



EDPS Formal comments on the draft Commission Implementing Regulation laying down rules for the application of Regulation (EU) 2024/903 of the European Parliament and of the Council, as regards the establishment and the operation of the interoperability regulatory sandboxes

THE EUROPEAN DATA PROTECTION SUPERVISOR,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC ('EUDPR')¹, and in particular Article 42(1) thereof,

HAS ADOPTED THE FOLLOWING FORMAL COMMENTS:

1. Introduction and background

1. On 14 February 2025, the European Commission consulted the EDPS on the draft Commission Implementing Regulation laying down rules for the application of Regulation (EU) 2024/903 of the European Parliament and of the Council, as regards the establishment and the operation of the interoperability regulatory sandboxes ('the draft implementing Regulation').
2. The objective of the draft implementing Regulation is to set out the detailed rules and the conditions for the establishment and the operation of the interoperability regulatory sandboxes, including the eligibility criteria and the procedure for the application for, selection of, participation in and exiting from the interoperability regulatory sandbox and the rights and obligations of the participants². The draft implementing Regulation supports with its checklists the eligibility check and authorisation of interoperability regulatory sandboxes by the Commission³ and clarifies, besides many other aspects, the involvement of data protection authorities⁴

¹ OJ L 295, 21.11.2018, p. 39.

² Article 12(10) of [Regulation \(EU\) 2024/903 of the European Parliament and of the Council of 13 March 2024](#) laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act); OJ L, 2024/903, 22.3.2024.

³ Recital 3 of the draft implementing Regulation.

⁴ Recital 4 of the draft implementing Regulation.



and the procedures that contribute to regulatory sandbox projects as environments that respect data privacy (sic)⁵.

3. The draft implementing Regulation is adopted pursuant to Article 12(10) of Regulation (EU) 2024/903⁶ ('basic act').
4. The EDPS previously issued Opinion 1/2023 on the Proposal for an Interoperable Europe Act⁷.
5. The present formal comments of the EDPS are issued in response to a consultation by the European Commission pursuant to Article 42(1) of EUDPR. The EDPS welcomes the reference to this consultation in Recital 14 of the draft implementing Regulation.
6. These formal comments do not preclude any additional comments by the EDPS in the future, in particular if further issues are identified or new information becomes available, for example as a result of the adoption of other related implementing or delegated acts⁸.
7. Furthermore, these formal comments are without prejudice to any future action that may be taken by the EDPS in the exercise of his powers pursuant to Article 58 of the EUDPR and are limited to the provisions of the draft implementing Regulation that are relevant from a data protection perspective.

2. Comments

2.1. General comments

8. In the Opinion 1/2023 on the basic act, the EDPS called into question whether there are relevant possible use cases for the processing of personal data in interoperability regulatory sandboxes that would pass the necessity and proportionality test⁹. The EDPS further cautioned against the use of personal data from a production environment for testing purposes and considered that without a compelling need to use original data, their use for testing purposes would not be justifiable¹⁰.

⁵ Recital 9 of the draft implementing Regulation.

⁶ [Regulation \(EU\) 2024/903 of the European Parliament and of the Council of 13 March 2024](#) laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act); OJ L, 2024/903, 22.3.2024.

⁷ [EDPS Opinion 1/2023 on the Proposal for an Interoperable Europe Act](#), issued on 13 January 2023.

⁸ In case of other implementing or delegated acts with an impact on the protection of individuals' rights and freedoms with regard to the processing of personal data, the EDPS would like to remind that he needs to be consulted on those acts as well. The same applies in case of future amendments that would introduce new or modify existing provisions that directly or indirectly concern the processing of personal data.

⁹ [EDPS Opinion 1/2023 on the Proposal for an Interoperable Europe Act](#), issued on 13 January 2023, p. 9.

¹⁰ [EDPS Opinion 1/2023 on the Proposal for an Interoperable Europe Act](#), issued on 13 January 2023, p. 9.

