A Response to the EC's Roadmap Report on the General Data Protection Regulation

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Position Paper

EFAMRO, EphMRA, BHBIA Position Paper

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This paper is submitted on behalf of:

- **EFAMRO**[1], the European Federation of Associations of Market Research Organisations. Founded in 1992, EFAMRO represents the interests of market, social and opinion research in Europe. Its members are national trade associations for research businesses.
- **EphMRA**[2] the European Pharmaceutical Market Research Association, develops and improves standards and techniques for global market research in the field of health and healthcare, supports its members in their international activities to create transparency to the general benefit.
- **BHBIA**[3], the British Healthcare Business Intelligence Association, is an industry association representing companies involved in healthcare market research and data analytics in the UK. It is a long established and association and almost all pharmaceutical, medical device and biotech companies and business intelligence agencies with a UK base, are members.

[1] www.efamro.eu EU transparency Register ID Number : 90847842431-88

[2] www.ephmra.org

[3] www.bhbia.org.uk

Background information about market and social research

Market, social and opinion research plays a key role in helping businesses and other constituencies better understand consumers, customers and citizens in developing goods and services and is essential for economic efficiency, innovation and progress. Social and opinion research is widely used by public bodies to understand citizens' preferences and measure key performance indicators, for example the Eurobarometer surveys carried out by the European Commission, and government studies used for improving educational, healthcare and police services.

Research in itself does not seek to change or influence opinions or behaviour. Unlike direct marketing, advertising or other commercial communications, it does not seek to promote the aims or ideals of those who conduct or commission it. While research is used by marketers to test their products or messages, it is not a commercial communication.

EFAMRO is pleased to contribute to the European Commission's (Commission) 2020 evaluation and review of the General Data Protection Regulation (GDPR).

This position paper is based on the feedback of EFAMRO's members on their experience with the application and implementation of the GDPR. EFAMRO members have a long-standing tradition in promoting, developing, supporting and regulating standards and innovation in the realm of privacy and data protection via the association Codes of Conduct and accompanying guidelines which underpin membership of the EFAMRO member associations.

1. Evaluate and review the application and functioning of the GDPR in its entirety by carrying out an extensive consultation process of society at large and analyse the practical implications of the regulation.

No matter the extent of EC's evaluation and review, EFAMRO strongly believes that this should be taken as valuable opportunity to gather business and civil society's practical experience with the implementation of the GDPR. As correctly pointed out by the Council of the European Union (Council), the Commission should evaluate and review the application and functioning of the GDPR beyond what is specifically mentioned in article 97 by also considering the experiences and input of relevant stakeholders. This will help to ensure that the evaluation is as comprehensive as possible[4].

2. International Transfers

a. Review and update Standard Contractual Clauses and adopt new EU processor to non-EU or EEA processor clauses

With only 13 adequacy decisions in place, businesses need to refer to other tools listed in Chapter V. Standard contractual clauses for data transfers to third countries have not been updated since they were originally adopted. The Commission should urgently review and revise the standard contractual clauses and consider the needs of controllers and processors with the addition of new clauses to cover EU processor to non-EU or EEA processor data transfers, following up the Article 29 Working Party *Working document 01/2014 on Draft Ad hoc contractual clauses "EU data processor to non-EU sub-processor"*.

[4] Council position and findings on the application of the General Data Protection Regulation (GDPR) – Adoption 14994/1/19 REV 1
https://data.consilium.europa.eu/doc/document/ST-14994-2019-REV-1/en/pdf

3. Codes of Conduct

The different sectorial experiences in devising sector Codes has demonstrated that there is some degree of uncertainty left regarding Codes of Conduct by sectors and the same Data Protection Authorities that should be in charge of adopting them[5]. Even greater uncertainty rests on how to use sector Codes in the framework of international transfers. The Commission should clarify the practical and technical implications of Art. 46(2 – e) *an approved code of conduct pursuant to Article 40 together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including as regards data subjects' rights.*

The EC should also take this occasion to clarify other important aspects of Codes of Conduct and in particular:

- Is it possible and admissible to have more than one approved Code of Conduct in a given sector?
- Is it possible and admissible for a single controller or processor to adhere to more than one Code of Conduct, including Codes applicable to different sectors? If so, how are potentially conflicting sector Code requirements resolved? By the European Data Protection Board (EDPB)?
- What is the binding mechanism of a Code of Conduct to processor who is not party to it?
- Can the Commission clarify Art 40.9 and how "implementing acts" will be adopted and with which effect?
- How will the interaction between national and transnational Codes be managed?
- In case of supervisory authority imposing fine on a Code's subscriber, what could be the consequences and liabilities for the Code holders?

[5] Preparation of the Council position on the evaluation and review of the General Data Protection Regulation (GDPR) - Comments from Member States https://data.consilium.europa.eu/doc/document/ST-12756-2019-REV-1/en/pdf

4. Harmonization and digital single market

The GDPR is directly applicable in all Member States but it also leaves a margin for national legislators to maintain or introduce more specific provisions to adapt the application of certain rules. This national margin has resulted in a fragmented legal landscape for some of the GDPR provisions. In turn, the non-uniform application of the GDPR across member states can create obstacles to cross border operations even intra EU.

