Recommendations:

The criteria for the granting of waivers for experts to participate in working groups and peer review meetings should be further clarified. The precise meaning of 'essential for the completeness of the draft output' is not sufficiently defined. The DCIM should moreover include an obligation to inform the other experts belonging to the working group of the waived expert when a waiver is granted. Although waivers are recorded in the minutes of the

³³¹ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, p. 12.

³³² Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 61.

³³³ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, pp. 13–14.

³³⁴ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, p. 13.

³³⁵ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts*.

³³⁶ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of Management Board members*, EMA/MB/89374/2020 Rev 1.

³³⁷ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, pp. 58–59.

meetings and in the ensuing scientific output,³³⁸ decisions granting a waiver should also be published.

3. *IT tool*

EFSA requires its actors, except for tenderers and participants in grant-awarding procedures, to submit their Dols through the dedicated IT tool.

The IT tool is recognised as one of the most appreciated features of EFSA's independence policy.³³⁹ However, the introduction of a new IT solution in 2021 has not been without problems. This revealed that EFSA did not have any alternative and equally efficient solution in place to carry out the screening of Dols.

Unlike EFSA, ECHA policy requires individuals to make written declaration of interest.³⁴⁰ Instead, EMA makes use of e-Dols and is considering replacing its current experts' database with an IT solution for handling experts, including the submission, evaluation and management of Dols.³⁴¹

Recommendations:

EFSA should extend the use of the IT tool to tenderers and participants in grant-awarding procedures. More importantly, EFSA should ensure that its independence-related activities are not undermined by possible shortcomings of the IT tool.

4. *Impact of the Transparency Regulation on the management of Cols of the Management Board members*

EFSA's Management Board is responsible for the management of its own Cols. To that end, the Management Board enjoys discretion in reaching its conclusion after the assessment of Cols carried out by the Executive Director.³⁴²

Differently from EFSA, ECHA's policy provides for the application of the same interest levels scale (ranging from A to C) for the Management Board, the Committees and the Forum.³⁴³ The Chair of the Management Board shall inform the Executive Director of any Col of the members of the Management Board and decide on remedial actions. In case such actions do not end the conflict of interests, the Chair of the Management Board shall send a formal notification to the appointing authority (either the Council, the Commission or the European Parliament). The appointing authority may then take a formal decision and apply sanctions (ranging from a reprimand letter to the revocation).³⁴⁴

Notably, EMA has adopted a specific Policy on the handling of competing interests of Management Board members.³⁴⁵ This Policy entrusts EMA's secretariat with the assessment of the Dols and reduces the discretion in the decision by providing for a high degree of automaticity. EMA has also adopted a specific breach of trust procedure for members of the

³³⁸ Article 21(5) DCIM.

³³⁹ Economisti Associati, 22 April 2021, *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management - Executive Summary Report*, p. 6.

³⁴⁰ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, p. 3.

³⁴¹ EMA, 18 March 2022, *2021 - European Medicines Agency Annual Report on Independence*, p. 6.

³⁴² Article 13(3) RoP.

³⁴³ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, pp. 12–14.

³⁴⁴ ECHA, 22 March 2022, *Prevention and Management of potential Conflicts of Interest*, p. 14.

³⁴⁵ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of Management Board members*.

Management Board.³⁴⁶ Like for EFSA, the final decision on potential breaches is taken by the Management Board itself.³⁴⁷ However, like ECHA's policy, this procedure envisages the involvement of the nominating authority, which may be consulted and shall be notified of any decision taken.³⁴⁸

Recommendations:

Compared to ECHA and EMA, EFSA recognises a wider margin of discretion to its Management Board in the management of its own Cols. In light of the new structure of the Management Board, which envisages more members and representatives of Member States and stakeholders, the reduction of such discretion may be desirable. EFSA should adopt a specific policy for its Management Board and increase the degree of automaticity of decisions. Moreover, following the example of ECHA, EFSA should ensure the involvement of the appointing authority – the Council³⁴⁹ – in the decisions concerning Cols of stakeholders' representatives.

D. Transparency on independence-related matters

1. *Publication of CVs*

The 2017 Policy on Independence and the 2018 DCIM are silent on the publication of CVs. Nevertheless, EFSA requires that any person assuming a function within the agency fills out and submits a pre-defined CV.³⁵⁰ These pre-defined CVs are not published on EFSA's website. EFSA publishes instead on its website a short biography of the Chair and Vice-Chair of the Management Board, the Executive Director, the Chief Scientist and the Heads of the Communication and Partnerships, Management Services, Risk Assessment Production and Risk Assessment Services departments.³⁵¹

Similarly to EFSA, ECHA's policy is silent on the publication of CVs. However, ECHA publishes on its website the CVs of the members of the Management Board, the Member State Committee, the Committee for Risk Assessment, the Committee for Socio-Economic Analysis, the Biocidal Products Committee Working Groups, the Enforcement Forum and the Board of Appeal.

EMA's policy provides for the publication on EMA's website of the CVs of the members of the scientific committees and the Agency's other bodies,³⁵² including the Management Board.³⁵³

Recommendations:

EFSA should publish the pre-defined CVs of its key actors, such as the Executive Director, the members of the Management Board and scientific experts, as recommended by the

³⁴⁶ EMA, 15 December 2022, *European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by Management Board members*, EMA/MB/309079/2012, Rev. 3.

³⁴⁷ EMA, 15 December 2022, *European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by Management Board members*, p. 3.

³⁴⁸ EMA, 15 December 2022, *European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by Management Board members*, p. 3.

³⁴⁹ Pursuant to Article 25(1a)(c) GFL, members of the Management Board representing stakeholders are appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission.

³⁵⁰ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 38.

³⁵¹ We note that through EFSA's website it is currently possible to request access to the CVs (and Dols) exclusively of *previous* panel members.

³⁵² EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts*, pp. 14–15.

³⁵³ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of Management Board members*, p. 9.

Commission³⁵⁴ and in line with the practice of ECHA and the rules of EMA. This would facilitate control by citizens or NGOs³⁵⁵ and is even more important when considering the new structure of the Management Board introduced by the Transparency Regulation.

2. *Rules concerning the publicity of meetings between the members of the Management Board and senior staff with interest representatives*

EFSA has no specific rules in place concerning the publicity of meetings between the members of the Management Board and senior staff with interest representatives. For ECHA we may observe that it requires its Executive Director and senior management to publicly register meetings with interest representatives.³⁵⁶ Similarly, EMA allows the Executive Director and its staff to meet only with interest representatives registered in the Transparency Register.³⁵⁷

Recommendations:

EFSA should consider adopting specific rules concerning the publicity of meetings of the members of the Management Board, the Executive Director and senior staff with interest representatives.

3. *Criteria to prohibit senior staff from taking up specific positions after their term-office*

EFSA has not published a set of specific criteria to prohibit senior staff from taking up specific positions after their term-office. In this regard, ECHA provides specific rules and criteria.³⁵⁸ Finally, the guidance provided by EMA does not include specific criteria.³⁵⁹

Recommendations:

EFSA should comply with the indication of the European Parliament and align its rules with the Ombudsman's recommendation in that respect. Therefore, EFSA should set out of the criteria for the adoption of a measure prohibiting senior staff from taking up positions after their term-office, preventively communicate these criteria to applicants for senior positions and adopt internal procedures to restrict access to confidential information once a staff member moves to another job.

4. *Criteria behind Covid-19 reprioritisation*

In 2020, the impact of Covid-19 required the reprioritisation of EFSA activities that also affected independence-related activities. The specific criteria governing such a reprioritisation were not made public. Conversely, no reprioritisation was undertaken by ECHA³⁶⁰ and EMA.³⁶¹

Recommendations:

More transparency about the reprioritisation criteria would have been desirable in order to communicate to the public how independence-related concerns were dealt with throughout the pandemic. In case of future pandemics or crises, transparency on re-prioritisation is needed.

³⁵⁴ European Commission, 10 December 2013, *Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies*, pp. 7 and 9.

³⁵⁵ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 38.

³⁵⁶ See <https://echa.europa.eu/directors-meetings/2022>.

³⁵⁷ See <https://ec.europa.eu/transparencyregister/public/homePage.do>; Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 46.

³⁵⁸ ECHA, 26 October 2018, *Post-employment guidance*, ED/72/2018.

³⁵⁹ EMA, 12 May 2022, *Guidance for usage of application form related to Article 16 of the Staff Regulations*, EMA/350617/2013, Rev. 1.

³⁶⁰ ECHA, April 2021, *Annual Report 2020*, pp. 44–46.

³⁶¹ EMA, 12 March 2021, *2020 - European Medicines Agency Annual Report on Independence*, EMA/34780/2021.

3. EFSA'S TRANSPARENCY

3.1. Framing the Notion of 'Transparency' within EU Law

Transparency is a well-recognised principle and value under EU law. Article 1 TEU clearly defines the EU as a union in which 'decisions are taken as openly as possible'.³⁶² Openness, and its corollary principle of transparency, are essential elements of the EU's constitutional commitments to democratic principles of representative and participatory democracy.³⁶³ As held by the Court in *Turco*, transparency 'enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system'.³⁶⁴ Transparency is thus considered a catalyst for public participation and democratic accountability of public authorities. In the Treaties, EU institutions are required to maintain 'an open, transparent and regular dialogue with representative associations and civil society',³⁶⁵ and to conduct their work as openly as possible in order to promote good governance in the EU and ensure the participation of civil society in decision-making.³⁶⁶ Such a fundamental commitment to transparency applies to legislative activities³⁶⁷ as well as to administrative activities.³⁶⁸ Article 15 TFEU specifically establishes 'a right of access to documents of the Union's institutions, bodies, offices and agencies, whatever their medium' – a right later enshrined also in Article 42 of the EU Charter of Fundamental Rights. Article 15(1) TFEU furthermore establishes a legal basis for the European Parliament and the Council to adopt legislative acts on the principles and the conditions for the exercise of the right of access to documents, which can be further elaborated by each institution, body, office or agency in its own Rules of Procedure.

Despite these clear constitutional commitments to transparency, the Treaties do not provide a definition of the term. In general terms, transparency is associated with the 'ability to see through', as opposed to opaqueness and secrecy, thus ensuring the visibility of an object to the observer.³⁶⁹ In public decision-making, it entails the disclosure or public release of information allowing the public access to documents and data retained by the institutions and agencies.³⁷⁰ This meaning of transparency as *visibility* has been embraced by EU institutions and by the case law of the Court since the Treaty of Maastricht,³⁷¹ through the introduction and enforcement of provisions on the holding of

³⁶² This commitment is repeated in Article 10(3) TEU. On transparency as an element of the principle of openness, see Alemanno, A., 2014, *Unpacking the Principle of Openness in EU Law: Transparency, Participation and Democracy*, European Law Review, Vol. 39 No. 1, p. 72.

³⁶³ See Lenaerts, K., 2004, 'In the Union we trust': *Trust-enhancing principles of Community law*, Common Market Law Review, Vol. 41 No. 2, pp. 317–343; Vos, E., 2009, *The EU regulatory system on food safety: between trust and safety*, in Vos, E., Everson, M. (eds.), *Uncertain Risks Regulated*, Routledge-Cavendish, pp. 249–267. On the relation between the principles of openness and transparency, see also Alemanno, A., 2014, *Unpacking the Principle of Openness in EU Law: Transparency, Participation and Democracy*, European Law Review, Vol. 39 No. 1, p. 73.

³⁶⁴ Joined Cases C-39/05 P and C-52/05 P *Sweden v Turco* [2008] ECLI:EU:C:2008:374, para 45.

³⁶⁵ Article 11 TEU.

³⁶⁶ Article 15(1) TFEU.

³⁶⁷ Article 15(1) TFEU, last sentence.

³⁶⁸ See Article 298(1) TFEU: 'the institutions, bodies, offices and agencies of the Union shall have the support of an *open*, efficient and independent European administration'.

³⁶⁹ Busuioc, M., Curtin, D., Almada, M., 2022, *Reclaiming transparency: contesting the logics of secrecy within the AI Act*, European Law Open, pp. 1–27, p. 3; Hood, C., 2010, *Accountability and Transparency: Siamese Twins, Matching Parts, Awkward Couple?*, West European Politics, Vol. 33 No. 5, pp. 989–1009. See also Alemanno, A., 2014, *Unpacking the Principle of Openness in EU Law: Transparency, Participation and Democracy*, European Law Review, Vol. 39 No. 1, p. 73.

³⁷⁰ Busuioc, M., Curtin, D., Almada, M., 2022, *Reclaiming transparency: contesting the logics of secrecy within the AI Act*, European Law Open, p. 5.

³⁷¹ See Treaty on European Union — Declaration No 17 on the right of access to information, 1992. On the pre-Lisbon understanding of transparency, see, *inter alia*, Peers, S., 2002, *From Maastricht to Laeken: the political agenda of openness and transparency in the European Union*, in Deckmyn, V. (ed.), *Increasing transparency in the European Union?*, Institut européen d'administration publique, p. 7; Tomkins, A., 1999, *Transparency and the Emergence of a European Administrative Law*, Yearbook of European Law, Vol. 19 No. 1, pp. 217–256..

meetings in public, the provision of information, and the right of access to documents.³⁷² In technically or scientifically complex contexts, however, another dimension of transparency is increasingly being emphasised: the *intelligibility* or comprehensibility of information provided to the public.³⁷³ In this sense, it is important not only to disclose certain information but also to explain it and to put the public in the condition to understand its meaning.³⁷⁴ This dimension, hence, invites to pay attention to the quality of information and requires an explanatory action by the institutions or agencies.³⁷⁵ Specifically for regulatory science, transparency of scientific data underpinning public decisions enables the reproducibility of studies, thus helping to ensure the epistemic quality of these data and, ultimately, expert accountability through public scrutiny.³⁷⁶ The notion of transparency, thus, today encompasses a vast array of features, such as provision of information, access or publication of documents and data, knowledge of decisional processes, as well as clarity, understandability, and giving of reasons for decision-making.³⁷⁷

The principle of transparency under EU law has been recognised to have also evolved from a passive or reactive approach, to an active or proactive one.³⁷⁸ Under a *passive* or reactive approach, EU institutions and agencies are required to give access to information related to decision-making after a request by interested actors. Regulation 1049/2001 regarding public access to documents (hereinafter, the ‘Access Regulation’) is the main instrument for this, establishing the principle of ‘widest possible access to documents’³⁷⁹ and regulating the procedure through which any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, can have access to documents of the institutions.³⁸⁰ This passive approach, which puts the burden of reclaiming transparency on the initiative (and resources) of citizens, has been increasingly questioned by scholars³⁸¹ and by the European Ombudsman.³⁸² A more *active* approach, which entails the systematic publication of documents by EU institutions and no longer depends on access requests, is considered to be more in line with the ‘modern standards of a democratic society’.³⁸³ The creation of publicly

³⁷² Craig, P.P., 2018, *EU Administrative Law*, Third edition, Oxford University Press, p. 389.

³⁷³ See de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, *European Journal of Risk Regulation*, pp. 1–19, p. 6; Hofmann, H., Leino-Sandberg, P., 23 October 2019, *An agenda for transparency in the EU*, *European Law Blog*, available at <https://europeanlawblog.eu/2019/10/23/an-agenda-for-transparency-in-the-eu/>.

³⁷⁴ See Case T-329/17 *Hautala v EFSA* [2019] ECLI:EU:T:2019:142, para 97. See also European Ombudsman, 9 February 2021, *Ombudsman calls on ECDC to be more open about its work as vaccine rollout begins*.

³⁷⁵ On the risks of this shift from transparency as ‘visibility’ to transparency as ‘explanation’ (especially in AI regulation), see Busuioc, M., Curtin, D., Almada, M., 2022, *Reclaiming transparency: contesting the logics of secrecy within the AI Act*, *European Law Open*.

³⁷⁶ Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, *Common Market Law Review*, Vol. 59 No. 3, p. 674; Smith, A., Parrino, L., Vrbos, D., Nicolini, G., Bucchi, M., Carr, M., Chen, J., Dendler, L., Krishnaswamy, K., Lecchini, D., Löfstedt, R., Patel, M., Reisch, L., Verloo, D., Vos, E., Zollo, F., Gallani, B., 2019, *Communicating to and engaging with the public in regulatory science*, *EFSA Journal*, Vol. 17 No. S1.

