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# EU Expert Bodies in Light of the Glyphosate Saga and the Dieselgate Scandal

# Cross-Sectoral Lessons to Be Learned in the Era of Emerging Risk Factors and Constant Crisis Management?<sup>2</sup>

Several scandals shed light on the eroding capacity and legitimacy of the Single Market's scientific decision-making in the current era of constant economic, environmental and societal challenges when the need for solid science has never been greater. A sector-specific nature still characterises the EU law and the Single Market competencies. Yet, the emerging relevance of the EU law's horizontal evolution inevitably leads us to the cross-sectoral elements of EU expert bodies and scientific decisionmaking. The purposes of this paper are 1. to describe the evolution of EU expert bodies with the comparison of two relatively diverse policy areas of the EU's food sector and transportation, which are similarly characterised by the scandals of the glyphosate saga and the Dieselgate scandal; 2. to explore the sector-specific elements of the scientific decision-making of these policy areas, while potentially identifying some cross-sectoral lessons to be learned.

**Keywords:** expert bodies, glyphosate saga, Dieselgate, expertisation, risk assessment and management, EU Agencies

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### The Evolution of EU expert bodies and scientific decisionmaking

Parallel to the expansion of the European Union's (EU) competencies, the involvement of high-level experts intensified in the EU's decision-making, especially in executive decision-making, which led to the creation of diverse models of expert bodies within the European Union. This process intensified in formulating and reformulating technical norms, policy documents, and further soft law sources related to EU legislative acts, as being highly relevant in creating the single market's harmonised regulation. In a broader context, the technocratic decision-making of the EU, epistemic as well as democratic worries about these processes, increased debates on the subjective and politicised science in academia.3 Several scandals shed light on the eroding capacity and legitimacy of the Single Market's scientific decision-making in the current era of constant economic, environmental and societal challenges when the need for solid science has never been greater.4 A sector-specific nature still characterises the EU law and the Single Market competencies. Yet, the emerging relevance of the EU law's horizontal evolution with the Commission's green and digital transition plan, or the Charter of Fundamental Rights-based cross-sectoral interpretation of the CJEU,5 inevitably leads us to the issue of cross-sectoral elements of EU expert bodies and scientific decision-making. The purpose of this paper is twofold: 1. to describe the evolution of EU expert bodies with the comparison of two relatively diverse policy areas of the EU's food sector and transportation, which are similarly characterised by the scandals of the glyphosate saga and the Dieselgate scandal; 2. to explore the sector-specific elements of the scientific decision-making of these policy areas, while potentially identifying some cross-sectoral lessons to be learned.

In terms of terminology (and practical methodology), the paper is based on the dichotomy of *risk assessment* vs. *risk management* with the main emphasis on risk assessor expert bodies of the EU, which theoretically are to provide scientific advice of the highest possible quality and objectivity by independent experts. Eyet, the interrelatedness of the assessors' and managers' positions inevitably leads to some risk management-related considerations.

#### Risk assessment vs. risk management

In general, two consecutive stages of science-based decision-making are to be separated and defined: the *risk assessment* as a scientific process that requires the identification and characterisation of a hazard, the assessment of exposure to the danger and the

EVERSON 2021: 144–161; HOLST-MOLANDER 2021: 647–665; GUÉGUEN-MARISSEN 2022; VOLPATO-OFFERMANS 2023: 253–270.

<sup>&</sup>lt;sup>4</sup> Falyuna–Krekó 2022: 15–36; Guéguen–Marissen 2022: 1.

Bonelli et. al 2022; Frantziou 2019; Widdershoven 2019: 5–34.

In broader context of risk regulation issues of law enforcement see CSABA-GECSEI 2021: 129–142.

characterisation of the risk<sup>7</sup> (assessment of the magnitude of the risk by experts and expert bodies),<sup>8</sup> while *risk management* as a technically later stage of scientific decision-making by policy-makers to determine the acceptable risk level for the society based on the outcome of the assessment.<sup>9</sup> Yet, other regulatory regimes, such as the ISO,<sup>10</sup> might follow a diverse approach.<sup>11</sup> The paper applies the three-element approach of Morvillo to both the Diselgate and glyphosate cases, which elaborates on the sources, the levels and the purposes of knowledge-making as the primary basis for tensions in the EU authorisation processes.<sup>12</sup> Firstly, the *sources* element refers to the precise requirements to be laid down, the scientific sources of which must be applied in risk assessment to have scientific advice of the highest possible quality and objectivity. Secondly, the *levels* refers to a clear set of competencies (Member States vs. EU-level actors) in risk assessment and management tasks. Thirdly, the *purposes* side reaffirms the need to have clear policy goals concretised in the related regulation to divide the roles of risk assessor and manager and avoid the blurred lines in their positions and accountability.<sup>13</sup>

#### The evolution of EU expert bodies

From an institutional point of view, the EU-level capacity of scientific expertise has been initially built up concerning the Commission, which could guarantee the administrative support and background for the functioning of such bodies (*in-house expert bodies*). <sup>14</sup> Yet, the list of Commission expert groups and similar entities is much broader <sup>15</sup> today, from which we present the sectorally most relevant ones:

The *Joint Research Centre* (JRC) has already been established under the Euratom Treaty as the leading actor of the Commission's in-house scientific capacity. However, much of its work relates to several other policy areas. The JRC operates as a separate Directorate-General (DG) with priorities set by the Commission President while having its own resources and strategic work plan. <sup>16</sup>

Furthermore, *Chief Scientific Advisors*, as particular risk assessors, are appointed in their personal capacity, acting independently and in the public interest (selected by an independent identification committee assisting the Commission in selection) to support the Commission by providing scientific advice on various topics. These advisors, having a 3-year extended mandate (renewable only one with a maximum timespan of 5 years), work closely with the Scientific Advice for Policy by European Academies (SAPEA)

STERN-FINEBERG 1996.

<sup>&</sup>lt;sup>8</sup> T-13/99, Pfizer Animal Health v Council, para 156.

