



## **EDPS Formal comments on the draft Commission Implementing Regulation laying down rules for the application of Regulation (EU) 2024/1938 of the European Parliament and of the Council as regards the technical specifications for the EU SoHO Platform to exchange information concerning substances of human origin intended for human application**

### **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')<sup>1</sup>, and in particular Article 42(1) thereof,

### **HAS ADOPTED THE FOLLOWING FORMAL COMMENTS:**

#### **1. Introduction and background**

1. On 7 April 2025, the European Commission consulted the EDPS on the Commission Implementing Regulation laying down rules for the application of Regulation (EU) 2024/1938 of the European Parliament and of the Council<sup>2</sup> as regards the technical specifications for the EU SoHO Platform to exchange information concerning substances of human origin intended for human application ('the draft implementing Regulation'). On 8 May 2025, the European Commission shared an updated version of the draft implementing Regulation, on the basis of which the EDPS issues the present formal comments.
2. The objective of the draft implementing Regulation is to provide for the establishment, management and maintenance of a digital platform to facilitate efficient and effective exchange of information concerning substances of human origin (SoHO)<sup>3</sup> intended for human application in the Union (the 'EU SoHO Platform')<sup>4</sup>.

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<sup>1</sup> OJ L 295, 21.11.2018, p. 39.

<sup>2</sup> Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC, OJ L, 2024/1938, 17.7.2024.

<sup>3</sup> Article 3(1) of Regulation (EU) 2024/1938 provides that 'substance of human origin' or 'SoHO' means any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance.

<sup>4</sup> Recital 1 of the draft implementing Regulation.



3. The draft implementing Regulation is adopted pursuant to Article 74(4), first subparagraph, of Regulation (EU) 2024/1938.
4. The EDPS previously issued Opinion 19/2022 on the Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC<sup>5</sup>.
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 10 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 acts<sup>6</sup>.
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. The EDPS welcomes that the draft implementing Regulation provides for rules dedicated to the protection of personal data processed in relation to the EU SoHO Platform. Such dedicated provisions relate to the protection of personal data of users of the EU SoHO Platform; responsible persons for SoHO entities; SoHO Coordination Board members and alternates; and of SoHO donors<sup>7</sup> and participants in a clinical evaluation, which constitute particular sensitive information.
9. The EDPS has several recommendations with the aim to clarify the responsibilities of parties involved in the processing of personal data in relation to the EU SoHO Platform, to ensure that the list of categories of personal data is comprehensive and

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<sup>5</sup> [EDPS Opinion 19/2022 on the Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC](#), issued on 7 September 2022.

<sup>6</sup> 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.

<sup>7</sup> Article 3(6) of Regulation (EU) 2024/1938 provides that 'SoHO donor' means a living or deceased SoHO donor. Article 3(5) of Regulation (EU) 2024/1938 provides that 'SoHO donation' means a process by which a person voluntarily and altruistically gives SoHO from their own body for persons in need, or authorises the use of such SoHO after their death; it includes the necessary medical formalities, examination and treatments and monitoring of the SoHO donor, irrespective of whether that donation is successful or not; it also includes, where applicable, the consent given by an authorised person in accordance with national legislation.

their storage period is appropriate, and to ensure appropriate technical and organisational measures to protect personal data in the EU SoHO Platform.

## 2.2. Roles and responsibilities

10. The EDPS understands that pursuant to the draft implementing Regulation, natural persons acting on behalf of SoHO entities and SoHO competent authorities of the Member States - as ‘actors’<sup>8</sup>, ‘authorised actors’<sup>9</sup>, ‘local actor administrators’<sup>10</sup>, as relevant - and the Commission would have access to the restricted part of the EU SoHO Platform and may be involved in the processing of personal data in the EU SoHO Platform.
11. Regulation (EU) 2024/1938 provides that SoHO entities and SoHO competent authorities of the Member States shall, in relation to their responsibilities to process personal data to comply with the obligations under that Regulation, be regarded as controllers within the meaning of Regulation (EU) 2016/679<sup>11</sup> (‘GDPR’)<sup>12</sup>.
12. Regulation (EU) 2024/1938 further provides that the Commission shall, in relation to its responsibility to establish and manage the EU SoHO Platform, as referred to in Article 73 of that Regulation and the processing of personal data, including health data, that might result from that activity, be regarded as a controller under the EUDPR<sup>13</sup>.
13. The EDPS notes that the draft implementing Regulation also refers to natural persons of the SoHO Coordination Board<sup>14</sup>, the European Centre for Disease Prevention and Control (ECDC), European Directorate for the Quality of Medicines & HealthCare (EDQM) as authorised actors with access to the EU SoHO Platform<sup>15</sup>.
14. Article 74 of Regulation (EU) 2024/1938 refers to the SoHO Coordination Board, ECDC and EDQM in relation to the EU SoHO Platform<sup>16</sup>. The EDPS understands that they are authorised actors for the purposes listed in that provision but would not be