³⁷⁷ Alemanno, A., 2014, *Unpacking the Principle of Openness in EU Law: Transparency, Participation and Democracy*, *European Law Review*, Vol. 39 No. 1, p. 82.

³⁷⁸ For an analysis of this evolution, see Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, *Common Market Law Review*, Vol. 59 No. 3.

³⁷⁹ Article 1 of 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, p. 43–48.

³⁸⁰ Article 6 of the Access Regulation.

³⁸¹ Alemanno, A., 2014, *Unpacking the Principle of Openness in EU Law: Transparency, Participation and Democracy*, *European Law Review*, Vol. 39 No. 1; Curtin, D., Leino-Sandberg, P., 2016, *Openness, Transparency and the Right of Access to Documents in the EU*, publication for the Committee on Petitions, Policy Department C: Citizens’ Rights and Constitutional Affairs, European Parliament, Luxembourg, available at [https://www.europarl.europa.eu/RegData/etudes/IDAN/2016/556973/IPOL_IDA\(2016\)556973_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/IDAN/2016/556973/IPOL_IDA(2016)556973_EN.pdf); Hofmann, H., Leino-Sandberg, P., 23 October 2019, *An agenda for transparency in the EU*, *European Law Blog*; Leino-Sandberg, P., 2014, *Transparency, participation and EU institutional practice: an inquiry into the limits of the ‘widest possible’*, *EUI Working Paper*, *EUI Law*, 2014/03; Mendes, J., 2020, *The Principle of Transparency and Access to Documents in the EU: for what, for whom, and of what?*, *University of Luxembourg Working Paper*, 2020–004, *University of Luxembourg*; Prechal, S., de Leeuw, M., 2007, *Dimensions of Transparency: The Building Blocks for a New Legal Principle?*, *Review of European Administrative Law*, Vol. 1 No. 1, pp. 51–62.

³⁸² European Ombudsman, 15 November 2021, *Ombudsman calls for EU access to documents law to be modernised*.

³⁸³ Especially if the publication is online. See Hofmann, H., Leino-Sandberg, P., 23 October 2019, *An agenda for transparency in the EU*, *European Law Blog*.

accessible online databases, such as the Transparency Register³⁸⁴ or the Register of Commission Documents,³⁸⁵ is an example of this new approach. More importantly, this approach requiring proactive publication of information by EU institutions and agencies is the logic that inspired the reform of the General Food Law and the new rules on the transparency of EFSA.³⁸⁶

3.2. Transparency of EU agencies

Since the Treaty of Lisbon, EU agencies are expressly mentioned in the Treaty provisions concerning transparency, openness and participation.³⁸⁷ The confirmation that agencies too are subjected to these constitutional values is of high importance. In addition, the 2012 Common Approach on EU agencies sets forth that all EU agencies should ensure transparency.³⁸⁸ This is to be achieved by maintaining multilingual websites to provide information, including on financial matters.³⁸⁹ The Commission has complemented this general requirement with a Communication Handbook for agencies.³⁹⁰ Yet, these codifications did not solve the fragmentation of the legislative framework governing the transparency of EU agencies and the incoherencies that still exist in practice.³⁹¹

The transparency rules applicable to EU agencies' work currently result from the interaction between horizontal instruments, founding regulations, sectoral legislation, and agency-specific practices.³⁹² The main EU horizontal instruments are the above-mentioned Access Regulation and the Aarhus Regulation, i.e. Regulation (EC) No 1367/2006 implementing the provisions of the Aarhus Convention *inter alia* on access to environmental information in the EU.³⁹³

With regard to the Access Regulation, its scope of application is expressly limited to the European Parliament, Council and Commission documents; it applies to EU agencies only by way of reference to it in each agency's founding regulation. This is the case for the vast majority of EU agencies.³⁹⁴ As mentioned, the Access Regulation establishes that 'any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the institutions'.³⁹⁵ This general right is, however, subject to a number of exceptions which apply, in particular, where the disclosure of a document would undermine the protection of:

³⁸⁴ European Commission, Transparency Register available at <https://ec.europa.eu/transparencyregister/public/homePage.do?locale=en#en>.

³⁸⁵ European Commission, Register of Commission Documents, available at <https://ec.europa.eu/transparency/documents-register/>.

³⁸⁶ Regulation (EU) 2019/1381. For an analysis, see Section 3.3.

³⁸⁷ Article 15(1) and (3) TFEU.

³⁸⁸ European Parliament, Council of the EU, European Commission, 19 July 2012, *Common Approach*, Annex to the Joint Statement on decentralised agencies, paras 64–65.

³⁸⁹ European Parliament, Council of the EU, European Commission, 19 July 2012, *Common Approach*, Annex to the Joint Statement on decentralised agencies, para. 64.

³⁹⁰ European Commission, 2013, *Communication Handbook for the EU Agencies*.

³⁹¹ de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, *European Journal of Risk Regulation*; Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, *Common Market Law Review*, Vol. 59 No. 3, p. 676. See also Chiti, E., 2013, *European Agencies' Rulemaking: Powers, Procedures and Assessment: European Agencies' Rulemaking*, *European Law Journal*, Vol. 19 No. 1, pp. 104–108.

³⁹² de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, *European Journal of Risk Regulation*, p. 7.

³⁹³ 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 [2006] OJ L 264, p. 13–19.

³⁹⁴ The founding regulations of 23 agencies refer to Regulation (EC) No 1049/2001 in their text, see Vos, E., 2018, *EU Agencies, Common Approach and Parliamentary Scrutiny*, Publication for the European Parliamentary Research Service, available at [https://www.europarl.europa.eu/RegData/etudes/STUD/2018/627131/EPRS_STU\(2018\)627131_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2018/627131/EPRS_STU(2018)627131_EN.pdf), Annex 9.

³⁹⁵ Article 2 of 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, p. 43–48.

- a) the public interest as regards public security, defence and military matters, international relations, financial, monetary or economic policy of the EU or a Member State;
- b) privacy and the integrity of the individual;³⁹⁶
- c) commercial interests of a natural or legal person, including intellectual property;
- d) court proceedings and legal advice;
- e) the purpose of inspections, investigations and audits;
- f) the institutions' decision-making process (the so-called 'space to think').³⁹⁷

The last four exceptions can be overcome where there is an overriding public interest in disclosure.³⁹⁸ Especially in relation to the protection of commercial interests, the Court of Justice has clarified that, in practice, EU institutions have to consider, firstly, whether the exception applies in substance, secondly to consider possible harm (which cannot be purely hypothetical) and, thirdly, assess whether a public interest in disclosure outweighs the harm of the protected interest.³⁹⁹ Moreover, it is established case law that these exceptions must be interpreted and applied narrowly.⁴⁰⁰ However, the Court has progressively developed a concept of general presumptions of confidentiality,⁴⁰¹ according to which EU institutions can withhold access to certain judicially recognised categories of acts without a case-by-case assessment of each document.⁴⁰² Also considering the recent judicial emphasis on the importance of openness in administrative activities, it is yet not clear whether such case law is applicable to administrative (especially authorisation) proceedings carried out by EU agencies.⁴⁰³ Moreover, the issue may be addressed by the legislator since the Access Regulation is currently undergoing a reform, although the process appears to be stalled.⁴⁰⁴

The Aarhus Regulation, conversely, applies directly to all 'institutions and bodies', thus expressly including EU agencies.⁴⁰⁵ However, its provisions concern only 'environmental information' held by EU institutions and bodies,⁴⁰⁶ constituting *lex specialis* vis-à-vis the Access Regulation. The Aarhus regulation establishes enhanced transparency guarantees for the public in this particular field. Not only is the right of access to information reaffirmed in more comprehensive terms,⁴⁰⁷ but EU institutions and bodies must also actively and systematically disseminate environmental information through electronic databases and registers.⁴⁰⁸ This information must be as up-to-date, accurate and comparable

³⁹⁶ Article 4(1) of Regulation (EC) No 1049/2001.

³⁹⁷ Article 4(2) of Regulation (EC) No 1049/2001.

³⁹⁸ Article 4(2) of Regulation (EC) No 1049/2001.

³⁹⁹ Joined Cases C-39/05 P and C-52/05 P *Sweden v Turco* [2008] ECLI:EU:C:2008:374, paras. 38-44. See also Leino-Sandberg, P., Korkea-aho, E., 2017, *Who owns the information held by EU agencies? Weed killers, commercially sensitive information and transparent and participatory governance*, Common Market Law Review, Vol. 54 No. 4, p. 1067.

⁴⁰⁰ *Inter alia*, Case C-280/11 P *Council v Access Info Europe* [2013] ECLI:EU:C:2013:671, para. 30.

⁴⁰¹ *In primis*, Joined Cases C-39/05 P and C-52/05 P *Sweden v Turco* [2008] ECLI:EU:C:2008:374, para. 50; Case C-139/07 P *TGI* [2010] ECLI:EU:C:2010:376.

⁴⁰² Such as acts relating to State aid, merger control, and cartels proceedings. See Adamski, D., 2012, *Approximating a workable compromise on access to official documents: The 2011 developments in the European courts*, Common Market Law Review, Vol. 49 No. 2, pp. 521-558; Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, Common Market Law Review, Vol. 59 No. 3; Rossi, L., Vinagre e Silva, P., 2017, *Public access to documents in the EU*, Hart Publishing, p. 152 ff.

⁴⁰³ See Case T-716/14 *Tweeddale v EFSA* [2019] ECLI:EU:T:2019:141, para 54; Case T-329/17, *Hautala v EFSA*, ECLI:EU:T:2019:142, para. 60. *Contra* Case T-729/15 *MSD v EMA* [2020] ECLI:EU:C:2020:24, paras 26-27 and 32. For an analysis, see Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, Common Market Law Review, Vol. 59 No. 3, pp. 684-689; Morvillo, M., 2019, *The General Court Orders Disclosure of Glyphosate-related Scientific Studies: Tweeddale, Hautala, and the Concept of Environmental Information in the Context of Plant Protection Products*, European Journal of Risk Regulation, Vol. 10 No. 2, pp. 419-427.

⁴⁰⁴ See European Commission, 21 March 2011, *Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents*, COM/2011/0137 final; European Parliament, 12 June 2013, *Resolution of 12 June 2013 on the deadlock on the revision of Regulation (EC) No 1049/2001*, 2013/2637(RSP).

⁴⁰⁵ Article 3 of Regulation (EC) No 1367/2006.

⁴⁰⁶ For the definition of environmental information, see Article 2(1)(d) of Regulation (EC) No 1367/2006.

⁴⁰⁷ Article 3 of Regulation (EC) No 1367/2006.

⁴⁰⁸ Article 4 of Regulation (EC) No 1367/2006.

as possible.⁴⁰⁹ Moreover, where the information requested relates to emissions into the environment, an overriding public interest in disclosure must be presumed to exist,⁴¹⁰ thus limiting the application of the exceptions to the right of access to documents. The CJEU has interpreted broadly the concept of 'emissions to the environment',⁴¹¹ and it did not hesitate to enforce vigorously these provisions in relation to the disclosure of studies and raw data held by EU agencies.⁴¹² When dealing with environmental information, therefore, all EU agencies are bound not only by the requirements of the Access Regulation, but also by the more far-reaching provisions of the Aarhus Regulation as interpreted by the case law.

The Access Regulation and the Aarhus Regulation concerning environmental information, thus, constitute the legislative framework for transparency for EU agencies, which is complemented by sectoral legislation and secondary measures. Several EU agencies' founding regulations, as well as legislative acts which govern specific procedures (such as the authorisation of pesticides or novel food) contain specific provisions on transparency for the relevant agency.⁴¹³ Each EU agency may adopt internal measures, guidelines and decisions implementing them in their work, thus drawing a multi-layered, composite picture which can vary significantly from agency to agency. This fragmentation of transparency rules across EU agencies, especially across agencies active in risk regulation, has been criticised in the academic debate.⁴¹⁴

3.3. EFSA's transparency policies

3.3.1. Implementation of the Transparency Regulation

Since 2003 EFSA has adopted a number of internal documents and policies to embed the principles of openness and transparency in all aspects of its work,⁴¹⁵ thereby progressively strengthening the implementation of these principles in its scientific and governance activities.⁴¹⁶ In 2015, following a public consultation on EFSA's discussion paper 'Transformation to an Open EFSA, the agency engaged in an ambitious plan to increase participation and transparency as a way of improving the overall quality of available information and data used for EFSA's outputs, and for complying with normative and societal expectations over its processes for developing regulatory science.⁴¹⁷ Still, EFSA's

⁴⁰⁹ Article 5 of Regulation (EC) No 1367/2006.

⁴¹⁰ Article 6 of Regulation (EC) No 1367/2006.

⁴¹¹ Case C-673/13 P *Greenpeace v Commission* [2016] ECLI:EU:C:2016:889, paras. 71-76; Case C-442/14 *Bayer CropScience* [2016] ECLI:EU:C:2016:890, para. 96; Case C-616/17 *Blaise* [2019] ECLI:EU:C:2019:800, para. 108.

⁴¹² Case T-716/14 *Tweeddale v EFSA* [2019] ECLI:EU:T:2019:141; Case T-329/17 *Hautala v EFSA* [2019] ECLI:EU:T:2019:142.

⁴¹³ For analysis of the specific transparency rules applicable to pesticides and novel food authorisations, see de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, *European Journal of Risk Regulation*.

⁴¹⁴ de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, *European Journal of Risk Regulation*; Chearnaigh, B.N., 2021, *Piecemeal Transparency: An Appraisal of Regulation (EU) No. 2019/1381 on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain*, *European Journal of Risk Regulation*, Vol. 12 No. 3; Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, *Common Market Law Review*, Vol. 59 No. 3, p. 701.

⁴¹⁵ EFSA, 16 September 2003, *Openness, Transparency and Confidentiality*; EFSA, 10 March 2005, *Decision of the Management Board of the European Food Safety Authority concerning implementing measures of transparency and confidentiality requirements*.

⁴¹⁶ EFSA, 16 September 2003, *Openness, Transparency and Confidentiality*; EFSA, 2010, *EFSA's approach on Public Consultations on scientific outputs*; EFSA, 2010, *EFSA's Communications Strategy: 2010 – 2013 perspective*; EFSA, 2011, *Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority*; EFSA, 2012, *Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interests*, EFSA/2012/05/LRA; EFSA, 2012, *Science Strategy 2012-2016*; EFSA, 16 December 2013, *Guidelines for Observers*.

⁴¹⁷ EFSA, 2014, *Discussion Paper - Transformation to an 'Open EFSA'*. See also EFSA, 27 March 2015, *Transformation to an Open EFSA: Preliminary Implementation Plan*.

transparency policies faced stark criticism by EU institutions⁴¹⁸ and civil society,⁴¹⁹ especially in connection to the re-approval of glyphosate in 2016. This, together with the findings of the fitness check of the General Food Law Regulation completed in January 2018,⁴²⁰ led to a significant reform with the enactment of the Transparency Regulation.

EFSA's current policies are based on the legislative framework on transparency established in the GFL Regulation⁴²¹ as amended by the Transparency Regulation as of 27 March 2021,⁴²² and in sectoral acts which govern specific administrative procedures where the agency is involved in decision-making. Eight of these sectoral acts were amended by the Transparency Regulation in line with the general objectives of the reform, namely Regulations No 1829/2003 (GMO), No 1831/2003 (feed additives), No 2065/2003 (smoke products), No 1935/2004 (food contact material), No 1331/2008 (food improvement agents), No 1107/2009 (plant protection), 2015/2283 (novel food) and Directive 2001/18/EC (GMO). Conversely, the transparency-related provisions in Regulation No 1924/2006 (health claims) and Regulation No 528/2012 (biocides) were not expressly amended, but they are affected by the reform through the application of the general provisions of the GFL.

The Transparency Regulation strengthened the existing rules on passive transparency and introduced new requirements of proactive publication of documents by EFSA, which have been widely praised in the literature.⁴²³ The Transparency Regulation requires EFSA to carry out its activities 'with a high level of transparency' in all phases of authorisation and approval processes (from the pre-submission phase to the renewal of authorisations) as well as in the work of the governance bodies.