<sup>&</sup>lt;sup>9</sup> Guéguen-Marissen 2022: 9.

<sup>&</sup>lt;sup>10</sup> International Organization for Standardization – ISO 2018.

The ISO's system applies risk management as the broader category including risk identification, risk analysis, risk evaluation followed by the management decision also involving at the end of this cycle risk treatment, eventually risk mitigation (AVEN 2016: 1–13).

<sup>&</sup>lt;sup>12</sup> Morvillo 2020: 427–431.

<sup>&</sup>lt;sup>13</sup> Morvillo 2020: 427–430.

Guéguen-Marissen 2022: 1.

<sup>&</sup>lt;sup>15</sup> European Commission – EC 2023b.

Guéguen-Marissen 2022: 14.

consortium, which gathers expertise in engineering, humanities, medicine, natural and social sciences from over 100 academies and societies across Europe. Together with a secretariat in the Commission's research and innovation department, the advisors and SAPEA are collectively known as the *Scientific Advice Mechanism* (SAM).<sup>17</sup>

Comitology committees consist of one representative per Member State, technically acting as specialist bodies when the Commission has been granted implementing powers in the text of a law. Their daily functioning depends on the Commission, which prepares the draft version of implementing acts to be submitted to these committees for their opinion, having the comitology committee meetings in Commission premises several times a year, and providing secretarial support for these actors. Regarding the assessment vs. management dichotomy, the comitology committees are risk managers, which determine the policy choices on acceptable risks like the glyphosate-related PAFF (standing committee on Plants, Animals, Food and Feed with national representatives) committee. 18

As a further form of risk assessor expert bodies, *EU (decentralised) agencies* have been created as a response to (scientific) crises originating from the inadequate risk assessment (and crisis management) at the national level combined with the lack of such capacities at the EU level. This has marked a new era with a shift of implementation competencies of EU policies towards relatively independent EU agencies<sup>19</sup> separated from the many times too bureaucratic, too politicised, and too generalist functioning of the Commission.<sup>20</sup> The agencification process reached its most intensive period in the 2000s as new EU agencies were established (or 'upgraded') with substantial capacities in scientific decision-making (European Food Safety Authority – EFSA in 2002; European Chemicals Agency – ECHA in 2007; European Medicines Agency – renamed as EMA in 2004). In this regard, the creation of EFSA as a significant actor in the glyphosate saga has been part of the crisis-driven agencification after the scientific mishandling of the BSE crisis of the 1990s.

Even if their number and powers conferred upon them increased substantially in the last decades, EU agencies have no detailed (sector-neutral) Treaty basis (incomplete constitutionalism).<sup>21</sup> The CJEU solved this problem in its judgments (ESMA – C-270/12) by referring to agencies as (functional) EU entities created by the EU legislature without having a considerable measure of discretion (limited by other actors and judicial review guaranteed before the CJEU).<sup>22</sup> Regarding the scientific side, the agencies' position has been reinterpreted in light of the ESMA judgment. This judgment concluded that any task conferred upon the Commission that cannot be carried out due to the lack of technical expertise could be left to EU agencies, stressing the agencies' primary role to function as bodies of technical expertise.<sup>23</sup>

European Commission – EC 2021.

European Commission – EC 2023a.

<sup>&</sup>lt;sup>19</sup> Kaeding-Versluis 2014: 73-87.

<sup>&</sup>lt;sup>20</sup> Everson-Vos 2021a: 26; Keleman 2002: 112.

<sup>&</sup>lt;sup>21</sup> Everson-Vos 2021b: 319-328.

<sup>&</sup>lt;sup>22</sup> EVERSON-Vos 2021a: 31-37.

<sup>&</sup>lt;sup>23</sup> Everson–Vos 2021a: 35.

The agencies, also called 'inbetweeners', have their potential inside a triangle consisting of EU institutions, national authorities and market participants. <sup>24</sup> Regarding the relationship with the Commission, the single commissioners do not function as a centralised ministerial administration. However, the Commission could have a substantial impact on the agency's work by influencing its staffing policy or initiating its budget proposals. The EU agencies recently started to refer to certain DGs as 'partners' in their reports. <sup>25</sup>

The actors of the abovementioned triangle resemble the agency's internal structure as well. Their management boards, primarily consisting of the representatives of Member States, are the central decision-making bodies with further involvement of representatives of the Commission, the European Parliament and other stakeholders. <sup>26</sup> Even if the national representatives have various integrity requirements related to their tasks based on the Treaties, the EU Staff Regulation, and the sector-specific laws that prioritise EU interest, in practice, the national or stakeholders' interests might overrule that of the Union. <sup>27</sup> Therefore, some EU agencies already follow modified internal structures and decision-making procedures. <sup>28</sup>

In the evolution of EU expert bodies, several forms occurred during the integration with less independent (Commission-related) 'in-house' bodies like JRC, SAM, or the comitology committees, and later with the more independent institutional forms of EU (decentralised) agencies. Yet, such bodies' independence and 'scientific performance' also rely on the policy framework many times shaped and reshaped by the EU's crisis-driven institutional evolution.

# The scientific decision-making concerns in the Dieselgate

Dieselgate and the aftermath of the greatest scandal in automotive history

A multi-layered set of EU norms has been enacted over the last decades to establish a harmonised framework for the approval of motor vehicles to facilitate their common registration, sale and entry into service within the Single Market. According to Directive 2007/46, the car manufacturer is primarily responsible for the (national) approval

<sup>&</sup>lt;sup>24</sup> EVERSON et al. 2014: 4.

<sup>&</sup>lt;sup>25</sup> EGEBERG et al. 2014: 620–624.

<sup>&</sup>lt;sup>26</sup> Common Approach Point 10.

<sup>&</sup>lt;sup>27</sup> Vos 2014: 26.

The European Food Safety Authority already had a smaller management board of 14 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission, from whom four members shall have their background in organisations representing consumers and other interests in the food chain (Regulation 178/2002 Article 25.), which has been changed due to the GFL Reform.

process at the national regulatory authority, including all aspects of the approval process and ensuring production conformity. Several further provisions have been added to this directive with technical details, such as the Commission's emission requirements.

