



Council of the European Union
General Secretariat

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (European Health Data Space)

Subject:	Proposal for a regulation on the European Health Data Space - Template for written feedback from delegations after the Working Party on Public Health meeting on 15 September 2023
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Delegations will find enclosed a template to provide written feedback after the Working Party on Public Health meeting on 15 September 2023.

Spanish Presidency

Request for feedback from delegations after the working party of

Friday, 15th of September 2023

Dear colleagues,

Please, find attached the request for feedback from the WP of Friday, 15th of September 2023.

Deadline for written comments: 22th of September 2023 COB.

If possible,

- submit the file with your comments in *both* Microsoft Word and PDF formats.
- name the file with your comments in the following manner:
"WP_2023_09_15_comments_< 2 digit country code¹>"

For example:

"WP_2023_09_15_comments_ES.docx"

"WP_2023_09_15_comments_ES.pdf"

We will continue working with the **Swedish presidency compromise text, document number ST8171 2023 REV1** (herein after, "current compromise text").

We may also refer to the original text proposed by the Commission² (herein after, "original text").

¹ https://en.wikipedia.org/wiki/ISO_3166-1_alpha-2

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197>

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EU Member State	<Please, write the name of your country here>
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[MOD.SU.7] Creation of an EU HDAB

Brief summary of modifications:
<p>1) New article 36A creating the EU HDAB</p> <p>2) Modification of Article 37(1)(q) which states that the EU HDAB shall also make available its dataset catalogue.</p> <p>3) Article 49, paragraph 1A (EU institutions as single data holders) is deleted, since data requests and data access applications for EU institutions would now be handled through the EU HDAB.</p> <p>4) Modification of Article 52: new paragraph 1A, which clarifies that the this new HDAB would act as the Union Institutions' contact point for secondary use of electronic health data and would be responsible for making electronic health data available for secondary use.</p> <p>5) Modification of Article 55 clarifying that there are: - national dataset catalogues provided by the Member States, which will be made available at least in one official language of the Member State (but may also be provided in other languages, such as English to facilitate re-use). <i>Note: this modification was not for the EU HDAB per se, but was introduced for technical implementability reasons: the previous wording seemed to restrict national dataset catalogues to <u>just one</u> official language of the Member State, excluding other possibilities (several official languages in one Member State; provision of information in languages different to the official languages of the Member State, such as English).</i> - a dataset catalogue for EU institutions, which will be available in all official languages of the Union</p> <p>6) The EU HDAB is also mentioned in the context of two modifications related to third countries</p>

First round of comments:

Does your delegation agree with the wording proposed by the presidency?
(Please, see flash note for the WP 2023-09-15 for details)

Please, select an option:

- ☐ Yes
- ☐ No

Second round of comments:

If no, please, briefly explain your position:

If you have suggestions for minor modifications, you may use the template below.

Wording of the current compromise text	Proposed new wording of the definition. (and/or a recital)
Please, consult document number ***** and include in this column only the aspects that you would like to modify.	<p><proposed new wording and/or recital></p> <p>Justification for the new wording: <justification of the new wording and/or recital></p>

Deadline for written comments: 2023-09-22

Third countries & secondary use of health data

[MOD.TC.1] Requirement for HDABs and SPEs to store health data in the EU/EEA when processing health data in the context of data access applications and data requests.

Brief summary of text modifications:

New Article 60A
New Recital 63A

First round of comments:

Does your delegation agree with the wording proposed by the presidency?
(Please, see flash note for the WP 2023-09-15 for details)

Please, select an option:

☐ Yes

☐ No

Second round of comments:

If no, please, briefly explain your position:

If you have suggestions for minor modifications, you may use the template below.

Wording of the current compromise text	Proposed new wording of the definition. (and/or a recital)
Please, consult document number ***** and include in this column only the aspects that you would like to modify.	<p><proposed new wording and/or recital></p> <p>Justification for the new wording: <justification of the new wording and/or recital></p>

Deadline for written comments: 2023-09-22

[MOD.TC.2] Reciprocity requirements in the secondary use of health data with third countries

Brief summary of text modifications:

New Article 47B

First round of comments:

Does your delegation agree with the wording proposed by the presidency?
(Please, see flash note for the WP 2023-09-15 for details)

Please, select an option:

☐ Yes

☐ No

Second round of comments:

If no, please, briefly explain your position:

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If you have suggestions for minor modifications, you may use the template below.

Wording of the current compromise text	Proposed new wording of the definition. (and/or a recital)
Please, consult document number ***** and include in this column only the aspects that you would like to modify.	<proposed new wording and/or recital> Justification for the new wording: <justification of the new wording and/or recital>

Deadline for written comments: 2023-09-22