EFSA has implemented the legislative amendment with the Decision of the Management Board of 27 March 2020⁴²⁴ as concerns the right of access to documents, and with the Decision of the Executive Director of 18 January 2021 as concerns the requirements of proactive transparency.⁴²⁵

3.3.2. Passive Transparency: Management Board's 2020 Decision

The Transparency Regulation has brought a significant improvement also of EFSA's rules on passive transparency by expressly referring to the Access Regulation and to the Aarhus Regulation in the new

⁴¹⁸ European Parliament, 18 April 2018, *Resolution of 18 April 2018 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2016*; European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*; European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*; European Parliament, 4 May 2022, *Resolution of 4 May 2022 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority (EFSA) for the financial year 2020*.

⁴¹⁹ European Citizens' Initiative, 2017, *Ban glyphosate and protect people and the environment from toxic pesticides*.

⁴²⁰ European Commission, 15 January 2018, Commission Staff Working Document - Fitness Check on the General Food Law (Regulation (EC) No 178/2002), SWD(2018) 38 final.

⁴²¹ Regulation (EC) No 178/2002 and Articles 6 and 7 of Regulation (EC) No 1367/2006.

⁴²² Regulation (EU) No 2019/1381.

⁴²³ de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, European Journal of Risk Regulation; Chernaigh, B.N., 2021, *Piecemeal Transparency: An Appraisal of Regulation (EU) No. 2019/1381 on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain*, European Journal of Risk Regulation, Vol. 12 No. 3; Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, Common Market Law Review, Vol. 59 No. 3.

⁴²⁴ EFSA, 27 March 2020, *Decision of the Management Board laying down practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006*, wp200327-a2 (Management Board's 2020 Decision).

⁴²⁵ EFSA, 18 January 2021, *Decision of the Executive Director of the European Food Safety Authority Laying down Practical Arrangements Concerning Transparency and Confidentiality*, ver. 2 - 18.01.2021 (Executive Director's 2021 Decision). See also EFSA, 2021, *Decision of the Executive Director of the European Food Safety Authority Laying down practical arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009*; EFSA, 2021, *Decision Laying Down the Practical Arrangements on Pre-Submission Phase and Public Consultation*. Internally, EFSA set up the Architecture Transformation Programme (ART) to prepare all relevant units of the agency for the requirements of the Transparency Regulation and drive the various changes related to processes, organisation, technology. The ART programme run from 2019 until 1st July 2022. See EFSA, Audio-recording of 91st Management Board Web meeting, available at <https://www.efsa.europa.eu/en/events/91st-management-board-web-meeting>.

Article 41 GFL. The Management Board has implemented the latter provision with its 2020 Decision which laid down the practical arrangements to handle requests in order to give the fullest possible effect to the right to access to documents held by EFSA.⁴²⁶

EFSA's policy covers all documents drawn up or received by EFSA and in its possession at the moment an application for access to documents is received by the agency.⁴²⁷ When the request concerns documents held by EFSA originating from a third party or from a Member State, EFSA is obliged to give a preliminary assessment of the applicability of the exceptions listed in Article 4 of the Access Regulation and to consult with the third party or the Member State about this.⁴²⁸ Member States can request EFSA not to disclose certain documents in line with their powers according to Article 4 of the Access Regulation. However, the Management Board's 2020 Decision provides that, following this consultation, EFSA can decide to provide access to documents against the explicit wish of the relevant third party or the Member State, notifying them of its decision.⁴²⁹

Application for access to documents must be submitted in writing in one of the EU official languages and in a sufficiently precise manner.⁴³⁰ Upon receipt of an application, EFSA has to acknowledge receipt⁴³¹ and verify the application of exceptions to access to documents in line with the Access Regulation. As mentioned, these exceptions include the protection of public interest, commercial interests, privacy and a 'space to think' for EU institutions in ongoing decision-making processes, which can be overridden by a proven public interest in disclosure.⁴³² The scope of application of the exception due to the protection of commercial interests is now further specified in Article 39(2) GFL.⁴³³ In line with the case law of the Court of Justice,⁴³⁴ these exceptions shall be interpreted and applied strictly. This is particularly stressed when the request concerns the access to environmental information for which Article 6 of the Aarhus Regulation establishes a legal presumption that (with the exception of commercial interests of a particular natural or legal person or inspections, investigations and audits) an overriding public interest in disclosure exists.⁴³⁵ This is considered to be in line with the described developments of the case law concerning environmental information.⁴³⁶ Moreover, when the exceptions considered are the commercial interests of a natural or legal person or the existence of a 'space to think' for the agency,⁴³⁷ EFSA shall balance the particular interest and the public interest at stake, ascertaining whether there is an overriding public interest for disclosure 'notwithstanding the fact that the interest in question would thereby undermined'.⁴³⁸

Following this assessment, documents are released in electronic form by EFSA. Article 4(7) of the Management Board's 2020 Decision allows EFSA to extend the deadline to reply by 15 working days in case of complex or voluminous applications. Neither the Management Board's 2020 Decision nor the

⁴²⁶ Article 1 of the Management Board's 2020 Decision. See also EFSA, 25 January 2021, *Standard Operating Procedure. Applications for Public Access to Documents (PAD)*.

⁴²⁷ Article 2 of the Management Board's 2020 Decision.

⁴²⁸ Article 7(2) and (3) of the Management Board's 2020 Decision.

⁴²⁹ Article 7(4) of the Management Board's 2020 Decision.

⁴³⁰ Article 4 of the Management Board's 2020 Decision. Clarifications can be asked by EFSA.

⁴³¹ This is done automatically by the IT tool enabling the automation of the public access to documents requests (PAD tool), see EFSA, 25 January 2021, *Standard Operating Procedure. Applications for Public Access to Documents (PAD)*, para. 1.1.

⁴³² Article 4 of Regulation (EC) No 1049/2001.

⁴³³ See Section 3.3.3(vii).

⁴³⁴ *Inter alia*, Case C-280/11 P *Council v Access Infor Europe* [2013] ECLI:EU:C:2013:671, para. 30.

⁴³⁵ Article 9 of the Management Board's 2020 Decision.

⁴³⁶ Case T-716/14 *Tweeddale v EFSA* [2019] ECLI:EU:T:2019:141; Case T-329/17 *Hautala v EFSA* [2019] ECLI:EU:T:2019:142. See de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, European Journal of Risk Regulation.

⁴³⁷ See Article 4(2) and (3) of Regulation (EC) No 1049/2001.

⁴³⁸ Article 8(3) of the Management Board's 2020 Decision.

Standard Operating Procedure document specifies the time limit for this extension of the deadline. With the agreement of the applicant, EFSA can also release the documents in batches, prioritize certain documents and further extend the time limits in light of resource-related constraints of EFSA.⁴³⁹

Responses to the requests shall be in writing and, unless differently agreed, in the same official language of the request. EFSA has to provide reasons for the refusal or partial refusal of the request.⁴⁴⁰ In case of refusal, partial refusal or silence on behalf of EFSA, the applicant can submit a confirmatory application which entails an independent review of the initial decision.⁴⁴¹ This confirmatory decision can be challenged through an action for annulment under Article 263 TFEU and be object of a complaint to the European Ombudsman.

For 2021, the first year of implementation of the Transparency Regulation, EFSA's Annual Report gives account of 232 documents disclosed in response to 46 applications carried forward from 2020 and 186 requests that were submitted in 2021.⁴⁴² This constitutes the highest number of requests for access to documents ever received by EFSA. The Annual Report does not explain to what extent the documents disclosed masked only personal data (for the protection of the privacy and integrity of individuals) or parts were not disclosed in application of other legislative exceptions, especially Article 4(2) of the Access Regulation.⁴⁴³ In 2021, EFSA received 3 confirmatory applications challenging partial disclosure, mainly based on the commercial interests' exception.⁴⁴⁴ Conversely, the 2022 Annual Report does not contain a dedicated section nor data on public access to documents requests.

3.3.3. Active Transparency: Executive Director's 2021 Decision

Article 38 GFL, as amended by the Transparency Regulation, contains a list of documents which have to be made public by EFSA in a proactive manner. The Executive Director's 2021 Decision has implemented this requirement by distinguishing between documents in relation to which confidentiality requests not to disclose certain elements are excluded⁴⁴⁵ and documents in relation to which such confidentiality requests can be submitted.⁴⁴⁶ For the latter, EFSA will carry out an assessment of the merits of the confidentiality request and take a decision. Accordingly, the documents will be published only once this decision is taken and following their 'sanitisation',⁴⁴⁷ meaning the removal of confidential information by masking or unmasking certain data or information.⁴⁴⁸ The Executive Director's 2021 Decision has also specified for each type of document when and where the publication must take place.⁴⁴⁹

i) Transparency of Documents of the Pre-Submission Advice

According to the new rules, EFSA is obliged to publish a summary of the questions received by applicants and advice provided to applicants in case they sought the Agency's pre-submission

⁴³⁹ Article 4(8) of the Management Board's 2020 Decision.

⁴⁴⁰ Article 5 of the Management Board's 2020 Decision.

⁴⁴¹ Article 6 of the Management Board's 2020 Decision.

⁴⁴² EFSA, 2022, *Annual Report on the implementation of EFSA's policy on independence 2021*, p. 71.

⁴⁴³ Namely, the protection of commercial interests (including intellectual property), court proceedings and legal advice, and the purpose of inspections, investigations and audits. See Article 4 of Regulation (EC) No 1049/2001.

⁴⁴⁴ Article 4 of Regulation (EC) No 1049/2001.

⁴⁴⁵ Article 5 of the Executive Director's 2021 Decision.

⁴⁴⁶ Article 6 of the Executive Director's 2021 Decision.

⁴⁴⁷ The procedural and substantive requirements for the submission of confidentiality requests, the decision on such requests, their review and withdrawal are regulated in detail in Chapter III of the Executive Director's 2021 Decision.

⁴⁴⁸ Article 3(1)(c) literally defines 'sanitisation' as 'the process of masking or unmasking scientific data, studies and other information in accordance with a confidentiality request or with a confidentiality decision, including the masking of personal data'.

⁴⁴⁹ Additional information on this can be found in EFSA, March 2021, *Questions and Answers on the EFSA Practical Arrangements*.

advice according to Article 32a GFL.⁴⁵⁰ The proactive disclosure of the pre-submission advice is done without delay after the related application has been considered valid or admissible and once a final decision on relevant confidentiality requests on the application becomes applicable.⁴⁵¹ On the summary itself, however, it is not possible to require sanitisation of information or data since it is considered not to contain any confidential information.⁴⁵² In order to allow prompt publication, when the procedure starts at the national level, the relevant national competent authorities shall inform EFSA without delay of any positive conclusion as regards the admissibility of that application.⁴⁵³ The disclosure of the summary of the pre-submission advice taking place only after the admissibility of the related application is in line with the recommendations which the Ombudsman addressed to EMA about publishing the pre-submission advice after the authorisation of the related medicine.⁴⁵⁴

Special rules apply when the application or notification concerns the renewal of an approval or an authorisation. In this case, EFSA is obliged to publish also the advice provided on the content of the intended renewal application or notification as well as on the design of the related studies which the potential applicant or notifier is obliged to notify.⁴⁵⁵ Moreover, since in the case of renewal of an approval or an authorisation a consultation of stockholders and the public takes place, also the comments received in the framework of this public consultation are made public by EFSA without delay after the closure of the public consultation.⁴⁵⁶

EFSA has operationalised these provisions through the creation of a dedicated portal connected to EFSA's website (Connect.EFSA portal) where potential applicants can fill in the dedicated form to request pre-submission advice.⁴⁵⁷ The summaries of advice are then published in another dedicated portal connected to EFSA's website (OpenEFSA portal).⁴⁵⁸ These portals are operational since March 2021, but their enhancement is still ongoing.⁴⁵⁹ The optimisation of EFSA's IT tools is expected by July 2023.⁴⁶⁰

ii) *Transparency of the Information Notified to EFSA*

Article 32b GFL introduced a notification system according to which business operators, laboratories or other testing facilities have to notify EFSA of any study commissioned or carried out by them to support an application or a notification within the remit of EFSA.⁴⁶¹ The rationale for this

⁴⁵⁰ Article 38(1)(i) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381. Before the submission of an application or a notification, a potential applicant or notifier can request the staff of EFSA to provide advice on the rules applicable to, and the content required for, the application or the notification. The pre-submission advice is non-committal for the applicant, for EFSA or its Scientific Panels; EFSA or the Member States are not bound by what was advised.

⁴⁵¹ Article 6(1)(f) of the Executive Director's 2021 Decision.

⁴⁵² Article 5(2)(f) of the Executive Director's 2021 Decision. For a definition of 'sanitization', see Article 3(c).

⁴⁵³ EFSA, 2021, *Decision Laying Down the Practical Arrangements on Pre-Submission Phase and Public Consultation*.

⁴⁵⁴ European Ombudsman, 17 July 2019, *Decision in strategic inquiry OI/7/2017/KR on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU*.

⁴⁵⁵ Article 38(1)(i) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381. According to Article 32c of the same Regulation, the potential applicant or notifier must notify EFSA of the studies it intends to perform for that purpose. EFSA is then obliged to launch a consultation of stakeholders and the public on the basis of the non-confidential version of the application or notification.

⁴⁵⁶ Article 5(2)(g) of the Executive Director's 2021 Decision.

⁴⁵⁷ Connect.EFSA portal, available at <https://connect.efsa.europa.eu/RM/s/>.

⁴⁵⁸ OpenEFSA portal, available at <https://open.efsa.europa.eu/questions>. We note that no summary of pre-submission advice is available on the portal yet nor at least easily retrievable.

⁴⁵⁹ EFSA, Digital enhancements overview, available at <https://www.efsa.europa.eu/sites/default/files/2021-12/Digital-enhancements-overview-Transparency.pdf>.

⁴⁶⁰ EFSA, Audio-recording of 91st Management Board Web meeting, available at <https://www.efsa.europa.eu/en/events/91st-management-board-web-meeting>.

⁴⁶¹ Article 32b(2) and (3) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381. Failure to notify any of the studies results in the invalidity or inadmissibility of the application or notification.

new system is to allow EFSA to be aware of all studies performed by an applicant with a view to supporting an application, preventing the applicant from concealing unfavourable studies. It thus ensures the completeness of the scientific data and a form of scrutiny over them.⁴⁶²

EFSA implemented this notification system through the decisions of the Executive Director (i) laying down the practical arrangements on pre-submission phase and public consultation,⁴⁶³ and (ii) laying down practical arrangements concerning transparency and confidentiality.⁴⁶⁴ Accordingly, the notification of studies shall be made without delay and include the title, the scope, the parties involved and the starting and completion date of the study.⁴⁶⁵ This information is collected in a database managed by EFSA which is accessible only to applicants and laboratories until the application or notification is received by EFSA.⁴⁶⁶

Once EFSA receives the application or the notification supported by these studies, an obligation of transparency is triggered: EFSA is obliged to make public the notified information in accordance with the general transparency rules established in Articles 38 and 39e GFL.⁴⁶⁷ The notification system, therefore, not only allows EFSA to enhance the excellence and independence of its scientific input, but it also contributes to the visibility of regulatory science used in the procedure and to EFSA's perceived transparency.

EFSA has operationalised the notification system through the creation of a dedicated portal connected to EFSA's website (Connect.EFSA portal) where business operators, laboratories or other testing facilities can submit study notifications.⁴⁶⁸ The notified information is then published in another dedicated portal connected EFSA's website (OpenEFSA portal).⁴⁶⁹ These portals are operational since March 2021, but their enhancement is still ongoing.⁴⁷⁰ The optimisation of EFSA's IT tools is expected by July 2023.⁴⁷¹

iii) *Transparency of documents related to risk assessment*

The Transparency Regulation significantly enhances the requirements of proactive transparency in relation to the risk assessment activities of EFSA, as well as to the information, studies, documents and which are used in such assessment.

First of all, applications for approval or authorisation submitted according to the sectoral legislative acts have to be made public by EFSA, together with the supporting information and any supplementary information supplied by the applicant.⁴⁷² The applicant can contextually request certain parts of the information submitted to be treated confidentially.⁴⁷³ Therefore, the applicant

⁴⁶² de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, European Journal of Risk Regulation, p. 9.

⁴⁶³ EFSA, 2021, *Decision Laying Down the Practical Arrangements on Pre-Submission Phase and Public Consultation*.