In particular:

- Age of consent of a child: the possibility to choose different age limits as provided by Article 8 has given rise to legal uncertainty concerning the applicable law among the Member States in situations where the national laws of two Member States are applicable to a single processing activity.
    - For instance, to give consent, a child has to be 13 years old in Sweden, 14 years old in Bulgaria and Spain; and 16 in Hungary and the Netherlands. In the other countries, maturity is required[6].
- Lawfulness of processing: the possibility for Member States to introduce more specific provisions for when processing is necessary for the performance of a task carried out in the public interest Article 6 1-e and 2, may lead to a rather relaxed approach on the Governments' side.
    - See UK Data Protection Act 2018[7] "democratic engagement" is listed as an example of processing activities that can be undertaken lawfully in the public interest and consider the extent of this when it comes to special categories of data.
    - See Irish Data Protection Act 2019[8] Section 39 *A specified person may, in the course of that person's electoral activities in the State, use the personal data of a data subject for the purpose of communicating in writing (including by way of newsletter or circular) with the data subject*. Moreover, the section goes on to state that: '*Communicating in accordance with subsection (1) shall, for the purposes of Article 6(1)(e), be considered to be the performance of a task carried out in the public interest*'.

[6] Consent to use data on children European Union Agency for Fundamental Rights https://fra.europa.eu/en/publication/2017/mapping-minimum-age-requirements/use-consent
[7] http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted
[8] http://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/html

- Scientific research: for EFAMRO members the most interesting example of national fragmentation, is the concept of scientific research which has resulted in a patchwork of safeguards, with 27 different interpretations of the concept and/or, the absence of a clear definition. The absence of common ground for scientific research is hindering the single market as it is very unlikely or very difficult to imagine European data processing operating in the strict framework of national borders. The concept of research, without additional specification, has raised practical difficulties. In the age of big data, data analytics activities of many organizations may qualify as research. Examples of different member states approaches can be found in:
    - Ireland: Irish Health Research Regulations 2018[9] on the processing of personal data for health research purposes, mandate "explicit consent" as one of the "suitable and specific measures" that must be undertaken when the processing of personal data (including health data) for the purposes of health research. Therefore, regardless of what legal basis is chosen to justify the processing of personal data for health research purposes, the explicit consent of the data subject is required unless the researcher has been granted a consent declaration.
    - Germany and the Netherlands: traditionally consider market, opinion and social research as falling within the scope of art 89 GDPR
    - More generally, the case of health research in the context of art 9(4) – art 89 – and the secondary use of data.

The aim of replacing the Directive 95/46/EC with a Regulation was to prevent the EU legal landscape from fragmentation. It would be useful for the Commission to investigate further and get a better understanding of how the issue of overlapping territorial scopes of national laws implementing the GDPR has affected controllers and processors and how they are dealing with such fragmentation.

In the meanwhile, it is our strong recommendation for the Commission, the EDPB and national Supervisory Authorities to re-evaluate the importance and critical need for practical guidance.

[9] Formally titled Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018

5. The Commission's upcoming evaluation report should also highlight the broad need for practical guidelines.

As a sector, EFAMRO and its members welcome the GDPR approach and in particular the Regulation being technologically neutral. However, it is proven more and more necessary to clarify how it applies in practice. Unfortunately, in the absence of a strong institutional and authoritative interpretation, we are currently witnessing a series of drawbacks.

On the one hand, businesses may accept the best analysis that fits their interests and consequently adopting practices that would fall in a grey area at best. On the other hand, by focusing relentlessly on the methods and impacts of tech giants, the realities of micro, small and medium-sized enterprises in the application of the regulation are being overlooked. As are those sectors, such as research, which follow existing rigorous Codes which support ethical personal data practice.

The EDPB guidelines are very important and useful tools for the application of the GDPR. We highly value EDPB's expertise and approach and appreciate the time and structural constraints which are affecting the amount of guidance that can be produced. Nevertheless, some uncertainty remains and in the absence of some detailed guidance in key areas, there are challenges for business when it comes to implementation.

Suggested topics to be covered ex novo, or in greater detail are:

- Healthcare data: how to navigate the use of personal data across the spectrum of health and healthcare systems and services; from biometric to *data which are manifestly made public by the data subject* (Art 9.2.e) to *processing necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services* (Art 9.2.h).
- Further clarifications about the appropriate legal bases to use depending on the different types of processing activities.
- Controllers and Processors: definition of roles according to the latest CJEU judgments and, more importantly, whether the recent EDPS interpretation is accepted as an appropriate approach.

- Scientific Research under Art 89: guidance on how to interpret the scope of "scientific research" in theory and in practice, how to read EPDS guidelines and how to face cross countries clash.

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