The shortcomings of the EU's regulatory system, combined with the deficiencies of the enforcement side, were revealed during the so-called Dieselgate of 2015 as the greatest scandal in the history of the European automotive industry. A small group of graduate students from the U.S. West Virginia University (WVU), supported by an NGO (the International Council for Clean Transportation – ICCT), began investigating "clean diesel" introduced to the U.S. market by conducting real-world driving tests on various European car models. They revealed that the software of several diesel engine models could detect defeat devices when the models were being tested under laboratory circumstances and accordingly adjust the car's emissions to minimum requirements, which has been noticed by the United States Environmental Protection Agency (US EPA) and the California Air Resources Board (CARB) for the European partners.

As a result, the European Parliament established a special committee, which issued an Inquiry Report (EP Dieselgate Report) in 2017. The primary deficiencies identified by this report included the failures in testing procedures, systemic severe concerns about the EU's type approval and in-service conformity provisions, the lack of transparency and further checks after type approval granted, the lack of specific EU-level oversight of the vehicle type approval and the weak enforcement powers of the Commission. The related EU reform steps remained relatively weak without creating a new EU road transport agency. Instead, the EU legislator increased the management of the Commission and national authorities and introduced a new testing procedure and requirements. The second second

## The data sources in automotive industry-related scientific decision-making – Towards a more realistic test cycle?

Regarding *sources* of scientific knowledge (and risk assessment), the fraudulent practice of the car manufacturer has its root causes in the significant deficiencies and loopholes of the former testing procedure.

It was identified long ago that there were substantial discrepancies between laboratory tests and real-world emission measures of the New European Driving Cycle (NEDC) introduced in the 1990s, and concerns were not limited to the VW vehicles equipped with prohibited defeat devices. NEDC has been designed to be performed under laboratory circumstances with defined parameters (time and distance of the test cycle with fixed driving phases combined with the criteria of average and maximum speed) not reflecting

<sup>&</sup>lt;sup>29</sup> Frigessi di Rattalma – Perotti 2017: 179–217; Mujkic–Klingner 2020: 611–620.

<sup>30</sup> Bovens 2016: 262.

<sup>&</sup>lt;sup>31</sup> European Parliament – EP 2017.

European Court of Auditors – ECA 2019.

on the (real) road driving conditions.<sup>33</sup> The car manufacturers exploited several flexibilities under the NEDC test cycle, like vehicle test mass, adjustment of brakes, tire specification and tire pressure, and running temperature.<sup>34</sup> Introducing new requirements with real driving emission rules (RDE) and the 'Worldwide Harmonised Light Vehicles Test Procedure' (WLTP) has only been decided as of 2017 to replace the obsolete NEDC.<sup>35</sup>

Additionally, clear concerns have been revealed about how these cycles were performed, as the Member States relied heavily on the tests performed in the car manufacturers' certified laboratories only under the supervision of national technical services. This also included consultancy services to car manufacturers on obtaining type approval. There was an apparent conflict of interest due to an additional financial link, as the national authorities were only kept responsible for validating the procedure at the end.<sup>36</sup>

Under such circumstances, the detection of defeat devices could have remained unnoticed – yet the EU-level expert bodies made clear signals for policy-makers in due time. The JRC started on-road testing of light-duty vehicles with portable emission measurement devices in  $2007^{37}$  and signalled in 2011 that there was a significant discrepancy between car emissions under laboratory conditions and those observed on the road. <sup>38</sup> Its 2013 report formulated the general policy goal to decrease the use of defeat devices as far as possible. <sup>39</sup> The 2016 SAM report showed that the  $CO_2$  emissions gap between type approval figures and those registered on the road could be greater than 50% in some instances, which, according to the JRC, could be reduced by introducing new WLTP cycles. <sup>40</sup> In this regard, the Commission's 'in-house' expert bodies have detected the risk of inconsistent testing procedures, the objectively fraudulent use of defeat devices, and the clear need for sound data sources, even publicly mentioned by some commissioners. <sup>41</sup> Moreover, the EU must move towards an even broader standard methodology to assess the entire life cycle of  $CO_2$  emissions of cars as a Green Deal goal. <sup>42</sup>

## The competence levels in automotive industry-related scientific decision-making – Nobody's baby?

Regarding *competence levels*, the automotive industry is primarily based on a national-level type approval process, in which authorities provide accreditation to technical services in

European Court of Auditors – ECA 2019: 23.

European Court of Auditors – ECA 2019: 22.

European Parliament – EP 2017: 5.

<sup>&</sup>lt;sup>36</sup> European Parliament – EP 2017: 12.

FRIGESSI DI RATTALMA – PEROTTI 2017: 207.

<sup>&</sup>lt;sup>38</sup> Weiss et al. 2011.

<sup>&</sup>lt;sup>39</sup> Weiss et al. 2011: 31.

Scientific Advice Mechanism – SAM 2016: 27.

FRIGESSI DI RATTALMA – PEROTTI 2017: 195.