⁴⁶⁴ Executive Director's 2021 Decision.

⁴⁶⁵ The exact information required by EFSA is outlined in Annex II of EFSA, 2021, *Decision Laying Down the Practical Arrangements on Pre-Submission Phase and Public Consultation*.

⁴⁶⁶ de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, European Journal of Risk Regulation, p. 9.

⁴⁶⁷ Article 32b(7) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁴⁶⁸ Connect.EFSA portal, available at <https://connect.efsa.europa.eu/RM/s/>.

⁴⁶⁹ OpenEFSA portal, available at <https://open.efsa.europa.eu/questions>. The portal contains already more than 1.100 results for questions submitted after the enter into force of the Transparency Regulation.

⁴⁷⁰ EFSA, Digital enhancements overview, available at <https://www.efsa.europa.eu/sites/default/files/2021-12/Digital-enhancements-overview-Transparency.pdf>.

⁴⁷¹ EFSA, Audio-recording of 91st Management Board Web meeting, available at <https://www.efsa.europa.eu/en/events/91st-management-board-web-meeting>.

⁴⁷² Articles 2(9), 3(1) 4(1), 5(1), 6(2), 7(1) and 8(3) of Regulation (EU) 2019/1381.

⁴⁷³ Article 39a(1) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381. See *infra* Section 3.3.3(vii).

must submit two versions of the dossier: a confidential and a non-confidential version. The non-confidential version, as submitted by the applicant, of the application, of scientific data, studies and other information part of, or supporting, the application shall be made public by EFSA, without delay, once a valid or admissible application has been received.⁴⁷⁴ Non-confidential versions of any additional or supplementary information are published upon receipt.⁴⁷⁵ To facilitate the implementation of this policy, applicants are required to submit any information supporting applications or requests for a scientific output, including scientific data and scientific studies and supplementary information, electronically and according to standard data formats pursuant to Article 39f(2) GFL.

If a request for scientific opinion is submitted to EFSA by the European Parliament, the Commission or a Member State, it has to be published once received by EFSA, together with scientific data and information, documents and data supporting such request.⁴⁷⁶ Requests by the European Parliament, the Commission or a Member State must be published even when they have been refused or modified; the justifications for the refusal or modification must be made public.⁴⁷⁷

Once the risk assessment has been concluded, EFSA is obliged to make public all information, documents or data related to it in their non-confidential version. They are specifically:

- a) all EFSA's scientific outputs, including the opinions of the Scientific Committee and the Scientific Panels, minority opinions as well as EFSA's conclusions on pesticides peer review processes;
- b) the results of consultations performed during the risk assessment process;
- c) information on which EFSA's scientific outputs (including scientific opinions) are based;
- d) scientific studies (including verification studies) commissioned by the Authority via a procurement or grant awarding procedure.

The information must be publicly available and easily accessible.⁴⁷⁸ This was realised through the creation of a portal connected to EFSA's website section of EFSA's website (OpenEFSA portal) where the information is stored in an electronic format which allows to download, print and search through it.⁴⁷⁹ The portal is operational since March 2021, but its digital enhancement is still ongoing.⁴⁸⁰ The optimisation of EFSA's IT tools is expected by July 2023.⁴⁸¹

In this way, EFSA has implemented the requirement of the Transparency Regulation to make relevant information public without delay, at the earliest possible stage in the risk assessment process.⁴⁸² In particular, the fact that scientific data, studies and other information part of, or supporting, an application are made public once a valid or admissible application has been received

⁴⁷⁴ Article 6(1)(c) of the Executive Director's 2021 Decision. This includes also any justifications to prove compliance with notification obligations.

⁴⁷⁵ Article 6(1)(c) of the Executive Director's 2021 Decision.

⁴⁷⁶ Article 6(1)(e) of the Executive Director's 2021 Decision.

⁴⁷⁷ Article 6(1)(j) of the Executive Director's 2021 Decision.

⁴⁷⁸ Article 38 GFL.

⁴⁷⁹ See <https://open.efsa.europa.eu/>. Some information is available also on EFSA's main website, on IUCLID portal or in EFSA's scientific journal. The OpenEFSA portal contains already more than 1.100 results for questions submitted after the enter into force of the Transparency Regulation.

⁴⁸⁰ EFSA, Digital enhancements overview, available at <https://www.efsa.europa.eu/sites/default/files/2021-12/Digital-enhancements-overview-Transparency.pdf>.

⁴⁸¹ EFSA, Audio-recording of 91st Management Board Web meeting, available at <https://www.efsa.europa.eu/en/events/91st-management-board-web-meeting>.

⁴⁸² Recital 28 of Regulation (EU) 2019/1381.

by EFSA (rather than after the adoption of the relevant opinion) is considered as the new 'gold standard' of transparency in the EU.⁴⁸³

iv) *Transparency of EFSA's meetings*

With regard to the meetings of the Scientific Committee, the Scientific Panels and their working groups, Article 38 GFL requires EFSA to make public the agendas, the participant lists and the minutes.⁴⁸⁴ In particular, the agendas and lists of participants of these meetings are made available without delay after the end of the relevant meeting and cannot be subject to sanitisation by EFSA.⁴⁸⁵ Conversely, sanitisation can be requested for the minutes of the meetings, which will then be made public in their non-confidential version after their finalisation.⁴⁸⁶ At the moment of the disclosure of the minutes, also the oral Dols made in relation to items on the agendas of these meetings are made public.⁴⁸⁷ As already mentioned, the ADols of the members of the Scientific Committee and the Scientific Panels, as well as the members of the working groups, and participants to pesticides peer review meetings, are published after their validation.⁴⁸⁸ We note that, on EFSA's website, the agenda and the minutes of the plenary meetings of the Scientific Committee and of the Scientific Panels are indeed published⁴⁸⁹ (with two exceptions),⁴⁹⁰ as well as the minutes of the working groups.⁴⁹¹ The lists of participants are contained in the minutes.

Since 2012, EFSA has made a number of its Scientific Committee and panels meetings open to observers, first as a pilot and then as stable commitment.⁴⁹² EFSA still hosts open plenaries (about one per scientific panel each year) which can be joined on site (in Parma) or remotely (via live web streaming) by observers upon registration. EFSA reviews the list of registered individuals as observers and draws a list of confirmed observers for the open plenary meeting, deciding generally on a first come, first served basis.⁴⁹³ Registered observers can attend the meeting, but they cannot: (i) hinder the work of the Scientific Committee and Scientific Panels; (ii) take part in the discussion, drafting, deliberation of the scientific output at hand or in other activities that require active engagement; or (iii) attempt to influence the meeting.⁴⁹⁴ However, they may have the opportunity to ask questions either after they have observed a discussion on a given topic or at the end of the open plenary meeting.⁴⁹⁵

With regard to the meetings of the Management Board, of the Advisory Forum and of EFSA's network, draft agendas and the supporting documents shall be published online no later than two

⁴⁸³ Hofmann, H., Leino-Sandberg, P., 23 October 2019, *An agenda for transparency in the EU*, European Law Blog.

⁴⁸⁴ Article 38(1)(a) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁴⁸⁵ Article 5(2)(a) of the Executive Director's 2021 Decision.

⁴⁸⁶ Article 6(1)(a) of the Executive Director's 2021 Decision.

⁴⁸⁷ Article 5(2)(c) of the Executive Director's 2021 Decision.

⁴⁸⁸ Article 5(2)(b) of the Executive Director's 2021 Decision.

⁴⁸⁹ The Study has considered the meetings held from the entry into force of the Transparency Regulation (March 2021) until the completion of the Study (March 2023). We note however that the minutes of the most recent meetings are not yet available online (e.g. 156th plenary meeting of the GMO Panel on 15 March 2023; 34th plenary meeting of the FAF Panel on 21 March 2023).

⁴⁹⁰ The minutes of the 106th plenary meeting of the PLH panel of 24 October 2022 and of 127th plenary meeting of the NDA panel 4 August 2022 are not available on EFSA's website.

⁴⁹¹ The list of participants and the agenda are contained in the working groups' minutes. The minutes of few working groups are marked as 'available soon'. See <https://www.efsa.europa.eu/en/events/advanced-search>.

⁴⁹² EFSA, *Seven Years of Open Panel Meetings*, available at <https://www.efsa.europa.eu/sites/default/files/seven-years-of-open-panel-meetings-at-EFSA.pdf>.

⁴⁹³ EFSA, 21 September 2018, *Guidelines for Observers for open plenary meetings*.

⁴⁹⁴ EFSA, 21 September 2018, *Guidelines for Observers for open plenary meetings*, p. 4.

⁴⁹⁵ EFSA, 21 September 2018, *Guidelines for Observers for open plenary meetings*, p. 4.

calendar days before the start of the meeting.⁴⁹⁶ The lists of participants of meetings must be published without delay after the end of the relevant meeting, together with all documents submitted to the Management Board for discussion or adoption.⁴⁹⁷ We note that, on EFSA's website, agenda and minutes of all the 93 Management Board meetings (from 18 September 2002 to 15 December 2022) are indeed published, together with their audio recordings as of 2009.⁴⁹⁸ It is also possible to register to attend the upcoming Management Board meetings via Microsoft Teams.⁴⁹⁹ This registration allows to observe the discussion, but not to ask questions or intervene. We note that some sessions of the Management Board meetings are, however, private and not open to the public.⁵⁰⁰ Still, the possibility to observe and listen to the recordings ensures a high level of transparency of Management Board meetings.

v) *Transparency of governance documents*

As described, also the activities of the Management Board and of the Advisory Forum are now subject to more stringent transparency requirements.⁵⁰¹ It is noteworthy that all the documents related to the governance activities of EFSA cannot be subject to confidentiality requests nor sanitisation by EFSA.⁵⁰²

As mentioned earlier, ADols made by the members of the Management Board, the Executive Director, members of EFSA's operational management and the members of the Advisory Forum are to be made public after their validation,⁵⁰³ while oral Dols made in relation to items on the agendas of meetings of the Management Board or the Advisory Forum are to be published together with the disclosure of the minutes of these meetings (upon their finalisation).⁵⁰⁴

According to Article 38 GFL, annual reports of EFSA's activities, adopted by the Management Board in accordance with Article 25(8) GFL, must be published without delay,⁵⁰⁵ that is, immediately after their adoption.⁵⁰⁶ The annual activity report for the years 2017-2021 are published in a dedicated page of EFSA's website,⁵⁰⁷ while the annual activity reports for the previous years are available among the corporate publications.⁵⁰⁸

vi) *Protection of personal data*

The release of documents following a request for access to documents and the publication of information according to Article 38 GFL are subject to the limitations imposed by the protection of personal data and confidentiality.

⁴⁹⁶ Article 15(3) RoP. We note, however, that EFSA's practice is not always compliant with this requirement. For instance, the relevant documents for the 94th Management Board meeting held on 23 March 2023 were not available on the website on 21 March 2023.

⁴⁹⁷ Article (5)(2)(a) and (e) of the Executive Director's 2021 Decision.

⁴⁹⁸ See https://www.efsa.europa.eu/en/events/advancedsearch?f%5B1%5D=event_participant%3A121&sort=computed_sort_date&order=desc.

⁴⁹⁹ See Article 15(2) and (4) RoP.

⁵⁰⁰ Members of the Management Board referred for instance to the 'private session' in the recording of the 92nd Management Board meeting.

⁵⁰¹ Article 38(1)(a) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁵⁰² Article 5 of the Executive Director's 2021 Decision.

⁵⁰³ We note that, on EFSA's website, under the heading 'Operational management' (see <https://www.efsa.europa.eu/en/people/operationalmanagement>) the ADols of the Chief Scientist, the Heads of the Financial Services Unit and the Human Capital Services Unit of the Management Services Department, the Head of the Biological Hazards & Animal Health and Welfare Unit are not available. This may be due to their ADols not having been screened yet, the ongoing restructuring of the website, or an omission.

⁵⁰⁴ Article 5(2)(b) and (c) of the Executive Director's 2021 Decision. See also Article 6(1)(a). This rule is also reproduced in Article 15(1) RoP.

⁵⁰⁵ Article 38(1)(g) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁵⁰⁶ Article 5(2)(d) of the Executive Director's 2021 Decision.

⁵⁰⁷ <https://www.efsa.europa.eu/en/corporate-pubs/annual-reports>.

⁵⁰⁸ <https://www.efsa.europa.eu/en/publications/corporate>.

According to Article 39e GFL, the names of the applicant, of the authors of published or publicly available studies, of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting, are always made public by EFSA, except in the case of involvement in testing on vertebrate animals or in obtaining toxicological information.⁵⁰⁹ This provision gives effect to the judgment of the CJEU on case *ClientEarth and PAN Europe*⁵¹⁰ where information on the names of experts (in particular external experts who had made certain comments on the draft of an EFSA's document) was qualified as 'personal data'.⁵¹¹ Nevertheless, its disclosure was considered necessary by the CJEU, 'so that the impartiality of each of those experts in carrying out their tasks as scientists in the service of EFSA could be specifically ascertained' and in order to ensure the transparency and accountability of EFSA.⁵¹²

vii) *Protection of confidentiality*

Any natural or legal person can submit a confidentiality request to EFSA according to Article 39a GFL as implemented in the practical arrangements laid down in the Executive Director's 2021 Decision.⁵¹³ Confidential requests can be made only in relation to specific items of information. In this sense, the Transparency Regulation brought an end to the case-by-case approach which EFSA adopted since 2003 with regard to confidentiality.⁵¹⁴ Article 39(2) GFL now expressly specifies the items of information which can be granted confidential treatment upon request:

- a) the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
- b) commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
- c) commercial information revealing sourcing, market shares or business strategy of the applicant; and
- d) quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.

Sectoral legislation on novel foods⁵¹⁵ and pesticides⁵¹⁶ further details these categories.⁵¹⁷ Where environmental information is concerned, the specific provisions of the Aarhus Regulation continue to apply.

The protection of these items is granted only where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree.⁵¹⁸ The

⁵⁰⁹ Article 39e of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁵¹⁰ Case C-615/13 P *ClientEarth and PAN Europe v EFSA* [2015] ECLI:EU:C:2015:489.

⁵¹¹ Case C-615/13 P *ClientEarth and PAN Europe v EFSA* [2015] ECLI:EU:C:2015:489, para. 34.

⁵¹² Case C-615/13 P *ClientEarth and PAN Europe v EFSA* [2015] ECLI:EU:C:2015:489, para. 58.

⁵¹³ Substantive and procedural requirements can be found in Articles 9 and 10 of the Executive Director's 2021 Decision. EFSA has created a dedicated portal connected to EFSA's website for the submission of confidentiality requests: Portalino.

⁵¹⁴ Under the 2003 policy, EFSA discussed directly with companies how to interpret the concept of commercially sensitive information. See EFSA, 16 September 2003, *Openness, Transparency and Confidentiality*, para. 6.

⁵¹⁵ Article 23(4)(a) and (b) of Regulation 2015/2283.

⁵¹⁶ Article 39(2)(b), (c) and (d) of Regulation 1107/2009.

⁵¹⁷ See EFSA, 2021, *Decision of the Executive Director of the European Food Safety Authority Laying down practical arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009*. See also de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, *European Journal of Risk Regulation*, p. 14.

⁵¹⁸ Article 39(2) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

burden of the proof, thus, lies with the applicant and it is qualified to the level of ‘a significant degree’. The Executive Director’s 2021 Decision further requires the applicant to show that the harm that may be caused is of a significance corresponding at least to 5% of the gross annual turnover for legal persons, or the gross annual earnings for natural persons, for the previous financial year. In literature, it has been remarked that the reason behind this percentage and the elements to be included in the calculation of the damage are not clearly explained by EFSA.⁵¹⁹ If the applicant cannot establish that the harm that may be caused by disclosure reaches at least 5%, the applicant must provide a specific justification as to why in the specific case the harm would be still significant.⁵²⁰

In addition, EFSA requires the applicant to demonstrate that the information on which the confidentiality request is made is worthy of protection. In particular, it must be established that:

- a) the information is not publicly available or is known only to a limited number of persons;
- b) the information was legally acquired;
- c) the information has not been finalised more than 5 years ago (novelty test);
- d) there is a direct causal link between the potential harm and the disclosure;
- e) the information does, or does not, fall under the definition of ‘environmental information’.⁵²¹

Even when the significant harm of the disclosure is demonstrated, EFSA may disclose this information ‘where urgent action is essential to protect human health, animal health or the environment’.⁵²² In the literature, it has been remarked that situations requiring ‘urgent action’ are more limited than situations covered by ‘overriding public interests’ which allow the disclosure of information upon access to documents request.⁵²³ Moreover, this rule confers a margin of discretion (since it ‘may disclose’) which the ‘overriding public interest’ clause does not allow.⁵²⁴ However, although this creates a misalignment between active and passive transparency, the variation does not appear particularly problematic since Article 39(2) GFL provides for an exception to confidential treatment for ‘information which is relevant to the assessment of safety’, particularly for information concerning the manufacturing or production process and the quantitative composition of the subject matter.⁵²⁵ This provision represents a tool to protect public interest in disclosure, but its scope and conditions of application have not been elaborated upon in EFSA’s practical arrangements.

