THE PROPOSED EU GENERAL DATA PROTECTION REGULATION

A guide for in-house lawyers

June 2015
Introduction to the Regulation

Background

- **Existing law:** Current EU data protection law is based on Directive 95/46/EC (the “Directive”), which was introduced in 1995. Since that time, there have been significant advances in information technology, and fundamental changes to the ways in which individuals and organisations communicate and share information. In addition, the various EU Member States have taken divergent approaches to implementing the Directive, creating compliance difficulties for many businesses.

- **Proposed changes:** The EU’s legislative bodies are preparing an updated and more harmonised data protection law (the “Regulation”) to replace the Directive. The Regulation remains under negotiation, but it is clear that it will significantly change EU data protection law in several areas. As described on page 4, it is anticipated that the text of the Regulation will be finalised in the first half of 2016. As organisations will require time to implement changes, it is likely that the Regulation will not come into force until 2017-2018.

Current status of the Regulation

- **Continuing negotiations:** The Regulation remains in draft form. It is being negotiated by the EU legislative bodies and the Member States, but the Council has stated that “nothing is agreed until everything is agreed”. Therefore, although the general approach to many issues is clear, there are likely to be further changes to the text before the Regulation is finalised.

- **Multiple drafts:** As with any EU legislation, multiple drafts of the Regulation will be created and edited before a final version is agreed upon. The current major drafts are:
  - The Council Texts – The Council has released a draft compromise text, and further drafts of specific chapters of the Regulation. A final text from the Council is expected in mid-2015.

This Guide is predominantly based upon the Commission Text, as that was the first published text, and has formed the starting point for the other texts. It has received the most attention from commentators and regulatory authorities. Where there are material differences between the texts that significantly affect businesses, those differences are noted in this Guide.

- An updated edition of this Guide will be published once the text of the Regulation is finalised.
## Progress of the Regulation

<table>
<thead>
<tr>
<th>Presidency of the Council</th>
<th>European Commission</th>
<th>European Parliament</th>
<th>Council of the European Union</th>
<th>Other Interested Parties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Denmark</strong>&lt;br&gt;Jan - Jun 2012</td>
<td>● January 2012 Commission Text Published by Vice-President Viviane Reding</td>
<td>● May 2012 – The European Parliament held an initial stakeholder meeting.</td>
<td>● February 2012 – The UK DPA published initial comments on the proposed Regulation.</td>
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<td><strong>Cyprus</strong>&lt;br&gt;Jul - Dec 2012</td>
<td>● July 2012 First Parliament working document (“LIBE Text”) published.</td>
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<td><strong>Italy</strong>&lt;br&gt;Jul - Dec 2014</td>
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<td>● October 2014 – EU Ministers partially agreed the “risk-based approach” (see page 20).</td>
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<td><strong>Latvia</strong>&lt;br&gt;Jan - Jun 2015</td>
<td></td>
<td>● EU Ministers work towards a final Council Text.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Luxembourg</strong>&lt;br&gt;Jul - Dec 2015</td>
<td>● A “trilogue”, involving the Council, the Parliament and the Commission will begin, with the aim of finalising the text of the Regulation. This will be a complex process and is likely to take some time to complete.</td>
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<tr>
<td><strong>Netherlands</strong>&lt;br&gt;Jan - Jun 2016</td>
<td>● Spring 2016 The Final Text of the Regulation is expected to be jointly agreed by the Commission, the Parliament and the Council no earlier than Spring 2016. It is unlikely that the Regulation will come into force before 2017-2018.</td>
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### Using this Guide

The purpose of this Guide is to provide in-house lawyers with the tools to:
- understand the key impacts of the Regulation on businesses; and
- explain those impacts to business decision-makers.

This Guide provides an overview of the topics in the Directive and the Regulation that are most likely to affect businesses. There are two pages for each topic:

- **On the left**, there is an explanation of why each topic matters to businesses and the key impacts that businesses should be aware of.
- **On the right**, there is a side-by-side comparison of the Directive and the Regulation, showing which issues materially change and which issues do not.

The page on the right uses the following symbols:

- **Some things stay the same** – Although the language of the Regulation often differs from the Directive, there are many issues for which the outcome is essentially the same. For each such issue, the text is shown in two grey boxes (the Directive on the left; the Regulation on the right) with an “approximately equals” sign between them, to indicate that there are no significant changes.

- **Some things materially change** – There are a number of areas in which the Regulation introduces changes that are likely to impact businesses. For these issues, the concepts are shown in blue, with an arrow between them, indicating the change.

- Some changes are broadly **positive for most businesses** (e.g., because they reduce the relevant compliance burden or provide greater certainty).
- Some changes make little **practical difference** for most businesses (e.g., because the new requirements create no new costs or burdens).
- Some changes are broadly **negative for most businesses** (e.g., increased compliance obligations or more severe penalties for non-compliance).

**Cross-referencing** – To enable easy cross-referencing to the original text, Articles from the Directive and the Regulation are identified with indented arrows where appropriate.

Defined terms and abbreviations used in this Guide are explained in the **Glossary** on page 42.
Conceptual Overview

Why is this issue important for businesses? Understanding the background to the EU’s data protection laws, as well as the changes that the Regulation will bring, is vital to any business assessing its data protection compliance obligations.

Affected sectors: All business sectors are likely to be affected by the proposed changes to EU data protection law that the Regulation will introduce.

Before 1995: Until the mid-1990s, the data protection laws of Member States were largely un harmonised. This meant that businesses operating in the EU faced different compliance obligations across the EU, depending upon national legal requirements.

The Directive: Introduced in 1995, the Directive created a broadly consistent set of data protection laws for the EU. The Directive (like any EU Directive) needed to be transposed into the national laws of Member States. Consequently, although the general principles of data protection law are similar across the EU, there remain differences between the laws of each Member State, and so businesses continue to face conflicting requirements.