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<sup>8</sup> Article 1(1) of the draft implementing Regulation provides that ‘actor’ means a natural person who registers a SoHO entity on the EU SoHO Platform after authentication.

<sup>9</sup> Article 1(2) of the draft implementing Regulation provides that ‘authorised actor’ means a natural person who, after authentication, has been granted access to the EU SoHO Platform to perform actions in accordance with the access rights assigned to the person’s profile and who acts on behalf of a Member State, a SoHO national authority, a SoHO competent authority, the SoHO Coordination Board, a SoHO entity, the Commission, the European Centre for Disease Prevention and Control (ECDC) or the European Directorate for the Quality of Medicines & HealthCare (EDQM).

<sup>10</sup> Article 1(3) of the draft implementing Regulation provides that ‘local actor administrator’ means an authorised actor who has the right to grant access to the EU SoHO Platform to other actors or authorised actors within the same Member State, SoHO national authority, SoHO competent authority or SoHO entity.

<sup>11</sup> 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.

<sup>12</sup> Article 76(6) of Regulation (EU) 2024/1938.

<sup>13</sup> Article 76(7) of Regulation (EU) 2024/1938.

<sup>14</sup> Pursuant to Article 68(2) of Regulation (EU) 2024/1938, each Member State shall appoint two permanent members and two alternates representing the SoHO national authority and, where the Member State chooses so, the Ministry of Health or other relevant authorities.

<sup>15</sup> Article 1(2) of the draft implementing Regulation.

<sup>16</sup> Article 74(2)(d)-(e) and Article 74(3)(d)-(f) and (k) of Regulation (EU) 2024/1938.

involved in the processing of personal data. The EDPS recommends clarifying in the recitals of the draft implementing Regulation that these authorised actors are not involved in the processing of personal data for the purposes listed in Article 74 of Regulation (EU) 2024/1938, or to further clarify their role under EU data protection legislation.

### 2.3. Categories of personal data

15. Annex II of the draft implementing Regulation provides for the categories of personal data to be processed in relation to the EU SoHO Platform and their storage periods.

#### *Point (1) of Annex II*

16. Point (1) of Annex II concerns the categories of personal data relating to authorised actors and responsible persons for SoHO entities.
17. The EDPS understands that the personal data of the authorised actors is processed to provide secure access to the restricted part of the EU SoHO Platform and to ensure traceability of all the modifications introduced in the EU SoHO Platform. The EDPS understands that, for the latter purpose, activity logs must be kept<sup>17</sup>.
18. The EDPS recommends that activity logs be included as a separate category of personal data in Annex II, considering that activity logs themselves may reveal information about the authorised actor (e.g. regarding their activity, such as moment of login, on the EU SoHO Platform), as well as the processing purpose and storage period of this personal data.
19. The EDPS further notes that ‘actors’<sup>18</sup> require authentication to access the EU SoHO Platform<sup>19</sup>, which would typically imply that personal data of actors is processed. Point (1) of Annex I does however only list categories of personal data relating to ‘authorised actors’, but not relating to ‘actors’ (which are defined separately by the draft implementing Regulation). The EDPS therefore recommends the Commission to clarify whether personal data of ‘actors’ is processed, and if so, list the categories of personal data, processing purpose and their storage period in Annex II of the draft implementing Regulation.

#### *Point (2) of Annex II*

20. Point (2) of Annex II concerns personal data exchanged through the EU SoHO Platform and required for the application of Articles 73 and 74 of Regulation (EU) 2024/1938<sup>20</sup>.

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<sup>17</sup> See Article 9 of the draft implementing Regulation, requiring “that authorised actors have access only to data covered by their access authorisation and that it is possible to verify and establish what data has been created, modified or deleted, by which authorised actor and at what time”.