When information is part of scientific outputs of EFSA (including scientific opinions) relating to foreseeable effects on human health, animal health or the environment, it is in any case made public.⁵²⁶

⁵¹⁹ de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, *European Journal of Risk Regulation*, n. 104.

⁵²⁰ Article 10(b)(iii) of the Executive Director’s 2021 Decision.

⁵²¹ Article 10(b) of the Executive Director’s 2021 Decision. See also EFSA, March 2021, *Questions and Answers on the EFSA Practical Arrangements*.

⁵²² Article 39(4)(a) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁵²³ Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, *Common Market Law Review*, Vol. 59 No. 3, p. 695; Leino-Sandberg, P., Korkea-aho, E., 2017, *Who owns the information held by EU agencies? Weed killers, commercially sensitive information and transparent and participatory governance*, *Common Market Law Review*, Vol. 54 No. 4, p. 1070.

⁵²⁴ Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, *Common Market Law Review*, Vol. 59 No. 3, p. 695.

⁵²⁵ See Article 39(2)(a) and (d) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁵²⁶ Article 39(4)(b) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

The submission of a confidentiality request does not guarantee that the information for which it was submitted will be withheld from public disclosure as this depends on the outcome of EFSA's decision-making process. EFSA is required to provide a concrete and individual examination of the confidentiality request and to adopt a reasoned decision on it.⁵²⁷ The decision shall be adopted within 10 calendar weeks from the receipt of the confidentiality request.⁵²⁸ Within 2 weeks from the notification of the decision, it is possible to ask the reconsideration of the decision by filing a confirmatory application which has suspensive effect.⁵²⁹ For items related to an application which are not given confidential status, their proactive publication by EFSA can be prevented by withdrawing the application dossier that contains them. Finally, when EFSA adopts a scientific output where information relating to foreseeable effects on human health, animal health or the environment have been granted confidential status, it shall review its decision on confidentiality and adopt a new resonated opinion within 20 working days.⁵³⁰

Aggregate data on confidentiality decisions adopted by EFSA according to Article 39b for the year 2021 have not been published in the Annual Activity Report 2021. The Annual Activity Report 2022 shows that EFSA issued 90 confidentiality decisions and received only five confirmatory applications for the revision of initial decisions.⁵³¹

3.3.4. Main concerns of the Institutions/bodies about EFSA's transparency policies

a. Recommendations of the European Ombudsman

On 17 December 2021, the European Ombudsman opened an inquiry on EFSA about its practice of extending the time limits for dealing with public access requests. The case originated from a request for public access to documents held by the agency concerning lead in ammunition. The applicant, an NGO representing the interests of hunters, intended to participate in a public consultation on the use of lead in ammunition and fishing and, for this purpose, requested certain related documents on 23 February 2021. Despite the fact that the applicant's request did not concern a very large number of documents or a very long document, EFSA released the documents in different batches and extended the deadline several times. This resulted in a delay of more than seven months, which did not allow the applicant to obtain the documents in time for the public consultation.

After having assessed EFSA's handling of the request, on 2 May 2022 the European Ombudsman found that the case constituted maladministration and issued two recommendations. Firstly, it recommended to EFSA to cease its practice of extending the time limits for dealing with public access requests beyond 30 working days. Article 4(7) of the Management Board's 2020 Decision, which allows EFSA to extend the deadline to reply, is not in line with the Access Regulation which sets forth that requests for public access must be handled promptly, i.e. within 15 days or, in exceptional cases, within 30 days from its registration. Moreover, in case of extension, the applicant must be notified in advance and detailed reasons must be given. The high number of requests received by EFSA in the same period or the consultation of third parties (which has in any case to be conducted as soon as possible) cannot justify such a delay on handling requests for access to documents. Secondly, the European Ombudsman recommended to EFSA that, when it considers that a request is formulated in broad terms, it should provide applicants with a list of the specific documents it identifies at an early stage, to

⁵²⁷ Article 39b of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁵²⁸ Article 11(4) of the Executive Director's 2021 Decision.

⁵²⁹ Article 39b(2) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁵³⁰ Article 14 of the Executive Director's 2021 Decision.

⁵³¹ EFSA, 2023, Annual Report on the implementation of EFSA's policy on independence 2022, p. 23.

enable the applicant to clarify their request if needed. This would provide more legal certainty for the applicant, who can then take an informed decision on the scope of his/her request.

To this date, the text of the Management Board's 2020 Decision still diverges from the provision of the Access Regulation since it provides for the possibility to extend indefinitely the deadline for dealing with requests for access to documents.

b. Main concerns of the European Parliament

Alongside the concerns relating to EFSA's independence policies, the European Parliament has repeatedly called EFSA to strengthen its policies concerning openness and transparency. In a Resolution of 2016 concerning to the renewal of the active substance glyphosate, the European Parliament called EFSA not only to disclose immediately all the scientific evidence which constituted the basis for the positive decision on glyphosate, but more in general 'to make all necessary efforts to facilitate full disclosure of the scientific evidence used in the context of the EU evaluation process'.⁵³² This strong call for more transparency vis-à-vis the studies and data supporting EFSA's decision-making process was repeated the following year,⁵³³ when the Parliament defined the transparency and public availability of scientific studies and of the raw data on which these studies are based as 'of the utmost importance'.⁵³⁴

These concerns have now been addressed specifically by the Transparency Regulation through the introduction of the described obligations to proactively make public scientific data, studies and other information part of, or supporting, applications to EFSA. In the latest years, the European Parliament has noted with satisfaction EFSA's efforts to increase transparency and openness in its activities.⁵³⁵

Furthermore, the European Parliament has encouraged EFSA to strengthen its transparency policies in relation to some specific aspects:

i) *The publication of the CVs of EFSA's staff members*

As mentioned in Section 2.3.5.c, in the context of the discharge procedures for the financial years 2017 and 2020, the European Parliament expressed regret for the fact that EFSA does not publish the curriculum vitae of its staff members online.⁵³⁶ As discussed also by scholars,⁵³⁷ their

⁵³² European Parliament, 13 April 2016, *Resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011*, para. 9.

⁵³³ Recital N of European Parliament, 24 October 2017, *Resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011*.

⁵³⁴ Recital K of European Parliament, 24 October 2017, *Resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011*.

⁵³⁵ European Parliament, 18 April 2018, *Resolution of 18 April 2018 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2016*, para. 27; European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, para. 20; European Parliament, 29 April 2021, *Resolution of 29 April 2021 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2019*, para. 20.

⁵³⁶ European Parliament, 26 March 2019, *Resolution of 26 March 2019 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2017*, para. 16; European Parliament, 4 May 2022, *Resolution of 4 May 2022 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority (EFSA) for the financial year 2020*, para. 19.

⁵³⁷ Vos, E., Athanasiadou, N., Dohmen, L., 2020, *EU Agencies and Conflicts of Interests*, p. 38.

publication would strengthen not only the transparency of EFSA but also its accountability and the public perception of its independence.

ii) *Transparency vis-à-vis societal stakeholders*

In the same procedures, the European Parliament encouraged EFSA to achieve higher transparency vis-à-vis stakeholders, meaning especially representatives of civil society and of the NGO community.⁵³⁸ While recognising EFSA's engagement with its stakeholders and the public through appropriate platforms and fora, the European Parliament has thus pointed to the specific function of transparency as enabler for civil society participation in decision-making and, ultimately, as pivot for the legitimacy of the related decisions.⁵³⁹

iii) *User-friendliness of the website and use of digital tools*

In its Resolutions of 26 March 2019 and of 14 May 2020, within the context of the described concerns about the public availability of studies and data, the European Parliament has called EFSA to increase the user-friendliness of the information provided on its website and facilitate data mining.⁵⁴⁰ This remark resonates with the recent calls of the European Ombudsman⁵⁴¹ and academics⁵⁴² towards EU institutions and agencies to make full use of modern IT tools to ensure timely, accessible pro-active publication of documents. Having a public register of documents, easy to access and to navigate, is considered an essential part of the policies and practices to give effect to transparency.⁵⁴³

3.4. Key Findings and Recommendations

On the basis of the analysis carried out in Sections 3.1, 3.2 and 3.3, this Section aims at summarising the main findings concerning EFSA's policy on transparency. This will be done by also including, where relevant, a comparison with ECHA and EMA.⁵⁴⁴

A. Passive transparency

1. *Time Limits for Processing Requests*

EFSA's implementation of the Transparency Regulation with regard to passive transparency, that is, the processing of access to documents requests, appears to be substantially in line with the legal framework established by the Access Regulation and the Aarhus Regulation, as well as with the described developments in the case law of the Court of Justice. The express mention of the Access Regulation and of the Aarhus Regulation introduced in the GFL and the subsequent adoption of updated practical arrangements 'to give the fullest possible effect to the right of public access to documents held by EFSA'⁵⁴⁵ are significant improvements towards

⁵³⁸ European Parliament, 4 May 2022, *Resolution of 4 May 2022 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority (EFSA) for the financial year 2020*, para. 20.

⁵³⁹ Alemanno, A., 2014, *Unpacking the Principle of Openness in EU Law: Transparency, Participation and Democracy*, European Law Review, Vol. 39 No. 1.

⁵⁴⁰ European Parliament, 26 March 2019, *Resolution of 26 March 2019 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2017*, para. 22; European Parliament, 14 May 2020, *Resolution of 14 May 2020 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2018*, para. 20.

⁵⁴¹ See European Ombudsman, 15 November 2021, *Ombudsman calls for EU access to documents law to be modernised*.

⁵⁴² Hofmann, H., Leino-Sandberg, P., 23 October 2019, *An agenda for transparency in the EU*, European Law Blog.

⁵⁴³ See European Ombudsman, 27 October 2021, *A short guide for the EU administration on policies and practices to give effect to the right of public access to documents*, SI/7/2021/DL.

⁵⁴⁴ See Annex 3.

⁵⁴⁵ Article 1 of the Management Board's 2020 Decision.

ensuring more transparency in the work of the agency which are widely recognised in literature.⁵⁴⁶

However, the Management Board's 2020 Decision does not contain an obligation for EFSA to process the access to document request within 15 working days from the registration of the application as established in Article 7(1) of the Access Regulation. Moreover, as critically found also by the European Ombudsman, it does not provide any time limit for the extension of the deadline in exceptional cases concerning complex and/or voluminous requests. Although the Standard Operating Procedure mentions the time limit of 15 working days,⁵⁴⁷ the practice has shown that at least in one case the deadline has been extended multiple times and the applicant has been informed of the extension only after its expiry.⁵⁴⁸

Conversely, the practical arrangements of ECHA and EMA, whose funding regulations also make reference to the Access Regulation,⁵⁴⁹ correctly set forth a time-limit of 15 working days for processing the application from the date of registration and a possible extension for further 15 working days in the case of a very long document or to a very large number of documents.⁵⁵⁰ Considering that the request for access to documents received by these two agency may be of the same complexity and length of the ones received by EFSA, the omission of the time-limits in EFSA's practical arrangements does not appear justified by specific circumstances. In the view that 'access delayed is access denied',⁵⁵¹ the provision of clear time limits for the processing of access to documents requests, as well as their respect in practice, is of fundamental importance for the transparency of EFSA.

Recommendations:

EFSA should include in its practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006 a provision on the time limit for dealing with access to documents requests and on the maximum extension of the time limit in exceptional cases. In line with the Access Regulation and the recommendations of the European Ombudsman, such extension should amount to a maximum of 15 working days. Moreover, as recommended by the European Ombudsman, EFSA should add a provision clarifying that, when it considers that a request is formulated in broad terms, it shall inform applicants about the specific documents it has identified in connection to the request, providing them with a list of the specific documents at an early stage. This will give applicants the possibility to clarify the request and possibly avoid delays in the reply.

2. Reporting on Access to Documents Requests

⁵⁴⁶ For a similar positive assessment, see de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, European Journal of Risk Regulation, p. 11; Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, Common Market Law Review, Vol. 59 No. 3, p. 698.

⁵⁴⁷ Article 5(1) of EFSA, 25 January 2021, *Standard Operating Procedure. Applications for Public Access to Documents (PAD)*.

⁵⁴⁸ European Ombudsman, 2 May 2022, *Recommendation on how the European Food Safety Authority (EFSA) dealt with a request for public access to documents related to a proposal to restrict lead in ammunition (case 2124/2021/MIG)*, para. 30.

⁵⁴⁹ For EMA, see Article 73 of Regulation (EC) No 726/2004; for ECHA, see Article 118(1) of Regulation (EC) No 1907/2006 and Article 66(1) of Regulation (EU) No 528/2012.

⁵⁵⁰ For ECHA, see Article 2(2) of ECHA, 25 March 2009, *Decision on the implementation of Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to documents to European Parliament, Council and Commission Documents*, MB/12/2008 final. For EMA, see Article 3(1) and (3) of EMA, 4 October 2018, *European Medicines Agency policy on access to documents*, EMA/729522/2016, which allows an exception for 'exceptional circumstances' and mentions 'a very long document or to a very large number of documents' as examples.

⁵⁵¹ European Ombudsman, 2 May 2022, *Recommendation on how the European Food Safety Authority (EFSA) dealt with a request for public access to documents related to a proposal to restrict lead in ammunition (case 2124/2021/MIG)*, para. 35.

According to Article 17 of the Access Regulation, each institution is obliged ‘to publish annually a report for the preceding year including the number of cases in which the institution refused to grant access to documents [and] the reasons for such refusals’.⁵⁵² Also the European Ombudsman, in its recent ‘Short Guide for the EU Administration’, stressed the importance of reporting annually on access to documents requests, including statistics on the number of requests and whether access was (or was not) granted. Although Article 12 of the 2020 Management Board’s Decision restates this obligation, EFSA’s compliance with it has not always been consistent: EFSA’s annual reports generally do not contain the reasons for refusals⁵⁵³ and in the 2022 Annual Activity Report information on access to documents requests is completely missing.

Also EMA and ECHA are bound by the same obligation to report under the Access Regulation. In line with its Policy on access to documents,⁵⁵⁴ EMA systematically includes an extensive overview of the number of access to documents requests and aggregated data on refusals in its Annual Reports.⁵⁵⁵ Conversely, ECHA’s policy on transparency does not mention this obligation⁵⁵⁶ and its Annual Reports do not contain information on access to documents requests.⁵⁵⁷

Recommendations:

EFSA should improve its reporting activities in relation to access to documents requests. It should publish a report or include a dedicated section in its annual report on access to documents requests, including not only the number of requests but also the reasons for the refusals of requests (at least in the form of aggregated data).

B. Active transparency

1. Publication of CVs

EFSA’s policies concerning the independence and the transparency of EFSA are silent on the publication of CVs. As remarked in Section 2.4, EFSA publishes on its website a short biography of the Executive Director, the Chief Scientist and the Heads of the various departments.

Similarly to EFSA, ECHA’s policy is silent on the publication of CVs. However, ECHA publishes on its website the CVs of the members of the Management Board, the Member State Committee, the Committee for Risk Assessment, the Committee for Socio-Economic Analysis, the Biocidal Products Committee Working Groups, the Enforcement Forum and the Board of Appeal.

EMA’s policy provides for the publication on EMA’s website of the CVs of the members of the scientific committees and the Agency’s other bodies,⁵⁵⁸ including the Management Board.⁵⁵⁹

⁵⁵² Article 17(1) of Regulation (EC) No 1049/2001.

