

To the European Data Protection Board

December 7, 2020

Boehringer Ingelheim feedback regarding the EDPB Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data

Boehringer Ingelheim welcomes the opportunity to provide feedback regarding the European Data Protection Board's "Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data" (the "Recommendations").

Clear, proportionate and stable rules for the international transfer of personal data are vital for EU-headquartered companies exporting goods and services.

Boehringer Ingelheim suggestions

1. We invite the EDPB to expressly recognize that the right to data protection is not absolute, but that other fundamental rights, such as the freedom to conduct a business, as enshrined in Article 16 of the Charter of Fundamental Rights of the European Union, must also be taken into consideration when determining the exact scope of legal obligations in the context of international data transfers. The Guidelines should be updated to reflect this more clearly, and the consequences of this important principle should be clarified for data exporters and data importers.

Recital 4 of the GDPR recognizes that the right to data protection is not an absolute right and that it must be balanced against other fundamental rights, in accordance with the principle of proportionality.

“(4) The processing of personal data should be designed to serve mankind. The right to the protection of personal data is not an absolute right; it must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality. This Regulation respects all fundamental rights and observes the freedoms and principles recognised in the

Charter as enshrined in the Treaties, in particular the respect for private and family life, home and communications, the protection of personal data, freedom of thought, conscience and religion, freedom of expression and information, freedom to conduct a business, the right to an effective remedy and to a fair trial, and cultural, religious and linguistic diversity.” (*emphasis added*)

This principle has also been recognized in the case law of the Court of Justice of the European Union (“CJEU”), including in the “Schrems II” (Grand Chamber) judgment:¹

[172] “However, the rights enshrined in Articles 7 and 8 of the Charter are not absolute rights, but must be considered in relation to their function in society (see, to that effect, judgments of 9 November 2010, Volker und Markus Schecke and Eifert, C-92/09 and C-93/09, EU:C:2010:662, paragraph 48 and the case-law cited, and of 17 October 2013, Schwarz, C-291/12, EU:C:2013:670, paragraph 33 and the case-law cited; and Opinion 1/15 (EU-Canada PNR Agreement) of 26 July 2017, EU:C:2017:592, paragraph 136).” (*emphasis added*)

Even more recently, the CJEU (Grand Chamber) has stated:²

[49] “None of those three fundamental rights constitutes an unfettered prerogative, as each of them must be considered in relation to its function in society (see, regarding the right to an effective remedy, judgment of 18 March 2010, *Alassini and Others*, C-317/08 to C-320/08, EU:C:2010:146, paragraph 63 and the case-law cited, and, concerning the rights to respect for private life and the protection of personal data, judgment of 16 July 2020, *Facebook Ireland and Schrems*, C-311/18, EU:C:2020:559, paragraph 172 and the case-law cited).” (*emphasis added*)

[50] “Thus, in a situation where several rights guaranteed by the Charter are involved in a given case and are liable to be at odds with each other, the necessary reconciliation of those rights, in order to ensure that a fair balance is struck between the protection attached to each of them, may lead to limitations being imposed on them (see, to that effect, judgments of 29 January 2008, *Promusicae*, C-275/06, EU:C:2008:54, paragraphs 63 to 65, and of 27 March 2014, *UPC Telekabel Wien*, C-314/12, EU:C:2014:192, paragraph 46).” (*emphasis added*)

¹ CJEU (Grand Chamber), judgment dated 16 July 2020 in the case C-311/18 – Facebook Ireland and Schrems, ECLI:EU:C:2020:559.

² CJEU (Grand Chamber), judgment dated 6 October 2020 in the joined cases C-245/19 and C-246/19) – État luxembourgeois v B and Others, ECLI:EU:C:2020:795.

2. We suggest confirming more clearly that all obligations of the GDPR, including the obligations regarding international transfers of personal data, must be interpreted in accordance with the principle of proportionality, and that this includes the recognition of a risk-based approach regarding international data transfers.