EUObserver 2023.

charge of testing new vehicles.<sup>43</sup> The EP Dieselgate Report pointed out several faults in the EU's composite administration, such as the different capacities of the national type approval authorities, which led to *forum shopping* by car manufacturers.<sup>44</sup> Additionally, severe concerns regarding in-service conformity and the lack of real EU-level powers related to enforcement and penalties have been identified.<sup>45</sup> The Report also noted that no national authority could find the defeat devices, particularly those Member States whose authorities type approved those vehicles.<sup>46</sup> The Commission neither undertook any further technical or legal research or investigation on its own or by mandating the JRC nor requested any additional information.<sup>47</sup>

The obvious implementation concerns related to the Member State-level market fragmentation have been addressed with increased powers given to national authorities, new rules for in-service conformity checks, and broadened market surveillance activities. The Commission may suspend and withdraw type approval and impose penalties on manufacturers. At the same time, it shall conduct compliance verifications with on-road and laboratory tests and perform inspections and assessments of approval authorities. The control of the contro

The post-scandal reform still focused on national-level authorities and technical services, even if the manufacturers' mandatory reporting and national authorities' checks regarding in-service conformity have also been enacted. Market surveillance will be performed at the national level (separated from type approval sources) and by the JRC's VELA (Vehicle Emissions Laboratories). As a result, the JRC new report already pointed out in 2022 above 90% pass rate in the framework of in-service-conformity checks and market surveillance testing; yet, defeat devices were found primarily for gasoline vehicles. <sup>50</sup>

Many NGOs $^{51}$  would have preferred emissions testing to be carried out by (more) independent environmental authorities, as in the United States, where the U.S. EPA conducts market surveillance and enforcement activities at the federal level. JRC's special VELA laboratories are accredited as WLTP and RDE test laboratories following integrated management and scientific integrity statements. $^{52}$  However, only some environmental authorities have such status in the EU. $^{53}$ 

To ensure better coordination and avoid further market fragmentation and *forum* shopping, an Implementation Forum has been established within the Commission to

Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No. 715/2007 and (EC) No. 595/2009 and repealing Directive 2007/46/EC, OJ L 151, 14.6.2018.

European Parliament – EP 2017: 11.

European Parliament – EP 2017: 13–14.

European Parliament – EP 2017: 9.

European Parliament – EP 2017: 10.

European Court of Auditors – ECA 2019: 17.

European Court of Auditors – ECA 2019: 9–10.

<sup>50</sup> BONNEL et al. 2022.

<sup>&</sup>lt;sup>51</sup> VCD 2015.

<sup>&</sup>lt;sup>52</sup> JRC VELA 2022.

European Court of Auditors – ECA 2019: 30.

promote best practices and harmonise implementation in Member States. This new body has members as representatives of national authorities and also involves the broader circle of interested parties (economic operators, safety and environmental stakeholders). The Forum may issue soft law opinions and recommendations within its advisory capacity. For Interestingly, no new EU road transport agency has been created, even if the railway, maritime and air traffic subsectors already had this kind of (more independent) EU-level actor. At the same time, the U.S. EPA's (and its CARB's) influence was demonstrated just at the beginning of the Dieselgate.

## The purposes of scientific decision-making related to the automotive industry

The *purpose* of clearly identifying underlying risks related to the automotive industry has been realised by risk assessors as the Commission's 'in-house' expert bodies identified the leading technical causes of the Dieselgate in due time. In a narrower context, the scandal revealed the car manufacturers' fraudulent practices and the deficiencies of national-level risk assessors with the relatively weak set of powers provided to the Commission and its expert bodies. The JRC VELA's capacity to conduct market surveillance activities and national-level bodies demonstrated the right direction of post-scandal reforms to address these concerns.

The risk management has proven even more problematic, as several much-needed policy steps have been hindered. Certain Member States prevented the formation of a QMV in the Real Driving Emissions – Light Duty Vehicles" (RDE-LDV) working group, delaying introducing a more ambitious Commission proposal for conformity factors in case of emission limits. There was an apparent conflict of interest in the representation of the RDE-LDV working group consisting mainly of experts from car manufacturers (and other automotive industries) without ensuring a balanced picture of the policy area. Better coordination between the different Commission services involved (including the JRC) could have been instrumental in accelerating the process of adapting the new test cycles. Even when the latest emission standards have been enacted, the Commission's related regulation granted a technical waiver for car manufacturers due to 'statistical and technical uncertainties' during RDE tests. The European Court of Auditors also pointed out in 2019 that car manufacturers might find new flexibilities in the WLTP laboratory tests to lower their CO<sub>2</sub> emissions. The European Court of Politicisation membership, the new Implementation Forum still functions with a risk of politicisation

European Parliament legislative resolution of 19 April 2018 [P8\_TA-PROV(2018)0179] Article 11.

European Parliament – EP 2017: 6–7; The JRC Report has proposed the finalisation of new test procedure until December 2013 (JRC Report, 2).

<sup>&</sup>lt;sup>56</sup> European Parliament – EP 2017: 8.

<sup>&</sup>lt;sup>57</sup> European Parliament – EP 2017: 7.

Commission Regulation (EU) 2016/646 of 20 April 2016 amending Regulation (EC) No 692/2008 as regards emissions from light passenger and commercial vehicles (Euro 6) [2016] OJ L 109.

<sup>&</sup>lt;sup>59</sup> European Court of Auditors – ECA 2019: 23.

and national double-hattedness. It cannot be labelled as a 'true' risk assessor. Compared to the U.S., the EU still lacks a central database on fuel consumption and emission of type approved vehicles. However, the JRC's market surveillance results of the 2021–2022 testing program have been made publicly available.<sup>60</sup> Such steps could enhance the overall accountability level in the still highly segmented sector involving actors of various groups with diverse mandates.

## The glyphosate saga and the EU's changing regulatory environment

#### The story of the glyphosate saga

Glyphosate has been the crucial active ingredient of the market-leading herbicides and plant protection materials since the 1970s. <sup>61</sup> Its carcinogenic effects have been centred on scientific (and public) debates based on theoretical contradictions and regulatory deficiencies. The re-authorisation of glyphosate has been marked by several cases before the CJEU and the EU Ombudsman, a specific European Citizens Initiative addressed to 'Ban Glyphosate' and public outcry over the EU's risk assessment and management controversy in food (and chemicals) sectors. <sup>62</sup>

According to the recent EU rules, namely Regulation 178/2002 (General Food Law – GFL) and Regulation 1107/2009 (Plant Protection Products Regulation – PPP Regulation),<sup>63</sup> risk assessment (and management) competencies are being divided based on the subject of the authorisation. The EFSA, as an EU agency, acts as risk assessor of active substances (like glyphosate) supported by a competent scientific authority of Rapporteur Member State (RMS), while the risk management decisions on active substances are to be taken by the Commission assisted by the PAFF (standing committee on Plants, Animals, Food and Feed with national representatives) comitology committee.<sup>64</sup> Additionally, the products containing that active substance shall be authorised at the national level and examined by RMS based on a zonal system (the Zonal Steering Committee appoints RMS, while other states may submit their comments).<sup>65</sup> This zonal system is combined with mutual recognition when, technically, Member States recognise

<sup>60</sup> BONNEL et al. 2022.