⁵⁵³ For instance, EFSA’s Annual Activity Reports of 2020 and of 2021 generically refer to Articles 4(2) and 4(3) of the Access Regulation, whereas EFSA’s Activity Reports of 2017, 2018 and 2019 only contain the number of access to documents requests.

⁵⁵⁴ EMA, 4 October 2018, *Policy on access to documents*, EMA/729522/2016, p. 5.

⁵⁵⁵ See, for instance, EMA, 2022, *Annual Report 2021*, p. 134-136; EMA, 2021, *Annual Report 2020*, p. 105-108; EMA, 202, *Annual Report 2019*, p. 103-106; EMA, 2019, *Annual Report 2018*, p. 88-89.

⁵⁵⁶ ECHA, 17 December 2014, *ECHA’s approach to Transparency*, MB/61/2014.

⁵⁵⁷ See, for instance, ECHA, 2022, *Annual Report 2021*, ECHA, 2021, *Annual Report 2020*.

⁵⁵⁸ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of scientific committees’ members and experts*, pp. 14–15.

⁵⁵⁹ EMA, 15 December 2022, *European Medicines Agency policy on the handling of competing interests of Management Board members*, p. 9.

Recommendations:

As mentioned in the recommendations relating to EFSA's independence, EFSA should publish the CVs of its key actors, such as the Executive Director, the members of the Management Board, of the Advisory Forum, of the Scientific Committee and of the scientific panels. This would provide more transparency of EFSA vis-à-vis the stakeholders and the public.

2. *Publication of Scientific Studies and Data*

EFSA's practical arrangements for the implementation of Article 38 of the General Food Law extensively detail the rules for the systematic publication of information, studies and data in support of applications. These provisions, together with the notification system and the publication of the information notified through it,⁵⁶⁰ significantly enhanced the transparency of EFSA. In the literature, EFSA's policy of proactive transparency is now considered the most advanced among EU agencies involved in risk assessments.⁵⁶¹

EFSA has operationalised these rules on the systematic publication of information, studies and data through the creation of a dedicated portal connected to EFSA's website (OpenEFSA Portal).⁵⁶² This portal is operational and allows the public to download, print and search through the information available.⁵⁶³ However, considering that EFSA's IT tools enhancement is still ongoing at the time of writing, a critical assessment on their effectiveness appears premature.

Under Article 119 REACH, also ECHA is obliged to make publicly available on the internet a database with information about pre-registered and registered substances (the so-called 'dissemination portal'), which includes physicochemical data concerning the substance and on pathways and environmental fate, and the result of each toxicological and ecotoxicological study.⁵⁶⁴ However, unlike EFSA, ECHA is not required to publish studies or raw data, but only the results of the studies on the substance's intrinsic properties and hazard profiles. ECHA may publish study summaries⁵⁶⁵ and (robust) studies summaries⁵⁶⁶ unless they are considered confidential.⁵⁶⁷ In light of the evolution of the notion of 'transparency' (also due to the enactment of the Transparency Regulation for EFSA), ECHA has committed to continuously improving its efforts in transparency.⁵⁶⁸ In particular, since 2021, it has committed to extend the publication of information from registration dossiers with additional items with the aim of making publicly available all relevant non-confidential information available to ECHA.⁵⁶⁹ In its transparency policies, ECHA stresses the importance of making the data published easily accessible and understandable by citizens to enhance their usability and transparency in its dimension of intelligibility.⁵⁷⁰

⁵⁶⁰ Article 32b of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁵⁶¹ See Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, Common Market Law Review, Vol. 59 No. 3; Hofmann, H., Leino-Sandberg, P., 23 October 2019, *An agenda for transparency in the EU*, European Law Blog.

⁵⁶² Some information is available also on EFSA's website, on IUCLID portal or in EFSA's scientific journal.

⁵⁶³ See OpenEFSA portal, available at <https://open.efsa.europa.eu/questions>. The portal contains already more than 1.100 results for questions submitted after the enter into force of the Transparency Regulation.

⁵⁶⁴ Article 119(1) of the Regulation (EC) No 1907/2006.

⁵⁶⁵ For a definition, see Article 3(29) of Regulation (EC) No 1907/2006.

⁵⁶⁶ For a definition, see Article 3(28) of Regulation (EC) No 1907/2006.

⁵⁶⁷ Article 119(2) of the Regulation (EC) No 1907/2006.

⁵⁶⁸ ECHA, 17 December 2014, *ECHA's approach to Transparency*.

⁵⁶⁹ ECHA, 17 December 2020, *ECHA's Transparency Approach – update on actions for 2021-2022*, MB/65/2020 final, p. 5.

⁵⁷⁰ ECHA, 17 December 2020, *ECHA's Transparency Approach – update on actions for 2021-2022*, p. 5.

Under Article 57 of Regulation 726/2004, EMA has to maintain a database on medicinal products, accessible to the general public, and ensure that it is updated, and managed independently of pharmaceutical companies.⁵⁷¹ This database includes summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling, as well as references to data on clinical trials currently being carried out or already completed.⁵⁷² EMA also publishes detailed information on its scientific assessment work. The information provided to the public must be worded in an appropriate and comprehensible manner.⁵⁷³ However, there is no obligation of proactive publication as such of studies or raw scientific data, except for clinical trials. According to Regulation (EU) No. 536/2014 on clinical trials on human medicines, all clinical trial-related information and all investigational medicinal products are to be published.⁵⁷⁴ EMA has implemented a very robust policy of proactive publication and dissemination of clinical data,⁵⁷⁵ in line with the recommendations of the European Ombudsman.⁵⁷⁶ However, in order not to undermine EMA's decision-making process, clinical data are published only once the concerned procedure has been finalised.⁵⁷⁷ Therefore, in comparison to EFSA, these data are published at a later stage, only after the risk assessment has been carried out. Moreover, it is important to remark that clinical trials are only one category of studies in support of an application; the scope of application of EMA's proactive transparency policy is thus more limited than EFSA's one.

Recommendations:

EFSA should continue to apply its transparency policies in line with the Transparency Regulation and proactively publish information, studies and data to remain at the forefront of proactive transparency among EU agencies. Moreover, EFSA should complete the programmed IT tools enhancement and optimise the digital tools available to stakeholders.

3. *Protection of confidentiality*

The actual level of transparency of EFSA also depends on the balance stroke between this principle and the protection of personal data and confidentiality in granting exceptions to disclosure. As mentioned, the reform of the GFL has brought a clarification to the items of information which can be granted confidential treatment.⁵⁷⁸ In implementing Article 39(2) GFL, EFSA has further elaborated on the conditions for granting confidential treatment, introducing additional requirements, such as the novelty test, which narrow down the scope of confidentiality in favour of transparency.⁵⁷⁹

Comparing EFSA's new framework with the one applicable to ECHA, it is noteworthy that Article 118(2) REACH provides for a list of items to be deemed confidential by ECHA, which mostly

⁵⁷¹ Article 57(1) of Regulation (EC) No 726/2004.

⁵⁷² Article 57(2) of Regulation (EC) No 726/2004.

⁵⁷³ Article 57(1) of Regulation (EC) No 726/2004. As of July 2018, database is published in the form of an excel document.

⁵⁷⁴ Article 80 of Regulation (EU) No 536/2014.

⁵⁷⁵ See EMA, 21 March 2019, *European Medicines Agency policy on publication of clinical data for medicinal products for human use*, EMA/144064/2019.

⁵⁷⁶ European Ombudsman, 24 November 2010, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency*.

⁵⁷⁷ See EMA, 21 March 2019, *European Medicines Agency policy on publication of clinical data for medicinal products for human use*, p. 8.

⁵⁷⁸ Article 39(2) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381.

⁵⁷⁹ EFSA, 2021, *Decision of the Executive Director of the European Food Safety Authority Laying down practical arrangements concerning transparency and confidentiality*.

differ from EFSA's confidential items.⁵⁸⁰ Different from EFSA's transparency policy, the burden of proof is placed on ECHA as these items 'shall normally be deemed to undermine the protection of the commercial interests of the concerned person'.⁵⁸¹ A similar approach was initially followed also by EMA which, in the absence of a legislative definition, developed the notion of confidential commercial information in its 2007 policy.⁵⁸² However, following an inquiry of the European Ombudsman on the matter⁵⁸³ and a clarification of the scope of confidential commercial information by the General Court,⁵⁸⁴ EMA revised its policy in 2018 in the sense of considering all information to be non-confidential unless the concerned person provides compelling arguments to prove the contrary.⁵⁸⁵

EFSA's transparency framework differs not only in clearly placing the burden of proof on the applicant, but also in the higher threshold that it poses. Such a threshold corresponds to 'significant' harm, which has been quantified by EFSA as 5% of the gross annual turnover for legal persons. Under the REACH Regulation and EMA guidance document, the applicant is expected to prove only that the disclosure of information will undermine his or her economic interest or competitive position.⁵⁸⁶ Although the ECHA's manual Dissemination and Confidentiality under the REACH Regulation refers to 'significant financial investment for the company concerned in relation to its turnover' as a supporting factor to request the confidentiality of information for studies or robust study summaries under Article 119(2) of the REACH Regulation,⁵⁸⁷ no specific threshold is identified and the applicants can always refer to additional elements to substantiate how disclosure would affect their financial position.⁵⁸⁸ Therefore, due to this higher threshold for applicants, EFSA's policy appears more in favour of the disclosure of commercial information than the ones of ECHA and EMA. Moreover, despite the reasons for it are not clearly explained, the quantification of 'significant harm' in 5% of the gross annual turnover provides applicants with more legal certainty.

Finally, Article 39 GFL provides that confidential information may be disclosed 'where urgent action is essential to protect human health, animal health or the environment'.⁵⁸⁹ This wording

⁵⁸⁰ In particular: (a) details of the full composition of a mixture; (b) the precise use, function or application of a substance or mixture, including information about its precise use as an intermediate; (c) the precise tonnage of the substance or mixture manufactured or placed on the market; (d) links between a manufacturer or importer and his distributors or downstream users. See Article 118(2) of Regulation (EC) No 1907/2006.

⁵⁸¹ See Article 118(2) of Regulation (EC) No 1907/2006.

⁵⁸² EMA's 2007 policy divided it in two categories: (i) 'confidential intellectual property', 'know-how' and trade secrets (including e.g. formulas, programs, process or information contained or embodied in a product, unpublished aspects of trademarks, patents etc.); and (ii) commercial confidences (e.g. structures and development plans of a company), see EMEA, 15 April 2007, *Principles to be applied for the deletion of commercially confidential information*. EMEA/45422/2006. However, its later policies defined it simply as 'any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information'. See EMA, November 2010, *HMA/EMA recommendations on transparency: Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on granting of a marketing authorisation*, EMA/484118/2010.

⁵⁸³ European Ombudsman, 8 June 2014, *Decision on own-initiative inquiry OI/3/2014/FOR concerning the partial refusal of the European Medicines Agency to give public access to studies related to the approval of a medicinal product*.

⁵⁸⁴ Case T-718/15 *PTC Therapeutics International Ltd v EMA* [2018] ECLI:EU:T:2018:66 and Case T-235/15 *Pari Pharma GmbH v EMA* [2018] ECLI:EU:T:2018:65; Röttger-Wirtz, S., 2018, *The EMA Access to Documents Policy Put to Trial*, European Pharmaceutical Law Review, Vol. 2 No. 2, pp. 108–115.

⁵⁸⁵ EMA, 4 October 2018, *European Medicines Agency policy on access to documents*; EMA, 21 March 2019, *European Medicines Agency policy on publication of clinical data for medicinal products for human use*. See also de Boer, A., Morvillo, M., Röttger-Wirtz, S., 2023, *Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation*, European Journal of Risk Regulation, p. 14.

⁵⁸⁶ Article 118 of Regulation (EC) No 1907/2006; EMA, November 2010, *HMA/EMA recommendations on transparency: Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on granting of a marketing authorisation*, p. 2.

⁵⁸⁷ ECHA, October 2022, *Dissemination and Confidentiality under the REACH Regulation*, p. 42.

⁵⁸⁸ ECHA, October 2022, *Dissemination and Confidentiality under the REACH Regulation*, p. 48.

⁵⁸⁹ Article 39(4)(a) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381

corresponds to that of Article 118(2) of the REACH Regulation,⁵⁹⁰ whereas no similar provision can be found in EMA's general policies. Conversely, disclosure of confidential information is possible where there is an overriding public interest related to clinical trials⁵⁹¹ and in connection to access to documents requests.⁵⁹² In the literature, it has been remarked that 'overriding public interests' include situations which are broader than those requiring 'urgent action'.⁵⁹³ Moreover, this rule provides that EFSA (and ECHA) 'may disclose' certain information in urgent situations. Therefore, this confers a margin of discretion which the 'overriding public interest' clause does not allow.⁵⁹⁴ However, while this creates a clear misalignment between active and passive transparency for ECHA, the variation appears less problematic for EFSA since Article 39(2) GFL provides for an exception to confidential treatment for 'information which is relevant to the assessment of safety' for certain kind of information.⁵⁹⁵ This provision represents a tool to protect public interest in disclosure, but its scope and conditions of application have not been elaborated upon in EFSA's practical arrangements.

Recommendations:

EFSA's legal framework strikes an adequate balance between the protection of confidential information and the public interest in disclosure. However, EFSA should consider elaborating further on the notion of 'information which is relevant to the assessment of safety' and its relation with the disclosure of confidential information for 'overriding public interest' under the Access Regulation. Furthermore, more information could be given on the choice to adopt 5% of the gross annual turnover as the threshold for proving 'harm to a significant degree'.

4. *Transparency of EFSA's meetings*

Observers can participate in selected open plenary meetings of EFSA's Scientific Committee or scientific panels as long as they register in advance. According to EFSA's Guidelines for open plenary meetings, they can attend with certain limitations in their participation, such as the possibility to ask questions at the end of the meeting at the Chair's discretion. Meetings of the Management Board are also open, except for some private sessions. They can be attended online upon registration, no questions can be asked.⁵⁹⁶ Recordings of the meetings are available online.

ECHA also opens up its meetings. Unlike EFSA, only so-called Accredited Stakeholders can participate as observers in the meetings of the Committee for Risk Assessment, Committee for Socio-economic Analysis, Member State Committee and Biocidal Products Committee. To become 'Accredited Stakeholders', stakeholders have to apply and fulfil the requirements listed in the Revised eligibility criteria for ECHA's Accredited Stakeholder Organisations.⁵⁹⁷ Observers are then selected from the list of interested stakeholder organisations and can be excluded

⁵⁹⁰ Article 118 (2) last sentence of Regulation (EC) No 1907/2006.

⁵⁹¹ Article 81(5) of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance, OJ L 158, 27.5.2014, p. 1–76

⁵⁹² See Regulation (EC) No 1049/2021.

⁵⁹³ Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, Common Market Law Review, Vol. 59 No. 3, p. 695; Leino-Sandberg, P., Korkea-aho, E., 2017, *Who owns the information held by EU agencies? Weed killers, commercially sensitive information and transparent and participatory governance*, Common Market Law Review, Vol. 54 No. 4, p. 1070.

⁵⁹⁴ Hickey, E., Weimer, M., 2022, *The transparency of EU agency science: Towards a new proactive approach*, Common Market Law Review, Vol. 59 No. 3, p. 695.

⁵⁹⁵ See Article 39(2)(a) and (d).

⁵⁹⁶ EFSA, 16 September 2003, *Openness, Transparency and Confidentiality*, p. 3.