9. The EDPS considers that these remarks are still appropriate, even though the co-legislators, by adopting the basic act, confirmed the existence of potential use cases for the exchange of personal data in interoperability regulatory sandboxes that could satisfy the necessity and proportionality test. The basic act makes it clear, most prominently in its Article 12(6)(b), that the processing of personal data can only occur in regulatory sandboxes under exceptional circumstances, namely where the functioning of the interoperability solution cannot be achieved by processing anonymised, synthetic, or other non-personal data. Regulation (EU) 2024/903 contains further limits to the purposes of the processing, not allowing merely operational purposes, such as the exchange of personal data within the framework of a sandbox to circumvent a legal obstacle to direct exchange. In line with this observation, the draft implementing Regulation recalls that interoperability regulatory sandboxes are “*fora to create regulatory learnings that are enabled through the development, training, testing and validation of innovative interoperability solutions in the frame of regulatory sandbox projects*”¹¹. The elements of regulatory learning, that ideally leads to better legislation, and innovation distinguish the purposes of regulatory sandboxes from merely operational purposes.
10. The EDPS notes that the draft implementing Regulation, in the recitals¹² as well as in the enacting terms¹³, aims to ensure that the purposes of an interoperable regulatory sandbox, as defined by the basic act, are observed during its lifecycle. The EDPS considers that by making this effort, the draft implementing Regulation considerably helps preventing the abuse of the instrument to enable the exchange of data in cases where no specific legal basis warrants the exchange.
11. The EDPS welcomes the approach taken by the Commission with the draft implementing Regulation, which contains many valuable clarifications with regard to data protection. The following specific comments therefore do not expose any issues of concern, but highlight some of the provisions or recitals that the EDPS deems particularly important from a data protection perspective.

¹¹ Recital 2 of the draft implementing Regulation.

¹² Cf. recital 6 of the draft implementing Regulation regarding regulatory learning.

¹³ Cf. Article 9(1) and (2)(e) of the draft implementing Regulation.

2.2. Necessity, proportionality, lawfulness and purpose limitation when processing personal data in interoperability regulatory sandboxes

12. Recital 9 recalls the data minimisation principle and defines the requirements for necessity, as already set out in Article 12(6)(b). In addition, Recital 9 clarifies that sandbox participants must demonstrate a valid legal basis for the operational use of sandbox results, where the processing may lead to new inferences about data subjects. Recital 9 also suggests some procedural guarantees and clarifies that without the aforementioned legal basis, operational personal data from the sandbox cannot be processed further. The EDPS welcomes these important clarifications that reflect the applicable data protection principles.
13. The operative part of the draft implementing Regulation mirrors these clarifications especially in Article 15(3) which provides that personal data that was exceptionally processed in order to reach the objectives of a regulatory sandbox project, shall not be used as operative data outside the regulatory sandbox project, unless there is a proper legal basis authorising a change of purpose.
14. Equally important is the requirement in Article 3(3)(a) of the draft implementing Regulation to lay out in a specific agreement between the future sandbox coordinators the sandbox's objective, scope and deliverables, in particular how the interoperability regulatory sandbox, including its projects, effectively contributes to the objectives set out in Article 11(2) of Regulation (EU) 2024/903, the innovative interoperability solutions that may be developed, trained, tested or validated in the regulatory sandbox projects and the open regulatory issues covered in the interoperability regulatory sandbox, as well as its planned duration. Clarity in the determination of these elements will make it easier to ascertain the legitimacy and necessity of the processing of personal data and the purposes of the processing. According to Article 3(3)(e), the agreement shall also specify the information referred to in Article 11(4) of Regulation (EU) 2024/903, that is purpose of the processing of personal data, the actors involved and their roles, the categories of personal data concerned and their sources, and the envisaged retention period.
15. The EDPS welcomes that the draft implementing Regulation provides the necessary clarity to ensure that sandbox projects solely set up to exchange personal data for operational purposes will be identified as such, and that other sandbox projects entailing the processing of personal data meet all necessity, proportionality, lawfulness and purpose limitation requirements.