<sup>&</sup>lt;sup>61</sup> TARAZONA et al. 2017: 2723.

<sup>62</sup> Leonelli 2018: 582–606; Morvillo 2020: 422–435.

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, OJ L31, 1.2.2002; Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 797117/EEC and 91/414/EEC, OJ L309, 2411.2009.

<sup>&</sup>lt;sup>64</sup> Articles 7–13 PPP Regulation (MORVILLO 2020: 426).

<sup>65</sup> Article 43 PPP Regulation.

a pre-existing authorisation granted by another national authority if an applicant has requested this.  $^{66}$ 

As mentioned, the re-authorisation process of glyphosate of 2017 has already been highly disputed with an ongoing Citizens Initiative campaign and the EP's resolution to consider the total phase out of glyphosate from the Single Market.<sup>67</sup> The scientific debate on the key characteristics of glyphosate is still ongoing,<sup>68</sup> while the re-authorisation process in 2023 led to EFSA's conclusions identifying "no critical areas of concern" about glyphosate.<sup>69</sup> At the same time, some Member States already follow diverse approaches in dissenting to the authorisation of glyphosate, challenging the EU's general approach.<sup>70</sup>

# The data sources and methodology controversies in the risk assessment of glyphosate

In 2012, the renewal of the authorisation was allocated to the German authority (Federal Institute for Risk Assessment – BfR) as RMS to submit its draft report to the EFSA, which adopted its final opinion in 2015 and reiterated the RMS's position on the *non-carcinogenic* nature of the glyphosate – also concluded by the U.S. EPA.<sup>71</sup> However, the UN's International Agency for Research on Cancer (IARC) categorised glyphosate and glyphosate-based herbicides (products instead of just the active substance) as "probably carcinogenic to humans" earlier in that year, which IARC monograph has been slightly revised and published in 2017 practically with the same conclusion.<sup>72</sup> The European Chemicals Agency (ECHA) later verified the non-carcinogenic nature of glyphosate in 2018,<sup>73</sup> while California labelled glyphosate as 'cancer-causing'<sup>74</sup> in 2017.

There are at least three data-based and methodological reasons for the different assessment results between EFSA/RMS (U.S. EPA) and IARC, summarised by Benbrook. Firstly, the data sources (research studies) have been diverse as the EU and U.S. EPA relied primarily on registrant-commissioned, unpublished regulatory studies, 99% of which were negative. In comparison, IARC relied primarily on peer-reviewed studies, of which 70% were positive (83 of 118). Secondly, the EU's and U.S. EPA's evaluation was primarily based on data from studies on technical glyphosate (as an active substance). In contrast, IARC's review heavily weighed the results of formulated glyphosate-based herbicides (products). Thirdly, the EU's and U.S. EPA's evaluation focused on the general population's dietary exposures assuming legal, food-crop uses, and did not consider nor address generally higher occupational exposures (e.g. farmers) applied in IARC's

<sup>&</sup>lt;sup>66</sup> Articles 40–41 PPP Regulation.

<sup>&</sup>lt;sup>67</sup> Leonelli 2018: 598–599.

<sup>&</sup>lt;sup>68</sup> Rana et al. 2023: 1–20.

<sup>&</sup>lt;sup>69</sup> European Food Safety Authority – EFSA 2023.

<sup>&</sup>lt;sup>70</sup> Leonelli 2023: 200–224.

<sup>&</sup>lt;sup>71</sup> Benbrook 2019: 1–16; Leonelli 2018: 590.

<sup>&</sup>lt;sup>72</sup> IARC 2017.

<sup>&</sup>lt;sup>73</sup> European Chemicals Agency 2022.

<sup>&</sup>lt;sup>74</sup> Leonelli 2018: 593.

assessment.<sup>75</sup> The different results have also been embedded in the PPP Regulation's vague set of assessment criteria combining the hazard and risk-based approaches due to being concretised by risk assessors – detailed later in this paper. The PPP Regulation also favours the data ownership paradigm, relying on the applicant's choice of which data is to be presented in its dossier, potentially excluding unfavourable research results by the applicant.<sup>76</sup>

A new reform package was enacted in 2019 to the GFL Regulation and related sectoral requirements (GFL Reform) mainly due to the already decade-long glyphosate saga labelled by Morvillo as the 'glyphosate effect' on the sectoral requirements.<sup>77</sup> To foster quality and openness, a new condition of mandatory publication of the studies commissioned to the private laboratories completed the EFSA's risk assessment to avoid excluding unfavourable research results (combined with the EFSA's public consultation).<sup>78</sup> Moreover, the GFL Reform included a voluntary pre-submission phase for applicants alongside active transparency measures (EFSA publishes all supporting data and information related to application documents).<sup>79</sup>

## Mixed competence levels in scientific decision-making related to glyphosate

The active substances-related authorisation has been set up following a hybrid system with primary reliance on EU-level actors (risk assessor as EFSA and risk management by the Commission) with the involvement of national counterparties (RMS and the PAFF comitology committee with national representatives). Additionally, Member States approve active substances according to the PPP Regulation's system on the share of competencies on zonal and mutual recognition approaches.

The potential deficiency of such highly mixed competencies leads to similar concerns as those identified in Dieselgate, namely that certain risks remain unnoticed. CJEU's Blaise judgment also reveals this: the EU assessment of active substances cannot provide the complete picture of their risks, and the determination that an active substance is safe enough to be approved at the EU level by no means implies that all pesticidal products containing it will also be safe enough to meet the relevant criteria. <sup>81</sup> The SAM report already proposed in 2018 to have an integrated process for substances and products risk assessment (a collaboration of EU-level risk assessors) and management (either Commission or Member States). <sup>82</sup> The EP's related report added that national authorities

<sup>&</sup>lt;sup>75</sup> Benbrook 2019: 1–16.