⁵⁹⁷ ECHA, 21 June 2011, *Revised eligibility criteria for ECHA's Accredited Stakeholder Organisations*, MB/34/2011 final. See also ECHA, 31 May 2021, *Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees*, ED-0052.01.

when business confidentiality requires closed sessions.⁵⁹⁸ ECHA has elaborated a specific document which outlines the main principles and criteria the ECHA Secretariat uses when deciding on the need for closed sessions of the meetings of the Member State Committee.⁵⁹⁹ The Code of Conduct applicable to accredited stakeholders in ECHA is very similar to the rules applicable to EFSA's observers.⁶⁰⁰ Unlike EFSA, the Chair may invite stakeholder observers to intervene in the discussions and not just to ask questions.⁶⁰¹ The meetings of the Management Board, however, are not open to the public.⁶⁰²

EMA ensures the transparency of its work in a similar manner. EMA's Management Board, in agreement and under the conditions decided with the European Commission, may allow individuals to participate, as observers, in certain aspects of the Committee's and working parties' work.⁶⁰³ Interested individuals can sign up for involvement in EMA's activities⁶⁰⁴ as representatives of patients' and consumers' organisations, representatives of their own organisation or as individual experts.⁶⁰⁵ The Pharmacovigilance and Risk Assessment Committee organises some public hearings during certain safety reviews of medicines where anyone can attend as observer or speaker upon registration.⁶⁰⁶ Moreover, during the Covid-19 pandemic, EMA held public meetings online to inform citizens and stakeholder groups about the development, evaluation, approval, roll-out and safety monitoring of COVID-19 medicines.⁶⁰⁷ The meetings of the Management Board, however, are not open to the public.⁶⁰⁸

Recommendations:

EFSA is the only agency among the ones considered to hold Management Board meetings in public. Despite the recent change in the Management Board's composition, EFSA should maintain its practice as it ensures a high level of transparency of its activities. Moreover, EFSA should consider developing and publish a document outlining clear criteria and principles to be used when deciding whether certain sessions of the Management Board's meetings and certain scientific meetings should be held in closed sessions, similar to the one published by ECHA's Member State Committee.

⁵⁹⁸ ECHA, 17 December 2014, *ECHA's approach to Transparency*, p. 2. The decision to hold a meeting or parts thereof in a closed session is of the Chair, see ECHA, 31 May 2021, *Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees*. See also ECHA, 7 March 2013, *Closed and open sessions of the plenary meetings of the Member State Committee*.

⁵⁹⁹ ECHA, 7 March 2013, *Closed and open sessions of the plenary meetings of the Member State Committee*.

⁶⁰⁰ ECHA, 18 December 2020, *Code of conduct for observers at ECHA meetings*, ED-0035.01.

⁶⁰¹ ECHA, 18 December 2020, *Code of conduct for observers at ECHA meetings*, p. 3.

⁶⁰² ECHA, 26 June 2020, *Operating framework of the Management Board of the European Chemicals Agency*, MB/52/2019 final REV2, para. 6.2.

⁶⁰³ Article 78 (1) and 78 (2) in Title IV of Regulation (EC) No 726/2004.

⁶⁰⁴ The form for the registration of interest individuals is available at <https://fmapps.ema.europa.eu/stakeholders/signup.php>.

⁶⁰⁵ EMA, 13 February 2009, *Rules of involvement of members of Patients'/Consumers' and Healthcare Professionals' Organisations in Committees related activities*, EMEA/483439/2008. See also EMA, 2011, *The role of patients as members of the EMA Human Scientific Committees*, EMA/351803/2010.

⁶⁰⁶ EMA, 13 February 2023, *Rules of procedure on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee (PRAC)*, EMA/11523/2023 Rev.2.

⁶⁰⁷ EMA, 2022, *Stakeholder Engagement Biennial Annual Report 2020-2021: Engaging with patients, consumers, healthcare professionals and academia*, EMA/562976/2021, p. 5.

⁶⁰⁸ See EMA, 7 October 2021, *Rules of procedure of the Management Board*, EMA/MB/115339/2004/en/Rev.8.

4. CONCLUSIONS AND RECOMMENDATIONS

4.1. Conclusions

Notion of independence within EU law

1. While there is no uniform definition of 'independence' within the EU law framework, 'independence' can be defined as a status which ensures that the body concerned can act completely freely, without taking any instructions or being put under any pressure. It is possible to distinguish between institutional and functional independence. Institutional independence refers to a separate legal entity and normally encompasses aspects of organisational, budgetary and staffing independence. Functional independence implies that an entity is shielded from any instruction given by external actors that might influence the entity's activities in the performance of its tasks.
2. To offer non-political and objective input to the political decision-making process, decentralised agencies must be isolated from the influence of political or contingent considerations.

EFSA's independence

Regulatory Framework

3. EFSA's current approach to independence is embedded in its 2017 Policy on Independence and the 2018 Decision on Competing Interest Management. These policy documents are in turn implemented by further internal documents. Following the entry into force of the Transparency regulation, the Management Board has adopted in 2022 new Rules of Procedure, a Code of Conduct and new Rules on the selection, appointment and operations of scientific experts.

Definitions of conflict of interests, experts and external experts

4. The definition of conflict of interests provided by EFSA covers actual and perceived conflicts but does not clarify the exact meaning of these terms nor provides specific examples to distinguish among them. Potential conflicts are not expressly included in the definition. EFSA refers to conflicts of *interest* and not to conflicts of *interests*. Although EFSA's definition does not mention 'national interests' or 'political pressure', its broad wording allows to include within its scope not only personal interests but also interests deriving from other public duties/roles of the concerned individual. It is desirable though to clarify and explicitly include national interest and reference to political pressure in the definition of conflict of interests.
5. There is unclarity as regards the definitions of 'experts' and 'external experts' in rules and practice. Some of the persons defined as 'experts' in EFSA's DCIM are, for example, considered in legislative provisions and EFSA's website as 'external experts'.

Scope of EFSA's independence policy

6. EFSA screens declarations of interests against the mandate of the relevant scientific group and not against EFSA's overall remit. Such a choice, which narrows down the material scope of EFSA's independence policy, has raised concerns by the European Parliament. We note that a

broadening of the material scope of EFSA's independence policy may conflict with the principle of scientific excellence.

7. The temporal scope of EFSA's independence policy is five years, in line with the Commission's orientation.
8. EFSA's CoI rules do not apply to Advisory Forum members and Network members who shall submit ADols but these ADols are not screened by EFSA. In this EFSA relies on the Advisory Forum's own Declaration of Intent, MoUs concluded with relevant Article 36 organisations and relevant national rules. Network members also need to submit an ADol but these ADols are not screened, assessed or validated. There is a need for more clarity as regards the applicable independence rules to these members, which becomes more pressing in view of the strengthening of Article 36 organisations in the preparation of EFSA scientific opinions. Here problems as regards independence from national pressure are likely to increase. Hearing experts are required to submit ADols but these ADols are not subject to screening.
9. EFSA applies a cooling-off period of two years in cases where private research finding exceeds 25% of the expert's total budget. This rule has been criticised by the European Parliament, which has proposed the elimination of such threshold. Moreover, we note that this rule has been assessed differently by the external reviews considered in this Study. While these cooling-off periods were acknowledged in a review as one of the reasons for the improvement of EFSA's reputation and the extension of their personal scope was recommended, in another review the 25% threshold was considered too high. We note that there is no uniform approach to this matter among EFSA, ECHA and EMA.
5. Although this was recommended by the European Parliament, EFSA does not have a specific rule obliging academic experts to declare the financial relationship between their university employers and their university employers' commercial partners. In that respect, we observe that ECHA and EMA have more detailed rules in place governing the independence of academic experts.

Declarations of interests

6. EFSA requires its actors to submit their DoI through the dedicated IT tool, with the exception of declarations submitted by tenderers and participants in grant-awarding procedures. The IT tool is recognised as one of the most appreciated features of EFSA's independence policy. External reviews suggest to extend the use of the dedicated IT tool to tenderers and participants in grant-awarding procedures. We note that the malfunctioning of the new IT solution launched in 2021 negatively impacted the independence-related activities carried out by EFSA in 2021 and 2022 and that EFSA did not have any alternative and equally efficient solution in place to carry out the screening of Dols.
7. EFSA does not require purely positive or negative declaration of interests. Instead, EFSA adopts an 'intermediary approach': the declaration of interests' forms are divided in different areas, but it is for the concerned individuals to assess whether they have any relevant interest in those areas. EFSA requires relevant actors to declare the interests which fall within the regulatory field of the Authority.
8. Hearing experts, tenderers and participants in grant-awarding procedures are required to submit declarations of interests. Observers are not required to submit declaration of interests.

Management of conflicts of interests

9. EFSA adopts a mixed system, whereby the automaticity which lays in the blacklist policy governing scientific experts' conflicts of interests is combined with the discretion of the rules governing conflicts of interests of the members of the Management Boards.
10. EFSA has a semi-centralised model which provides for the screening of DoIs at the level of each working group or panel and the validation of such DoIs by the LA Unit. ECHA's approach is mainly decentralised and EMA adopts a decentralised model.
11. For scientific experts, EFSA distinguishes between *unconditional* restrictions, which entail an absolute incompatibility with any scientific activity carried out by EFSA, and *qualified* restrictions, which are only relevant when overlapping with the mandate of the relevant scientific group and for which cooling-off periods apply. Conflicts falling outside the scope of unconditional and qualified restrictions are assessed on a case-by-case basis.
12. The reform of the structure of the Management Board does not raise concerns about EFSA's independence when considering the strict appointment criteria for members of the Management Board and the functional separation between the Management Board and EFSA's scientific activity. Moreover, the diluted voice of members of the Management Board representing the interests of stakeholders prevents undue influence of those interests on EFSA's operations.
13. The declaration of interests of the members of the Management Board are assessed by the Executive Director. Final decisions about conflicts of interests of members of the Management Board are taken by the Management Board itself. We note that the discretion allowed to members of the Management Board is broader than in ECHA and EMA.
14. The enforcement of EFSA's independence policy is based on compliance and veracity checks that are carried out twice a year on random samples of declarations of interests. The omission of information that would have resulted in a finding of conflict of interests is considered a breach of the rules and may cause sanctions that range from a reprimand letter to dismissal from the relevant body or scientific group. We note that the enforcement of EFSA's policy was hindered by the reprioritisation of certain independence-related activities due to COVID-19. The criteria behind such reprioritisation were not made public by EFSA.
15. When a conflict of interests is identified but the participation of the expert to a working group or peer review meeting is essential and cannot be handled through his or her participation as hearing expert, the Executive Director may grant a waiver. The criteria for the granting of a waiver do not appear sufficiently clear and there is no obligation to communicate or publish the decisions granting a waiver.

Declarations of interests and conflicts of interests reported over the period 2018-2022

16. Statistics concerning conflicts of interests screening are not conclusive due to the reprioritisation of some independence-related activities during the COVID-19 pandemic and technical issues linked to the launch of a new IT tool in 2021. We observe that the sectors where conflicts of interests occur more often are 'Animal Health and Welfare' and 'Pesticides'.
17. EFSA has granted waivers in more than half of the cases of CoIs detected over the 2018-2022 period.
18. Conflicts of interests are rare among staff members, who are subject to the Staff Regulations. Over the period 2018-2022, only non-compliance led to the adoption of remedial measures.

Main concerns of the Institutions/bodies about EFSA's independence policies

19. In the context of discharge procedures, the European Parliament has repeatedly invited EFSA to improve its independence policy. It asked EFSA to screen the interest against its overall remit and to introduce every research funded-related Col within the scope of the cooling-off period for research funding.
20. The European Parliament has invited EFSA to align its policies with the recommendations of the European Court of Auditors and the European Ombudsman to strengthen the accounting officer's independence and the setting of criteria to prohibit its senior staff from taking up specific positions after the termination of their jobs. EFSA has not fully complied with these recommendations yet.

Notion of transparency within EU law

21. Transparency is a fundamental principle and value under EU law. EU Treaties require EU institutions and agencies to adopt decisions as openly as possible (Article 1 TEU), in an open, transparent and regular dialogue with representative associations and civil society (Article 11 TEU), and guarantee a right of access to documents held by EU institutions and agencies (Articles 15 TFEU and 42 EU Charter of Fundamental Rights).
22. Transparency entails the visibility of information, activities and actors involved in public decision-making, as opposed to its opaqueness and secrecy. It encompasses an array of features, such as provision of information, access or publication of documents and data, and holding of meetings in public.
23. Transparent information needs not only to be visible but also to be intelligible or comprehensible. It is important not only to disclose certain information, but also to explain it and put the public in the condition to understand its meaning. For regulatory science, transparency of scientific data enables the reproducibility of studies, increasing their epistemic quality and, ultimately, expert accountability through public scrutiny.
24. The principle of transparency has recently evolved from a passive or reactive approach, focused on the right of access to documents, to active or proactive publication. Under the active approach to transparency, EU institutions and agencies are required to systematically publish documents or data, especially in online databases.

EFSA's transparency*Regulatory Framework*

25. Since 2003 EFSA has adopted a number of internal documents and policies to embed the principles of openness and transparency in its work. In 2015, it has committed to an ambitious plan to increase transparency and participation (OpenEFSA). Still, EFSA's transparency policies were strongly criticised by EU institutions, academia and civil society. This led to the adoption of the Transparency Regulation in 2019. EFSA has implemented the legal provisions of this Regulation by means of the Management Board decision of 2020 and the Executive Director's decision of 2021.

Passive Transparency

26. The Transparency Regulation expressly refers to the Access Regulation and to the Aarhus Regulation. EFSA implemented the provisions concerning the right to access to documents

through the adoption of the Management Board's decision of 2020 which aims to give 'the fullest possible effect to the right of public access to documents'.

27. The Management Board's 2020 decision lays down the practical arrangements for the access to documents requests. It contains the exceptions to access to documents, namely the protection of public interest, commercial interests, privacy and a 'space to think' in ongoing decision-making processes. These exceptions are to be interpreted narrowly and appear to be in line with the recent case law of the Court of Justice.
28. The operating procedure and the practical arrangements adopted by EFSA appear in line with the Access Regulation and to the Aarhus Regulation, with the exception of the deadline for the extension of the time limit in case of complex or voluminous applications, which is not specified. We note that instead EMA and ECHA's policies specify a time limit of 15 working days and an extension of 15 working days in exceptional cases, in line with the provisions of the Access Regulation.
29. EFSA is obliged to report annually on access to documents requests, including on the number of requests and whether access was (or was not) granted. EFSA has not consistently complied with this obligation, in particular in its 2022 Annual Activity Report. We note that EMA instead systematically includes an extensive overview of the number of access to documents requests and aggregated data on refusals in its Annual Reports.

Active Transparency

30. Article 38 of the General Food Law, as amended by the Transparency Regulation, contains a list of documents which have to be made public proactively by EFSA. EFSA implemented this provision through the Executive Director's decision of 2021 which specifies the moment of publication for each category of documents, and determines for which categories of documents it is possible to submit a confidentiality request.
31. EFSA has operationalised the provisions of the Transparency Regulation concerning the pre-submission advice and the notification of studies through the creation of the Connect.EFSA portal. The summaries of pre-submission advice and the notified information are then published in the OpenEFSA portal.
32. EFSA publishes the non-confidential version of applications, scientific data, studies or other information part of, or supporting, the application on the OpenEFSA portal once a valid application has been received. EFSA is the only agency providing this systematic publication of studies and data supporting applications, representing the forerunner of proactive transparency of regulatory science.
33. Once the risk assessment has been concluded, EFSA publishes EFSA's scientific outputs, the information on which EFSA's scientific outputs are based, and the scientific studies commissioned by EFSA in the EFSA Journal. The comments received during public consultations are published in the OpenEFSA portal.
34. EFSA publishes annual reports of its activities on its website immediately after their adoption.
35. The EFSA's portals and website are operational, but since further enhancement of EFSA's IT tools is expected by July 2023 a critical assessment of their effectiveness appears premature.

Transparency of EFSA's meetings

36. EFSA publishes the agendas, list of participants and minutes of the Scientific Committee, the Scientific Panels and their working group. The participants' Dols and ADols are also made public. Some of the meetings are open and can be joined by observers upon registration. Observers cannot take part in the discussion, but they can ask questions at the end of the meeting.
37. EFSA publishes the agendas, list of participants and minutes of the meetings of the Management Board, Advisory Forum and EFSA's networks. The participants' Dols and ADols are also made public. The meetings of the Management Board can be observed by the public upon registration. The recordings of these meetings are available online. We note that EFSA ensures a higher level of transparency of Management Board's meetings than EMA and ECHA.

Protection of personal data

38. Transparency of EFSA's documents can be limited for the protection of personal data. However, the names of the applicant, of the authors of published or publicly available studies, of all participants and observers in meetings are made public, except in the case of involvement in testing on vertebrate animals or in obtaining toxicological information. This is in line with the recent case law of the Court of Justice.

