

## **Monitoring Report – 15 /02/2019 (No. 5 of 2019)**

***The efamro monitoring report covers selected legal and regulatory developments and events in data protection and privacy of particular interest to the research sector.***

### Regulatory guidance

The European Data Protection Board (EDPB) held a plenary meeting on 13 February during which it adopted an Information Note on [Data Transfers under the GDPR in the Event of a No-Deal Brexit](#), and an Information Note on [BCRs for Companies Which Have ICO as BCR Lead Supervisory Authority](#). The notes naturally reiterate that as the UK will be a third country after Brexit day the UK regulator will “no longer be part of the BCR community”. The EDPB also adopted its long-awaited (but yet to be published) guidance on Codes of Conduct.

Recent EDPB guidance on clinical trials and health research might be of particular interest to those carrying out research in Ireland as the EDPB’s [Opinion](#) conflicts with Irish legislative requirements under the Health Research Regulations 2018. The EDPB has opined consent will generally not be the right legal basis for clinical research protocols (which is the required approach in Ireland). The opinion also suggests that there will need to be some reliance on public interest as part of the lawfulness of processing. This may also make it more difficult for commercial pharmaceutical companies as this is partially dependent on national interpretations/implementation of GDPR.

EDPB has also published an ambitious work program for 2019-2020. Among the issues of particular importance to the research sector include guidelines on codes and certification, controllers and processors, data protection by design and default. It will also publish an Opinion on the interplay between ePrivacy and GDPR and has suggested the issue of best practice in research projects as a possible topic for additional work.

### Legislative initiatives

The Bulgarian President recently vetoed the Implementing Law of the GDPR in light of concerns that the new provisions in the law undermined the freedom of speech and access to information and may affect the independence of journalists and academics.

Council Working Party on Telecommunications and Information Society will continue to consider the proposal for a Regulation on ePrivacy at meetings next week.

### Research, artificial intelligence and data ethics

Over 500 stakeholder responses received by the Commission on the draft AI principles developed by the High Level Expert Group (HLEG).

## **Regulatory guidance**

### ***EDPB - Seventh Plenary session: EDPB 2019/2020 Work program, opinion on the draft AA in the field of financial markets supervision, Brexit, guidelines on codes of conduct***

On February 12th, the EEA Data Protection Authorities and the European Data Protection Supervisor, assembled in the European Data Protection Board, met for their seventh plenary session. During the plenary a wide range of topics were discussed. **EDPB 2019/2020 Work program** The Board adopted its two-year work program for 2019-2020, according to Article 29 of the EDPB Rules of Procedure. The EDPB work program is based on the needs identified by the members as priority for individuals, stakeholders, as well as the EU legislator- planned activities.

#### **Draft administrative arrangement in the field of financial markets supervision**

The EDPB adopted its [first opinion](#) on an administrative arrangement (AA), based on article 46.3.b of the GDPR, for transfers of personal data between EEA financial supervisory authorities, including the European Securities and Markets Authority (ESMA) and their non-EU counterparts. This arrangement will be submitted to the competent supervisory authorities (SAs) for authorisation at national level. The competent supervisory authorities will monitor the AA and its practical application to ensure that there are in practice effective and enforceable data subject rights and appropriate means of redress and supervision.

#### **Brexit**

The EDPB adopted an information note addressed to commercial entities and public authorities on data transfers under the GDPR in the event of a no-deal Brexit.

- [Information note on data transfers under the GDPR in the event of a no-deal Brexit](#)
- [Information note on BCRs for companies which have ICO as BCR Lead Supervisory Authority](#)

#### ***Data flows from the EEA to UK***

In the absence of an agreement between the EU and the UK (no-deal Brexit), the UK will become a third country from 00.00 am CET on 30 March 2019. As a consequence, the transfer of personal data from the EEA to the UK will have to be based on one of the following instruments: Standard or ad hoc Data Protection Clauses, Binding Corporate Rules, Codes of Conduct and Certification Mechanisms and the specific transfer instruments available to public authorities. In the absence of Standard Data Protection Clauses or other alternative appropriate safeguards, derogations can be used under certain conditions.

### *Data flows from UK to the EEA*

As regards data transfers from the UK to the EEA, according to the UK Government, the current practice, which permits personal data to flow freely from the UK to the EEA, will continue in the event of a no-deal Brexit.