Article 8 PPP Regulation (MORVILLO 2020: 428).

<sup>&</sup>lt;sup>77</sup> Morvillo 2020: 431–433.

Newly rephrased Article 32 GFL.

<sup>&</sup>lt;sup>79</sup> Newly rephrased Articles 38–39 GFL.

Articles 7–13 PPP Regulation (MORVILLO 2020: 426).

C-616/17 Blaise (LEONELLI 2023: 221).

Scientific Advice Mechanism – SAM 2018: 31–33.

lack the institutional and technical-scientific expertise and further resources to act appropriately.<sup>83</sup> Moreover, the segmentation of the single market became visible, as some Member States already started to ban the use of glyphosate recently.<sup>84</sup>

As a result of the GFL Reform, the EFSA management board has been rearranged with the broader involvement of national representatives; the EP, civil society and food chain organisations appoint further members. The EFSA scientific panels' membership is to be proposed by the Member States while guaranteeing high-level expertise, independence and territorial balance as well. The broader involvement of national representatives might have addressed the overly mixed system of competence shared between EU and national levels, yet 'double-hattedness' concerns could also prevail, as revealed by a recent expert report. The expert report is a revealed by a recent expert report.

#### The purposes of scientific decision-making related to glyphosate

The 2018 SAM Report on the PPP Regulation already concluded that the risk manager's political decisions on acceptable risks have been left to the risk assessor in this sector, namely to the EFSA (and RMS). Moreover, the PPP Regulation combined the hazard and risk-based approach with less exact criteria serving as a basis for risk assessment. The PPP Regulation lists diverse criteria as relevant properties that could serve as a basis for rejection. These include carcinogenic, mutagenic; toxic for reproduction; persistent, bio-accumulative and harmful for the environment (PBT); persistent organic pollutant (POP); very persistent and very bio-accumulative (vPvB); or endocrine disruptive. Yet, the mutagenic, PTB, POP and vPvB criteria are strictly excluded based on the hazard, while carcinogenic, toxic for reproduction and/or endocrine disruptive PPPs can be approved as a derogation if human exposure is negligible under realistic proposed conditions of use.

Moreover, these criteria are also diverse, having a relatively clear-cut formulation like persistency (half-life in soil is more than 120 days). At the same time, other properties require 'weight of evidence determination' from a wide range of data sources, including laboratory animal experiments, epidemiological studies and clinical case reports. <sup>88</sup> The EFSA and RMS's experts in the glyphosate saga referred to these risk assessment ambiguities (differences in criteria and methodological considerations for weighing and assessing the evidence or the requirements of analysing the general population's lower-level exposure instead of higher occupational exposures) as such, which could lead divergent interpretations by IARC. <sup>89</sup> Not to mention that deciding on these criteria and the applied methodology seemed to be precisely that more comprehensive (or even very wide?) margin of discretion excluded as powers to be conferred upon EU agencies due to the Meroni/ESMA doctrine.

<sup>&</sup>lt;sup>83</sup> European Parliament – EP 2018: 7–26.

<sup>&</sup>lt;sup>84</sup> Leonelli 2023: 200–224.

Newly rephrased Article 28(5) GFL.

Newly rephrased Article 28(5a) GFL.

<sup>&</sup>lt;sup>87</sup> Vos et al. 2023.

Scientific Advice Mechanism – SAM 2018: 25, 42; MORVILLO 2020: 430.

<sup>&</sup>lt;sup>89</sup> TARAZONA et al. 2017: 2739–2740.

These risk assessment ambiguities impacted the risk management phase since the Commission could not muster QMV in the PAFF comitology committee for almost two years, resulting in a reduced (only 5-year-long) renewal period in 2017. The GFL Reform later only included a new amendment to the purposes and risk management side of the food law regime, providing the power to the Commission to request verification studies from the EFSA in exceptional circumstances (serious controversies or conflicting results to verify its assessment's evidence also with a broader scope than the evidence subject to verification). Yet, the reform's ambition to define a more structured risk assessment vs. risk management framework remained unfulfilled.<sup>90</sup>

#### Any cross-sectoral lessons to be learned?

#### Diverse mechanisms addressing epistemic worries of expertisation

Both scandals and the post-scandal reforms remained highly sector-specific, yet they also revealed some sector-neutral lessons to be learned. In a broader context, the worries about expertisation in responding to crises have been discussed long ago. 91 Using the framework of Holst and Molander, the two scandals and the related reform steps could demonstrate how epistemic worries of expertisation should be addressed with specific mechanisms such as fora-based enhanced accountability of expertisation as well as cognitive diversity and the disciplinary pluralism built into the scientific decision-making. 92

As for the fora-based accountability, the primary forum for testing experts' judgements and detecting fallacies and biases can be extended to economic experts or other relevant fora such as the administrative fora of regulators, further elected assemblies, stakeholder fora, or the wider public of engaged citizens. The post-scandal reform steps of both cases revealed how relevant civil society's, CJEU's, or EP's role could be in exerting accountability.<sup>93</sup>

A further group of mechanisms could target expert inquiry and judgment conditions by encouraging groups that typically work with a larger pool of ideas and information and more often weed out bad arguments. 94 In case of the EU, this kind of pluralism in policy- and decision-making mainly refers to Member State or stakeholder pluralism – yet cognitive diversity and disciplinary pluralism in a broader sense could also serve the abovementioned goals. 95

These mechanisms are inevitably interrelated, aiming for pluralism with the inclusion of further external actors into scientific decision-making, while they could also be potentially combined with the other group of mechanisms to "democratise expertise"

<sup>90</sup> Article 32d GFL; MORVILLO 2020: 433.