Protection of confidentiality

39. Any natural or legal person can submit a confidentiality request to EFSA in order to avoid the disclosure of certain information. Article 39(2) General Food Law now specifies the items of information for which a confidentiality request can be submitted. Protection is granted only if the applicant can prove that the disclosure of certain information may potentially harm its interests to a significant degree. According to EFSA's Executive Director's 2021 decision, the disclosure of certain information is presumed not to harm the applicant to a significant degree if the potential harm affects less than 5% of the gross annual turnover for legal persons, or the gross annual earnings for natural persons; if the document is publicly available; and if it was finalised more than 5 years before the confidentiality request.
40. Even when the significant harm of the disclosure is demonstrated, EFSA has discretion to disclose the information where urgent action is essential to protect human health, animal health or the environment. The relation between the disclosure due to these reasons and the 'overriding public interest' allowing access to documents has not been clarified in EFSA's practical arrangements.

Main concerns of the Institutions/bodies about EFSA's transparency policies

41. On 22 May 2022, the European Ombudsman has found a case of maladministration in the handling of an access to documents request. EFSA took more than seven months to reply to the applicant. The European Ombudsman recommended to EFSA to introduce a time limit of 15 working days for the extension of the deadline for exceptional cases. Moreover, the European Ombudsman recommended to EFSA that, when it considers that a request is formulated in broad terms, it should provide the applicants a list of documents at an early stage, to enable applicants to clarify their requests. We note that EFSA has not implemented these recommendations yet.
42. The European Parliament has repeatedly called EFSA to strengthen its policies regarding transparency and, especially after the glyphosate case, to facilitate full disclosure of the

scientific evidence used in risk assessment. These concerns have now been addressed by the Transparency Regulation and implemented by EFSA in its policies on proactive publication of information, studies, documents and data.

43. The European Parliament has also encouraged EFSA to improve its transparency policies in relation to some specific aspects, namely the publication of CVs of EFSA's staff members, and the engagement with stakeholders, especially representatives of civil society. In line with the European Ombudsman's and scholars' calls, the European Parliament has stressed the importance of the user-friendliness of EFSA's website and the accessibility of data published online.

4.2. Recommendations

A. Definitions of conflict of interests, experts and external experts

1. From a terminological perspective, the use of the word *interests* rather than *interest* is more accurate, since the notion of conflict requires at least two different interests which are incompatible with each other and thus conflict. The definition provided by EFSA should expressly cover potential conflicts. Moreover, to improve clarity, it should provide precise definitions and examples to describe each of its elements (e.g., actual, potential and perceived interests). Finally, especially in light of the amendments made by the Transparency Regulation, foreseeing a greater collaboration with national scientific organisations, the definition of Col should expressly include national interests and political pressure.
2. To avoid confusion in relation to the application of the rules on the prevention and management of conflicts of interests to the various kinds of experts EFSA resorts to, EFSA should adopt a precise definition of 'expert' and 'external expert' and ensure the consistency of its internal documents and website.

B. Scope of EFSA's independence policy

3. EFSA should consider providing for 'intermediate' solutions that allow for regimes of reduced participation (e.g., participation as hearing experts or exclusion from chairship, vice-chairship, rapporteur, etc.) in presence of 'minor' Cols. This would require EFSA to adopt a clear and reasoned definition of what constitutes a 'minor' Col.
4. EFSA should more clearly define the rules applicable to the experts of organisations listed in Article 36 GFL who participate in the preparation of EFSA's opinions. This would help ensuring the actual and perceived consistency of EFSA's independence policy. EFSA should more clearly define and publicise the rules and standards applicable to members of scientific networks. EFSA should screen the Dols of hearing experts.
5. Further explanation about the threshold and length of the cooling-off period for research funding would be desirable, especially considering that EFSA has opted for the shortest cooling-off period among the agencies which adopt cooling-off periods.
6. EFSA should consider strengthening its policy and introduce specific rules for the declaration of financial relationships between their university employers and their university by academic experts. The policies adopted by ECHA and EMA can be of example.

C. Management of conflicts of interests

7. EFSA should consider increasing the automaticity of its decision making in relation to Col while simultaneously broadening the possible forms of 'intermediate' participation in EFSA's activities.
8. The criteria for the granting of waivers should be further clarified. The precise meaning of 'essential for the completeness of the draft output' is not sufficiently defined. The DCIM should moreover include an obligation to inform the other experts belonging to the working group of the waived expert when a waiver is granted. Although waivers are recorded in the minutes of the meetings and in the ensuing scientific output, decisions granting a waiver should also be published
9. EFSA should extend the use of the IT tool to tenderers and participants in grant-awarding procedures. More importantly, EFSA should ensure that its independence-related activities are not undermined by possible shortcomings of the IT tool.
10. EFSA recognise a wide margin of discretion to its Management Board in the management of its own Cols. In light of the new structure of the Management Board, which envisages more members and representatives of Member States and stakeholders, the reduction of such discretion may be desirable. EFSA should adopt a specific policy for its Management Board and increase the degree of automaticity of decisions. Moreover, following the example of ECHA, EFSA should ensure the involvement of the appointing authority – the Council – in the decisions concerning Cols of stakeholders' representatives.

D. Transparency of independence-related matters

11. EFSA should publish the pre-defined CVs of its key actors, such as the Executive Director, the members of the Management Board and scientific experts, as recommended by the Commission and in line with the practice of ECHA and the rules of EMA. This would facilitate control by citizens or NGOs and is even more important when considering the new structure of the Management Board introduced by the Transparency Regulation.
12. EFSA should consider adopting specific rules concerning the publicity of meetings of the members of the Management Board, the Executive Director and senior staff with interest representatives.
13. EFSA should comply with the indication of the European Parliament and align its rules with the Ombudsman's recommendation to set out of criteria for the adoption of a measure prohibiting senior staff from taking up positions after their term-office, preventively communicate these criteria to applicants for senior positions and adopt internal procedures to restrict access to confidential information once a staff member moves to another job.
14. More transparency about the reprioritisation criteria adopted during the COVID-19 pandemic would have been desirable in order to communicate to the public how independence-related concerns were dealt with throughout the pandemic. In case of future pandemics or crises, transparency on re-prioritisation is needed.

E. Passive Transparency

15. EFSA should include in its practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006 a provision on the time limit for dealing with access to documents requests and on the maximum extension of the time limit in exceptional cases. In line with the Access Regulation and the recommendations of the

European Ombudsman, the time limit for dealing with requests and for the extension should amount to a maximum of 15 working days.

16. As recommended also by the European Ombudsman, EFSA should add in its practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006 a provision clarifying that, when it considers that a request is formulated in broad terms, it shall inform applicants about the specific documents it has identified in connection to the request, providing them with a list of the specific documents at an early stage. This will give applicants the possibility to clarify the request and possibly avoid delays in the reply.
17. EFSA should improve its reporting activities in relation to access to documents requests. It should publish a report or include a dedicated section in its annual report on access to documents requests, including not only the number of requests but also the reasons for the refusals of requests.

F. Active Transparency

18. EFSA should continue to apply its transparency policies in line with the Transparency Regulation and proactively publish information, studies and data to remain at the forefront of proactive transparency among EU agencies. Moreover, EFSA should complete the programmed IT tools enhancement and optimize the digital tools available to stakeholders.
19. EFSA's legal framework strikes an adequate balance between the protection of confidential information and the public interest in disclosure. However, EFSA should consider elaborating further on the notion of 'information which is relevant to the assessment of safety' and its relation with the disclosure of confidential information for 'overriding public interest' under the Access Regulation. Furthermore, more information could be given on the choice to adopt 5% of the gross annual turnover as the threshold for proving 'harm to a significant degree'.
20. EFSA should maintain its practice to hold the Management Board's meetings and certain Scientific Committee and scientific panels' meetings in public since this ensures a high level of transparency of its activities. However, EFSA should consider developing and publishing a document outlining clear criteria and principles to be used when deciding whether Management Board's meeting and scientific meetings should be held in closed sessions.

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ANNEX 1: DECLARATIONS OF INTERESTS

Table 2: EFSA's staff members' Dols

	Dols screened	Cols identified and prevented
2022	384	0
2021	67	0
2020	375	1
2019	393	1
2018	380	0

Source: Authors' own elaboration on the basis of the data available in EFSA's consolidated annual reports.

Table 3: EFSA's Management Board members' Dols

	Dols processed	Former MB members' Dols published
2022	78	4
2021	17	2
2020	18	6
2019	17	4
2018	23	4

Source: Authors' own elaboration on the basis of the data available in EFSA's consolidated annual reports.

Table 4: EFSA's Selection Boards⁶⁰⁹ and recruitment procedures

	Selection boards members' Dols processed	Pre-selected candidates' Dols screened	Pre-selected candidates' Cols identified	Pre-selected candidates requiring the adoption of ordinary mitigating measures
2022	128	101	0	Yes
2021	138	101	1 ⁶¹⁰	Yes
2020	86	108	0	Yes
2019	n/d	46	0	Yes
2018	n/d	45	0	Yes

Source: Authors' own elaboration on the basis of the data available in EFSA's consolidated annual reports.

⁶⁰⁹ Selection Boards for the selection procedures for vacant positions as EFSA statutory staff members.

⁶¹⁰ Resulting in non-recruitment.

Table 5: EFSA’s procurement and grant awarding procedures

	Institutional Dols screened	Individual Dols screened	Cols identified and prevented
2022	90	420	0
2021	279	566	3
2020	74	390	0
2019	59	179	5
2018	20	50	0

Source: Authors’ own elaboration on the basis of the data available in EFSA’s consolidated annual reports.

Table 6: Former staff members leaving EFSA and wishing to engage in occupational activities

	Applications evaluated (private sector)	Applications identified as overlapping with EFSA’s task	Restrictions applied
2022	7 (2 ⁶¹¹)	5	0
2021	13 (5 ⁶¹²)	8	5
2020	10 (5 ⁶¹³)	8	3
2019	14 (9 ⁶¹⁴)	0	0
2018	6 (1 ⁶¹⁵)	0	0

Source: Authors’ own elaboration on the basis of the data available in EFSA’s consolidated annual reports.

⁶¹¹ Companies providing consultancy services; industry founded organisation active in the research and collecting and sharing information about sugar and food in relation to nutrition and human health.

⁶¹² Companies providing consultancy services; industry founded non-profit organisation active in food safety; agrochemical and industrial chemical company; clinical-stage biotechnology company; foundation whose mission is to prevent the youth from smoking.

⁶¹³ Pharmaceutical company, food company, companies providing consultancy services, non-profit network composed by scientists and scientific organisation concerning food safety.

⁶¹⁴ IT private firm; companies providing consultancy services; private firm specialised in the development and marketing of innovative medicines; private firms providing recruitment services; private firm providing workforce project management and consulting solutions; private Engineering and Validation services company.

⁶¹⁵ Research organisation.

Table 7: EFSA's enforcement activities

	Compliance and Veracity checks carried out	Minor non-compliances identified	Non-compliances requiring the adoption of remedial measures	Breaches of applicable rules	Measures adopted
2022	2	18	0	2	2 ⁶¹⁶
2021	1	5	0	2	2 ⁶¹⁷
2020	n/d ⁶¹⁸	0	0	1	1 ⁶¹⁹
2019	2	8	0	1	1 ⁶²⁰
2018	2	17	1 ⁶²¹	0	0

Source: Authors' own elaboration on the basis of the data available in EFSA's consolidated annual reports.

Table 8: Awareness-raising and training sessions delivered by EFSA

	Training sessions for Dols assessors and validators	e-training modules	Training sessions for scientific panels' members	Training sessions for EFSA procurement team	Training sessions for all staff members	Training sessions for administrative staff
2022	11	0	1	0	0	1
2021	3	0	0	0	0	0
2020	0	1	0	0	0	0
2019	1	2	11	1	0	0
2018	2	1	0	1	1	0

Source: Authors' own elaboration on the basis of the data available in EFSA's consolidated annual reports.

⁶¹⁶ Reprimand letters.

⁶¹⁷ Reprimand letters.

⁶¹⁸ Suspended as a result of an internal reprioritisation exercise connected to the immediate impact of COVID-19.

⁶¹⁹ Reprimand letter.

⁶²⁰ Not specified.

⁶²¹ Review of the relevant scientific output by EFSA's Legal and Assurance Services.

Table 9: Organisations classified as ‘public institutions’ by EFSA

	Organisations classified
2022	70
2021	171
2020	457
2019	360
2018	514

Source: Authors’ own elaboration on the basis of the data available in EFSA’s consolidated annual reports.

ANNEX 2: CONFLICTS OF INTERESTS 2018-2022

Table 10: Competing interests identified and prevented by sector (i)

	Animal Health and Welfare	Biological Hazards	Communications Engagement & Cooperation	Contaminants	Feed	Food Additives and Flavourings	Food Contact Materials, Enzymes and Processing Aids
2022	3	0	0	0	0	0	0
2021	6	0	0	0	1	0	0
2020	17	3	1	0	0	1	0
2019	3	5	1	1	0	2	0
2018	3	1	0	2	2	1	3
Total	36	9	2	3	3	4	3

Source: Authors' own elaboration on the basis of the data available in EFSA's consolidated annual reports.

Table 11: Competing interests identified and prevented by sector (ii)

	Front-Desk & Workforce Planning	GMOs	Nutrition	Pesticides	Plant Health	Plant Protection Products and their Residues	Scientific Committee
2022	1	0	0	2	0	0	1
2021	0	1	0	1	0	0	0
2020	0	2	0	4	0	0	3
2019	0	0	0	17	0	0	2
2018	0	2	4	4	4	4	2
Total	1	5	4	28	4	4	8

Source: Authors' own elaboration on the basis of the data available in EFSA's consolidated annual reports.

ANNEX 3: ELEMENTS OF COMPARISON BETWEEN EFSA, ECHA AND EMA

Table 12: Elements of comparison between the independence policies of EFSA, ECHA and EMA

	EFSA	ECHA	EMA
Temporal scope of the independence policy	5 years	5 years	3 years
Material scope of the independence policy	Dols are screened against the specific mandate of each scientific group	Interests not relevant to the work of the respective body are deemed as 'cleared'	Declared interests are assessed against the specific agency's activity in which the expert is involved
Cooling-off periods for research funding	2 years for private research funding exceeding 25% of the expert's total budget	5 years for private research funding from a commercial entity exceeding 25% of the expert's total budget, limited to decision-making directly concerning that commercial entity	No
Col management system	Semi-centralised	Mainly decentralised	Decentralised
Degree of automaticity of Col management decisions	Mix of automaticity and discretion	Semi-automatic	Mostly automatic
Rules concerning the publicity of meetings between the members of the Management Board and senior staff with interest representatives	No	The Executive Director and other staff shall publicly register meetings with interest representatives.	The Executive Director and other staff shall meet only with interest representatives registered in the Transparency Register
Rules on publication of CVs of key actors	No	No	Yes

Source: Authors' own elaboration.

Table 13: Elements of comparison between transparency policies (active publication) of EFSA, ECHA and EMA

	EFSA	ECHA	EMA
Agendas and list of participants of Management Board's meetings	Yes	Yes	Yes
Agendas and list of participants of scientific meetings	Yes	Yes	Yes
Minutes of Management Board's meetings	Yes	Yes	Yes
Minutes of scientific meetings	Yes	Yes	Yes
ADols and ODols of Management Board's members	Yes	Yes	Yes
ADols and ODols of scientific experts	Yes	Yes	Yes
Annual reports	Yes	Yes	Yes
Pre-submission questions and advice	Summary	Summary	n.a.
Public consultations	Yes	Summary	Yes
Applications	Yes	List	Yes
Scientific data, studies, and other information supporting applications or requests	Yes	Only clinical trials	Summary or robust summary
Scientific outputs	Yes	Yes	Yes

	EFSA	ECHA	EMA
Information on notification of studies	Yes	Only clinical trials	n.a.

Source: Authors' own elaboration.

This study has been commissioned by the European Parliament's Policy Department for Economic, Scientific and Quality of Life Policies, Directorate-General for Internal Policies at the request of the ENVI Committee. It analyses EFSA's independence and transparency policies and examines how legislative provisions have been implemented by EFSA and whether rules and practices adopted by EFSA can be improved.

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