<sup>18</sup> Article 1(1) of the draft implementing Regulation.

<sup>19</sup> See Article 1(1) and 4(1) of the draft implementing Regulation.

<sup>20</sup> See Article 76(2) of Regulation (EU) 2024/1938.

21. The EDPS recommends providing examples of categories of personal data and situations in which personal data are exchanged for the purposes listed under point (2) of Annex II in the recitals of the draft implementing Regulation.
22. According to the draft implementing Regulation, some diseases can have a long incubation time and may cause symptoms after 25 to 30 years, and therefore it is considered necessary to apply a storage period of up to 30 years after donation or human application for personal data related to the safety, quality and effectiveness of SoHO<sup>21</sup>.
23. The EDPS understands that certain diseases may be discovered only after a certain period of time, and that the exchange of information on such discovery could therefore take place up to 30 years after donation of the SoHO. The EDPS recommends assessing whether a shorter storage period could be provided for in certain instances, for example taking into account the moment that matters related to the safety, quality and effectiveness of SoHO that required the exchange of personal data<sup>22</sup> are addressed (e.g. once a risk associated with a particular donation has been properly addressed).

### 2.3. Technical and organisational measures

24. The EDPS welcomes that the draft implementing Regulation requires the Commission to put in place measures to safeguard the safety and security of personal data processed through the EU SoHO Platform<sup>23</sup>. The draft implementing Regulation specifies that *'measures shall include prevention of unauthorised access, reading, copying, modification or deletion of personal data, and shall ensure that authorised actors have access only to data covered by their access authorisation and that it is possible to verify and establish what data has been created, modified or deleted, by which authorised actor and at what time.'*
25. The EDPS recalls that the Commission should, when applying the implementing Regulation, consider for any measures *'the risks of varying likelihood and severity for the rights and freedoms of natural persons'*<sup>24</sup>, and that in practice, defining the measures should be done through a risk management<sup>25</sup> process, which includes performing a risk assessment<sup>26</sup>. As part of its risk assessment, the EDPS recommends the Commission in particular to determine the measures necessary to ensure the security of communications channels (data in transit), a functionality of the EU SoHO Platform listed in Annex I to the draft implementing Regulation. Considering the

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<sup>21</sup> Recital 4 of the draft implementing Regulation.

<sup>22</sup> As provided for in Article 76(2) of Regulation (EU) 2024/1938.

<sup>23</sup> Article 9 of the draft implementing Regulation.

<sup>24</sup> See Article 33 EUDPR.

<sup>25</sup> ISO 31000: Coordinated activities to direct and control an organization with regard to risk.

<sup>26</sup> ISO 31000: Overall process of risk identification (find, recognize and describe risks that might help or prevent an organization achieving its objectives), risk analysis (comprehend the nature of risk and its characteristics including, where appropriate, the level of risk) and risk evaluation (comparing the results of the risk analysis with the established risk criteria to determine where additional action is required).

sensitivity of the data processed in the SoHO platform, the EDPS recommends the Commission as part of its application of the draft implementing Regulation to also assess the necessity of implementing data encryption for data at rest, based on its risk assessment.

26. Regarding communication channels, the EDPS notes that point (7) of Annex I of the draft implementing Regulation concerns a collaboration module with different secure communication channels. Also some of the other modules of the EU SoHO Platform allow for communications<sup>27</sup>. While in some cases it is specified that such communication channels are secure, this is not specified in all instances. The EDPS recommends the Commission to ensure an appropriate level of security for all relevant communications channels, taking into account the relevant risks.
27. The draft implementing also provides rules on the access of the actors, authorised actors and local actor administrators to the EU SoHO Platform<sup>28</sup>. The EDPS welcomes the use of access controls as organisational measure to ensure the security of personal data, which is of particular importance for the protection of health data exchanged through the EU SoHO Platform<sup>29</sup>.

Brussels, 2 June 2025

*(e-signed)*

Wojciech Rafał WIEWIÓROWSKI

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<sup>27</sup> See e.g. point (4)(a) and point (5)(d) and (e) of Annex I to the draft implementing Regulation.

<sup>28</sup> Article 4 of the draft implementing Regulation.

<sup>29</sup> Point (2) of Annex II of the draft implementing Regulation.