### **Guidelines on codes of conduct**

The EDPB adopted guidelines on codes of conduct. The aim of these guidelines is to provide practical guidance and interpretative assistance in relation to the application of Articles 40 and 41 GDPR. The guidelines intend to help clarify the procedures and the rules involved in the submission, approval and publication of codes of conduct at both the national and the European level. These guidelines should further act as a clear framework for all competent supervisory authorities, the Board and the Commission to evaluate codes of conduct in a consistent manner and to streamline the procedures involved in the assessment process. The guidelines will be subject to public consultation.

### ***EDPB – Opinion on the Interplay between the Clinical Trials Regulation and the GDPR***

The European Data Protection Board (EDPB) recently adopted an Advisory Opinion on the interplay between the European Union's Clinical Trials Regulation and the General Data Protection Regulation.

Interestingly it advocates a restrictive approach to the use of consent as a legal basis for processing personal data for research activities in the context of a clinical trial protocol. Reliance on public interest as part of the lawfulness of processing may also make it more difficult for commercial pharmaceutical companies as this is partially dependent on national interpretations/implementation of GDPR.

Source: EDPB

URL: [https://edpb.europa.eu/sites/edpb/files/files/file1/edpb\\_opinionctrq\\_a\\_final\\_en.pdf](https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_opinionctrq_a_final_en.pdf)

### ***EDPB – Work Program 2019/2020***

The European Data Protection Board (EDPB) also published its [work program](#) for the next two years. It lists the guidelines, consistency opinions, and other types of activities the EDPB intends to carry out and is based on the needs identified by the EDPB as priority for individuals, stakeholders, as well as the EU legislator planned activities.

Guidelines of particular interest to the research community include:

- Guidelines on Codes of Conduct and Monitoring Bodies
- Guidelines Certification and Codes of Conduct as a tool for transfers
- Guidelines on Certification (finalisation after the public consultation)
- Guidelines on Data Protection by Design and by Default
- Guidelines on Targeting of social media users
- Guidelines on video surveillance
- Guidelines on children's data
- Guidelines on reliance on Art. 6(1) b in the context of online services
- Guidelines on concepts of controller and processor (Update of the WP29 Opinion)
- Guidelines on the notion of legitimate interest of the data controller (Update of the WP29 Opinion)
- Guidelines on the Territorial Scope of the GDPR (finalisation after the public consultation)
- Guidelines on data subjects rights with main focus at a first stage on the rights of access, erasure, objection, restriction and limitations to these rights.

In addition, the EDPB intends to publish a Consistency Opinion on the interplay between the GDPR & e-Privacy and a possible topic for further consideration is “good practices regarding research projects”.

Source: EDPB

URL: [https://edpb.europa.eu/sites/edpb/files/files/file1/edpb-2019-02-12plen-2.edpb\\_work\\_program\\_en.pdf](https://edpb.europa.eu/sites/edpb/files/files/file1/edpb-2019-02-12plen-2.edpb_work_program_en.pdf)

## **Legislative initiatives**

### ***GDPR Implementation – Presidential veto of Bulgarian implementing law***

Wolf Theiss reports that the Bulgarian President recently vetoed the Implementing Law of the GDPR due to concerns regarding the regulated data processing for journalistic purposes and the purposes of academic, artistic or literary expression.

After extensive public consultations and parliamentary procedures, on 24 January 2019 the law implementing the General Data Protection Regulation (GDPR) into the Bulgarian Personal Data Protection Act ("Implementing Law") it was officially adopted by the Bulgarian Parliament. The President outlined that new provisions in the law undermined the freedom of speech and access to information and may affect the independence of journalists and academics.

Following the President's veto, the controversial article of the Implementing Law is to be returned for further discussions by the Bulgarian Parliament. The veto can be overridden if the Parliament adopts the Implementing Law with a majority of more than half of all members of Parliament. In this case, the President shall promulgate the Implementing Law in the State Gazette within 7 days as of its receipt.

Source: Wolf Theiss

URL: <https://www.wolftheiss.com/knowledge/client-alerts/detail/bulgaria-the-president-vetoes-local-law-implementing-the-gdpr/#undefined>

### ***ePrivacy Regulation – Working Party on Telecommunications and Information Society***

Attachés/Counsellors of the WP on Telecommunications and Information Society met on 7 February. Agenda items included proposal for a Regulation on ePrivacy - Discussion on possible compromise solutions.