<sup>91</sup> MERTON 1973; MERCIER 2011: 313-327; EVERSON 2021: 144-161; HOLST-MOLANDER 2021: 647-665.

<sup>92</sup> Holst-Molander 2021: 660.

<sup>93</sup> Holst-Molander 2021: 661.

<sup>94</sup> Mercier 2011: 313-327.

<sup>95</sup> HOLST-MOLANDER 2021: 661.

with the broader involvement of laypeople (in the selection of expert groups or even ensuring firmer competences for European parliaments).<sup>96</sup>

## The data sources and the applied methodology in scientific decision-making – Towards a more flexible approach?

Both the Dieselgate scandal and the glyphosate saga revealed that the risk assessment of the related EU-level authorisation processes must meet diverse expectations at the same time. These expectations include ensuring legal certainty for market participants as product developers (applicants) with well-detailed criteria to be fulfilled for their product to enter the market while guaranteeing the proper level of protection for Union citizens. The role of the risk assessor expert bodies has theoretically been determined in the policy framework with the risk assessment rules, the data collection and allocation procedures, and the list of potentially applicable methodologies. Yet, the inevitable flexibilities of such highly complex policy areas led to significant inconsistencies: in the Dieselgate, the market participants' exploitation practices undermined the abovementioned protection goals, resulting in only formal-level conformity regardless of using defeat devices. In the glyphosate saga, the EU food sector's regulatory flexibility embedded the potential evidence-related and methodological divergence of global and regional (EU) scientific risk assessment, even if the underlying issue of the carcinogenicity of glyphosate seemed to be binary (carcinogenic or not) in its nature.

In general, flexibility needs to be part of such highly complex policy frameworks due to the related technical issues of the marketed products and industrial complexity related to the authorisation processes. This complexity and the required flexibility could impose opportunities and threats in both policy areas. Both cases revealed the need to have a better simulation of the consumers' circumstances within the EU's risk assessment procedures, which justifies the broader involvement of the relevant data sources combined with the analysis of further market scenarios (including the diverse-level exposure to products based on their daily as well as realistic use). This supports the introduction of different disciplinary pluralism in risk assessment, which could be an integral part of the policy frameworks with a potentially more comprehensive set of data and methodological plurality. Even if legal certainty should be ensured for market participants, the EU legislator has taken steps by introducing the new WLTP cycle or the food laws' recent amendments already labelling "serious controversies or conflicting results". This further shift could also be an opportunity to avoid the still ongoing optimisation practices of the car manufacturers or to reconcile the risk assessments' methodological differences of the pesticide authorisations.

The fora-based enhanced accountability with the potential involvement of external actors' assessments could also serve as a basis for broader cognitive diversity and disciplinary pluralism, as these elements already played a pivotal role in identifying the related market deficiencies. First and foremost, the activity of civil society organisations

<sup>96</sup> Holst-Molander 2021: 662.

(NGOs) such as the US-based ICCT can be mentioned in this regard. Yet, the EU's accountability 'immune system' performed in due time since the Transport & Environment green NGO's study pointed out the discrepancies in diesel engines' real-life emissions as early as 2006. Photo cases led to further civil society and expertisation initiatives like a pilot study on the health hazards of glyphosate sponsored by worldwide crowd-funding The car's life cycle assessment (LCA) methodology designed by the Green EuroNCAP. The level of external accountability could be enhanced with the transparency of the underlying datasets and dossiers, especially with the publication of comparable databases. The GFL Reform's active transparency measures can be seen as innovative regulatory elements with a potential spill-over effect on other policy areas, just like the JRC's recently published report on market surveillance results (already using active instead of only risk-based reactive methodologies in testing). In the stop be concretised by risk assessors in the upcoming years how broadly flexibility and active approach can be applied to avoid unnecessary assessments while closing the gaps of the market participants 'exploitation manoeuvres'.

## The competence levels in scientific decision-making – Multi-level expert bodies with diverse independence and accountability models

The competence levels of scientific decision-making, especially that of risk assessment in both cases, led to deficiencies due to the overreliance on market participants' inputs combined with the national-level actors' highly segmented capacities in risk assessment. As a result, both areas' policy framework can be characterised by the relative overweight of certain Member States' role in risk assessment in light of the *forum shopping* practices identified in Dieselgate or related to the zonal/mutual recognition system of the food safety and pesticides area. This constellation has been made even more complex due to the process-based (national competencies with more in-service and conformity checks on the level after the scandal) or subject-based (active substance by EU risk assessor vs. product assessment by national actors) differentiation of the authorisation and risk assessment cycles. The EU legislators have taken some steps in post-scandal reforms of competencies allocation towards better coordination between the Member States with the automotive sector's new Implementation Forum (yet without being a true risk assessor) and JRC's increased powers or with the EFSA's revised internal structure.

As for the risk assessment based on the expert body's type, we might conclude that both the Commission's 'in-house' risk assessors and the more independent agency could perform well. JRC and SAM signalled in due time the systematic concerns later revealed by the Dieselgate scandal. Additionally, JRC acquired substantial powers to enhance its risk assessment capacity further. In both cases, a considerable latency period has passed

<sup>97</sup> FRIGESSI DI RATTALMA – PEROTTI 2017: 195.

<sup>98</sup> Landrigan-Belpoggi 2018: 1.

<sup>99</sup> EUObserver 2023.

<sup>100</sup> BONNEL et al. 2022: 3.

until fundamental reform steps – once again revealing the relevance of effective communication. The JRC's credibility could depend on its future transparency (culture) in producing (and publishing) market surveillance results. The more independent EFSA's assessment relies heavily on its practices, as it has been built up in light of the new transparency measures and pre-submission phases.