2.3. Roles and responsibilities of sandbox participants; principle of accountability; cooperation with data protection supervisory authorities

16. According to Article 3(3)(b) of the draft implementing Regulation, the future regulatory sandbox coordinators should in their aforementioned specific agreement on the establishment of an interoperability regulatory sandbox also lay out a governance plan, including management of the sandbox, arrangements for collaboration between participants, regulatory authorities, and other actors involved, also outlining roles and responsibilities of the participants. Where personal data is processed, the aforementioned letter (e) of the same paragraph applies in addition. Article 3(3)(c) of the draft implementing Regulation requires the future coordinators to describe their risk management mechanism, also addressing the protection of personal data.
17. The EDPS recalls that the roles and processes to be set up will also need to comply with other provisions of applicable data protection law, ensuring, for instance, the handling of access requests. The EDPS welcomes the requirement to set up these responsibilities from the outset. The EDPS further welcomes the reference in recital 13 to other applicable risk management procedures, explicitly mentioning cyber security and the protection of personal data.
18. According to recital 3 of the draft implementing Regulation, the eligibility check and authorisation of interoperability regulatory sandboxes by the Commission does not constitute an assessment of the legality of activities within such sandboxes. This restraint has its counterpart in data protection law in the principle of accountability, which leaves the data controller responsible for the legality of its processing operations and requires it to document its processes and decisions in such a way that it is able to prove their legality at any time. The EDPS therefore considers the lack of external legality control by the Commission in the case of sandboxes entailing the processing of personal data as in line with Article 5(2) and 24 GDPR.
19. Article 9(3) of the draft implementing Regulation obliges the regulatory sandbox coordinators to take the necessary measures to allow for the competent data protection authorities to effectively carry out their supervision tasks, as provided for in Article 11(1) of Regulation (EU) 2024/903. The EDPS welcomes this clarification. The EDPS further welcomes the clarification in Article 12(3) of the draft implementing Regulation, that the project risk manager may suspend any regulatory sandbox project and consult the relevant authorities.

2.4. Role of data protection supervisory authorities

20. Article 11(1) of Regulation (EU) 2024/903 provides that interoperability regulatory sandboxes entailing the processing of personal data are to be operated under the supervision of the national data protection authorities or the EDPS. How this supervisory engagement will be designed in concrete terms, falls within the scope of duties of the independent data protection supervisory authorities. However, the EDPS welcomes that recital 4 lists some factors to be considered in determining the intensity of involvement, such as the complexity of the data processing operations, the categories and amount of data concerned as well as the risks associated with the processing.
21. Recital 4 further explains that the operation of the interoperability regulatory sandboxes under the supervision of data protection supervisory authorities constitutes an additional task for the supervisory authorities. The EDPS welcomes this clarification, which is fully in line with the accountability approach adopted by the GDPR¹⁴, EUDPR and LED¹⁵, which replaced the prior checking approach of the former Directive 95/46/EC¹⁶.
22. The EDPS equally welcomes the appeal in recital 4 that data protection supervisory authorities should be allocated sufficient resources for this new task¹⁷.
23. Lastly, the EDPS welcomes recital 3, which concerns the role of the supervisory authorities and clarifies that the supervisory and corrective powers of competent authorities over these sandboxes remain unaffected, in accordance with Article 12(4) of Regulation (EU) 2024/903.

2.5. Cooperation among data protection supervisory authorities in supervising a sandbox

24. As the interoperable regulatory sandboxes require at least three participating public sector bodies from Member States or Member States and at least one EU institution,

¹⁴ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation); OJ L 119, 4.5.2016, p. 1–88.

¹⁵ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA; OJ L 119, 4.5.2016, p. 89–131.

¹⁶ Cf. Article 20 of [Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995](#) on the protection of individuals with regard to the processing of personal data and on the free movement of such data; OJ L 281, 23.11.1995, p. 31–50.

¹⁷ Even though such appeals all too often go unheard.

body or agency, according to Article 11(4) of the basic act, several data protection supervisory authorities may be competent for monitoring the sandbox. Therefore, the question arises how to proceed if there are several competent data protection supervisory authorities to be involved in the supervision of a sandbox. The draft implementing Regulation does not regulate this case, but it refers to the cooperation mechanisms already in place, namely in Article 61 of the GDPR, as well as in Article 61 and Article 62 of the EUDPR.

25. The EDPS welcomes these references.

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(e-signed)

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