Please access [here](#) to access information by the Presidency on possible compromise solutions for the Proposal for a Regulation of the European Parliament and of the Council concerning the respect for private life and the protection of personal data in electronic communications and repealing Directive 2002/58/EC (Regulation on Privacy and Electronic Communications).

## **Research, artificial intelligence and data ethics**

### ***DG CNECT - Over 500 comments received on the draft Ethical Guidelines for Trustworthy Artificial Intelligence***

The consultation on the draft Ethics Guidelines on Artificial Intelligence (AI) concluded on 1 February 2019 with over 500 comments received from a wide array of European and international stakeholders.

The process had been launched with [the presentation of the document](#) by the High-Level Expert Group on Artificial intelligence (AI HLEG) on 18 December 2018. During the consultation, organisations (including companies, civil society, trade associations and others), members of the academic and research community and individual European citizens had the possibility to submit extended comments on the distinct chapters as well as the document as a whole.

The following document includes the total of input received during the consultation process on the draft Ethics Guidelines for Trustworthy AI. Reflecting the choice of participants with regard to the publication modality of comments, the document presents this input on an identified, anonymised or confidential basis.

- [Download the document with feedback from the consultation](#)

#### **Next Steps**

All the comments received are currently being analysed and considered by the AI HLEG for the preparation of a revised version of the Ethics Guidelines that will be delivered to the European Commission by the beginning of April.

#### **Background information**

Following its [European approach to AI](#) published in April 2018, the Commission set up a High-Level Expert Group on AI, which consists of 52 independent experts representing academia, industry, and civil society. This first draft of the Ethics Guidelines was prepared through a number of meetings since June 2018 and takes into account feedback from many discussions through the European AI Alliance. It also follows the announcements of the [EU coordinated plan](#) with the Member States, the [Declaration of Cooperation](#) on AI and the proposed investment of at least €7 billion in AI research from the [Horizon Europe](#) and [Digital Europe](#) programmes.

#### **Related documents:**

[Consultation on Draft AI Ethics Guidelines](#)

## ***Upcoming Events***

### ***February 2019***

#### ***Council of Europe - High Level Conference on artificial intelligence in Helsinki***

26 – 27 February 2019, Helsinki

The conference is co-organised by the Finnish Presidency of the Council of Europe Committee of Ministers and the Council of Europe. The overall aim of the Conference is to engage in a critical, open and inclusive discussion on how to address AI development to maximise benefits for society and minimise risks to human rights, democracy and the rule of law. The conference will bring together high-level experts from governments, international organisations, businesses, technology, academia and research, civil society and the media. From the perspective of the Council of Europe's core mandate and values, the debates will explore ways to ensure that emerging technologies are designed, developed and applied to create value for individuals, democratic societies and the viability of legal and institutional frameworks.

- [Concept note](#)
- [Programme](#)

#### **[Background Information](#)**

### ***March 2019***

#### ***Forum Europe - 9th Annual European Data Protection and Privacy Conference***

20 March 2019, Brussels, Belgium

The 9th European Data Protection and Privacy Conference will explore how the power of data can truly be harnessed through trust and responsible use, in order to deliver economic growth and societal benefits.

It will also debate how an international system based on shared principles and ethics might be developed – all in the context of increasing technological innovation, on-going regulatory discussions in the EU around digital evidence and ePrivacy, and other global political developments that either distract from or give focus to such developments.

- [Conference Programme & Speakers](#)
- [Registration](#)

**April 2019**

***Forum Europe - 9th Annual European Data Protection and Privacy Conference***

4<sup>th</sup> April, Brussels, Belgium

To remain competitive in the global race for artificial intelligence (AI), the European Union will need more investment, more workers trained in AI-relevant skills, more shared resources including data, and a regulatory environment that will foster the development and use of AI. To that end, in December the European Commission released a "[Coordinated Plan on AI](#)" which encourages all member states to develop their own national AI strategies by mid-2019 and to work with the Commission to develop common metrics to measure AI adoption.

While some member states have already created national AI strategies, others have not or have only included dimensions of AI within broader digital strategies. Moreover, every member state is different, so the policies, priorities, and financial commitments in each national AI strategy will vary.

Join the Center for Data Innovation for a discussion that will take stock of the progress achieved so far across member states; compare targets, priorities, and dimensions; and assess the extent to which these national strategies will support Europe's goal of becoming a global leader in AI.

Registration details here: <https://www.eventbrite.com/e/european-ai-strategies-where-do-member-states-stand-and-where-are-they-headed-tickets-56188139237>