The EU agency cannot be labelled as an 'always-true solution' as a risk assessor. Yet, its institutional weight could be substantial compared to an 'in-house' expert body publicly seen as an integral part of an overly bureaucratic and politicised Commission. The creation of (more) independent expert bodies, even as a new EU road transport agency, has been proposed by the EP and other representatives of the automotive industry, <sup>101</sup> potentially following a more proactive attitude, having a greater motivation to create some self-profile and this way acting as a sector-specific counterbalance against global market players. <sup>102</sup> Considering the highly different U.S. administrations, especially the CARB's activity, the potential of a more independent agency as a policy actor seems proven. Yet, the unique logic of agencification by acquiring new powers from national authorities (i.e. the railway sector) could also be highly relevant. <sup>103</sup> Combined with the new active transparency policy, as a crucial part of the fora-based accountability, a more independent agency could acquire substantial credibility. Therefore, EU agencies' transparency practices might have a spill-over effect, especially in the case of EFSA, ECHA and EMA. <sup>104</sup>

## The 'true' purpose of scientific decision-making – Objective risk assessment vs. inevitably politicised considerations?

The *purpose side* of both cases can be considered the most sectoral or policy-specific issue. These complex and, to some extent, flexible frameworks determine the risk assessors' mandate, concretising risk assessment rules, the data collection and allocation procedures, and the list of potentially applicable methodologies. Yet, both cases demonstrated that risk assessor expert bodies got involved in the delicate role of balancing between diverse policy expectations.

In case of glyphosate, the PPP Regulation itself left some discretion for the risk assessors in choosing between assessment options and methodological alternatives, involving the theoretically objective experts making decisions in politicised matters, e.g. on socially acceptable risk. In case of the Dieselgate, the revised risk assessment rules with stricter new emission requirements and testing cycles led to emission reductions. Nevertheless, the new rules inherently contain flexibilities to be further exploited by

Euractiv 2017; Frigessi di Rattalma – Perotti 2017: 209.

<sup>&</sup>lt;sup>102</sup> Szegedi 2018: 90–100.

<sup>&</sup>lt;sup>103</sup> Chamon 2015: 167–188.

<sup>&</sup>lt;sup>104</sup> Vos et al. 2023: 102–103.

car manufacturers.  $^{105}$  Some scholars have noted a clear need to liberate the technocratic from its impossible status as a substitute for political will.  $^{106}$ 

The risk assessors' tasks cannot be seen as merely technocratic analysis of the underlying facts and risks. Still, further safeguards must be well-placed to ensure that the assessment results are a basis for final management decisions. In the Dieselgate, several other policy steps are needed because assessment results on the apparent need to reform the testing cycles have later been undermined (and postponed). In the glyphosate saga, the PAFF committee as risk manager has proven more resistant, as the Commission's proposal on the renewal of glyphosate was enacted in 2017 after two-year-long multi-cycle amendments. In this regard, the EP Resolutions, the related European Citizens Initiative, the CJEU cases and the massive public outcry on the reauthorisation of glyphosate demonstrate the potential of enhanced external accountability and how it could address ambiguous risk assessment results or even biased risk management decisions.

## Some cross-sectoral conclusions in search of 'sound' science

The EU expert bodies' evolution had demonstrated apparent similarities even in comparison to two relatively diverse policy areas of the EU's food sector and transportation. Theoretically, the EU legislator has divided the risk assessor and risk management positions in both policy areas. In contrast, centralised EU-level risk assessors' bodies have been set up as Commission-related in-house expert bodies and sometimes with the creation of more independent EU agencies.

The type of EU-level expert bodies might be relevant in searching for well-established scientific decision-making. Yet, these bodies' performance (and the deficiencies) could and should be evaluated using the trichotomy of *sources* vs. *levels* vs. *purposes* of scientific decision-making. Both policy areas' institutional and policy frameworks have been reshaped by the recent market scandals of Dieselgate and the ongoing glyphosate saga. The sources of scientific decision-making and applied methodologies have been extended with the centralisation of risk assessment cycles. As for the issue of levels, the EU needs to address the issue of multi-level players since both Dieselgate and the glyphosate saga highlighted some inconsistencies in this regard. The related EU competencies are formally addressed to global-level market participants. However, while national actors still implement EU requirements, the EU could only act as a regional (EU-level) regulator. This institutional setup is even more complicated than the scientific decision-making systems due to the risk assessors' vs. managers' mandate divisions. Even if this kind of clear division also seems rather theoretical in the era of highly complex scientific assessment and methodologies inevitably including management-type considerations.

European Court of Auditors – ECA 2019: 23.

<sup>&</sup>lt;sup>106</sup> Everson 2021: 144–161.

As demonstrated by the U.S.'s model by the U.S. EPA (especially of the CARB's) mandate, the 'added value' of more independent agencies could be identified in the detection of such market failures, presenting more rigorous 'best practice' for other states or having the prerogative to support initiatives like the project of ICCT targeting clean diesel. Further research could address the agency model's characteristics in U.S.–EU comparison<sup>107</sup> and the legal and political potential of creating its self-profile as an agency acting as a sector-specific counterbalance against global market players.

What made these two crisis management cycles even more interesting is how differently the globally marketed products can be treated in diverse jurisdictions' scientific decision-making, even in investigating their pivotal characteristics like toxicity, carcinogenicity, or the harm caused by them. Even if the EU functions as an entirely diverse political and administrative system compared to the U.S. or other regions/states, minimum (same) level protection must be guaranteed for each Union citizen regardless of their (occupational) exposure levels or Member State-specific locations. As the Future of the EU conference pointed out, climate change and the environment are paramount for Union citizens, combined with the demand for more accountability and better engagement.<sup>108</sup> Both cases refer to the new area of the EU law's horizontalisation, in which green policy might substantially affect other EU policies while losing its sector-specific character. Further evolution of the EU's reform steps in scientific decision-making (even in other policy areas) could also mark this new era in reformulating the EU's (extended green) requirements with the increased external accountability mechanism and broader involvement of its citizens. This direction of future policy-making in the EU's scientific decision-making could also support reinforcing the Union's self-profile as the Union of values, not just interest. 109

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<sup>&</sup>lt;sup>107</sup> Mujkic-Klingner 2020: 611–620.

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<sup>&</sup>lt;sup>109</sup> Orbán 2018: 271–297.

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