Article 24(1) GDPR confirms that the risk-based approach is a general principle applicable to all obligations in the GDPR:

“Taking into account the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for the rights and freedoms of natural persons, the controller shall implement appropriate technical and organisational measures to ensure and to be able to demonstrate that processing is performed in accordance with this Regulation. Those measures shall be reviewed and updated where necessary.” (*emphasis added*)

3. We suggest including additional Use Cases into the Guidelines with clarifications for day-to-day situations that do not involve cloud-type services. This includes clarifications of the scope of applicability of Use Case 7.

From the perspective of an EU/EEA-based company that does business in countries outside of the EU, the current wording of the Guidelines may raise questions whether, in the view of the EDPB, there is a legal basis for e.g. the following activities:

- An employee based in the EU/EEA sending an email with an offer for certain goods to a potential customer outside the EU/EEA
- Informing an employee in a country outside the EU/EEA about the name and telephone number of a superior who is based in the EU/EEA
- Operating a website which contains provider information identifying the name and further information about one or several natural persons, as required by Article 5 of Directive 2000/31, and (if the controller is a natural person) Article 13/14 of the GDPR
- Travel of EU/EEA employees to a country outside the EU/EEA with technical devices or paperwork that contain e.g. names and email addresses of colleagues, and/or preparatory notes with names and email addresses of contacts in the country of destination

We respectfully submit that the legal framework described in the Guidelines, especially Use Case 7 is not an appropriate approach to deal with these kinds of routine everyday transfers, that a one-size-fits-all approach will not work in practice and is not required under GDPR, and that a framework for these kinds of use cases must take into consideration the risk-based approach and the principle of proportionality.

4. We invite the EDPB to reconsider its Use Case 6 and to differentiate between a transfer of personal data where the data is ultimately stored outside the EU/EEA, and a transfer which consists of only granting a third party access to data stored in the EU.

In our view, these two situations differ substantially both from a technical and from a legal perspective. The Guidelines should reflect these differences, and respect that the legal framework for these two types of transfers in the GDPR is different.

Access to data stored in the EU can be granted in many may forms, and most of these do not have a risk profile that would be remotely similar to the situation discussed in the CJEU's *Schrems II* decision. We respectfully submit that applying the *Schrems II* considerations to all forms of "transfer" is inappropriate, not proportionate and not required by the Charter of Fundamental Rights of the EU.

The Guidelines should clarify that merely granting access to data stored in the EU should be subject to a much "lighter" set of restrictions than other forms of transfers.

5. We would very much appreciate if the EDPB would commission and publish a study on the interpretation of the term "electronic communications service provider" in Section 702 of the U.S. Foreign Intelligence Surveillance Act.

There is still significant uncertainty regarding the interpretation of the term "electronic communications service provider" under the U.S. Foreign Intelligence Surveillance Act ("FISA"). Virtually all exporters of personal data in the EU would benefit from a uniform understanding of this definition, and most exporters do not have the resources to resolve this question.

6. *We ask the EDPB to clarify the relationship between Article 3 GDPR and Chapter V of the GDPR.*

Certain recipients of personal data outside the EU may be subject to the GDPR because of Article 3 GDPR. There are currently still uncertainties whether additional safeguards in the meaning of Article 46(1) GDPR are required when personal data is transferred to these kinds of recipients.

In this context, we would like to mention that the response to this question of very significant practical relevance for internal data transfers of EU/EEA-based controllers to e.g. branch offices and affiliates outside the EU/EEA.

7. *We invite the EDPB to clarify that data transfers to a recipient in the EU are out of scope of the Guidelines, even if such recipient in the EU may have a parent company outside of the EU.*

We respectfully submit that this situation is different from the scope of the Guidelines. Possible conflicts in situations where the parent company may request that the EU-based recipient makes available certain personal data to the non-EU parent should be examined in a different guidance document.

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As a world-leading, research-driven pharmaceutical company, more than 51,000 employees create value through innovation daily for our three business areas: Human Pharma, Animal Health, and Biopharmaceutical Contract Manufacturing. In 2019, Boehringer Ingelheim achieved net sales of 19 billion euros. Our significant investment of almost 3.5 billion euros in R&D drives innovation, enabling the next generation of medicines that save lives and improve quality of life.

We realize more scientific opportunities by embracing the power of partnership and diversity of experts across the life-science community. By working together, we accelerate the delivery of the next medical breakthrough that will transform the lives of patients now, and in generations to come.

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