New technologies: With the rise of the internet, technology evolved rapidly and the ways in which personal data could be used by businesses expanded. The explosive growth of social networking and big data analytics (among other things) made it increasingly clear that a new approach to data protection was required.

The Regulation: The Regulation is designed to further harmonise national data protection laws across the EU while, at the same time, addressing new technological developments. The Regulation will be directly applicable across the EU, without the need for national implementation. Businesses are likely to face fewer national variations in their data protection compliance obligations. However, as noted on page 40, there remain areas in which there will continue to be differences from one Member State to another.

Some concepts stay the same: The law still applies to all personal data, and responsibility for compliance continues to be allocated to parties in the roles of ‘controller’ and ‘processor’.

Some concepts change, and are likely to be good for businesses: For example, the increased harmonisation of data protection laws across the EU should result in fewer conflicting obligations and should make it easier to do business across the EU, relying on a single set of principles.

Some concepts change, and are likely to present challenges for businesses: In particular, new penalties (including fines of up to the greater of €100 million, or 2-5% of annual worldwide turnover) mark such a significant departure from the existing regime that they constitute a conceptual change. Data protection will be as significant as antitrust in terms of compliance risk. Under the Regulation, data protection will no longer be an area in which businesses can afford to take casual risks.

Going forward: The Regulation is likely to require organisation-wide changes for many businesses. In-house lawyers should start to consider the impact of these changes and plan ahead. Failure to do so could mean that businesses are left with new requirements to implement, without having set aside appropriate resources. However, the Regulation remains in draft, and nothing is set in stone yet, so such plans should remain reasonably flexible at this stage.

The Directive

Purpose: The purpose of the Directive is to provide a set of rules to govern the processing of personal data.

Scope: The Directive covers data protection law on an EU-wide basis, and applies to both the public and private sectors.

Implementation: The Directive needed to be implemented at a national level, requiring transposition into national law by the national legislature of each Member State.

Application: The Directive is an ‘omnibus’ privacy law – it applies across all business types and all sectors.

Harmonisation: Under the Directive, data protection law varies from one Member State to another, depending on national approaches to implementation and enforcement. These differences can be significant (e.g., in some Member States there is no obligation to register as a controller, in others it is a criminal offence to fail to do so).

Enforcement: Enforcement of the Directive (as implemented into national law) is carried out by national DPAs.

Penalties: Penalties are determined by national law and the maximum penalties are generally comparatively low (e.g., in the UK, the largest single fine issued to date is £250,000, and in other Member States fines have not exceeded the low millions of Euros).

The Regulation

Purpose: The purpose of the Regulation is to provide a new set of rules to govern the processing of personal data, replacing the Directive.

Scope: The Regulation covers data protection law on an EU-wide basis, but also has extra-territorial effect (see page 10). (A separate EU Directive, operating in parallel with the Regulation, will cover the processing of personal data in connection with the prevention, detection, investigation or prosecution of criminal offences and related judicial activities.) The Regulation applies to both the public and private sectors.

Implementation: The Regulation is directly applicable in all Member States. This means that the Regulation applies automatically in each Member State and (subject to the limited exceptions noted on page 40) it does not require any national implementation by Member States.

Application: The Regulation is an ‘omnibus’ privacy law – it applies across all business types and all sectors.

Harmonisation: Under the Regulation there is much greater harmonisation between the national data protection laws of Member States, because there is no need for national implementation. However, differences remain in a few areas (e.g., in relation to employment law and national security – see page 40).

Enforcement: Enforcement of the Regulation is carried out by national SAs. However, the Consistency Mechanism is intended to ensure that national SAs apply the Regulation consistently across the EU. In addition, the EDPB will play a significant part in enforcement decisions through the Consistency Mechanism (see pages 14-15).

Penalties: Penalties are specified in the Regulation. The maximum penalty is €100 million, or 2-5% of annual worldwide turnover, whichever is greater.
Definitions

Why is this issue important for businesses? Definitions form the building blocks of both the Directive and the Regulation. Understanding the nature and extent of the changes to these definitions is critical to understanding the Regulation.

Affected sectors: All business sectors will be affected by these new definitions.

- **Continuity of many core definitions**: As the comparison on page 9 (opposite) illustrates, many of the core definitions from the Directive (e.g., ‘controller’, ‘processor’ and ‘processing’) are essentially unchanged under the Regulation.

- **Continuity of many core definitions**: As the comparison on page 9 (opposite) illustrates, many of the core definitions from the Directive (e.g., ‘controller’, ‘processor’ and ‘processing’) are essentially unchanged under the Regulation.

- **Practical benefits of continuity**: The general continuity of definitions means that, in several areas, it is possible to build upon existing compliance structures and commercial arrangements, rather than starting again. For example:
  - **Contracts and contractual language** – If a business has already entered into contracts (e.g., data processing agreements) that use language such as ‘controller’ and ‘processor’, that language will continue to work under the Regulation largely as it did under the Directive (although it is important to consider whether any provisions should be updated to reflect the obligations of Processors under the Regulation – see page 26).
  - **Employee training** – If a business has already trained its employees to identify ‘personal data’, that training remains useful. Any data that were personal data under the Directive continue to be personal data under the Regulation.

- **Consent becomes harder to obtain**: In particular, the definition of ‘consent’ makes valid consent significantly more difficult to obtain (see page 28). Businesses that rely on consent will need to carefully review their existing practices and ensure that any consent they obtain is explicit, and indicates affirmative agreement from the data subject (e.g., ticking a blank box). Mere acquiescence (e.g., failing to un-tick a pre-ticked box) does not constitute valid consent under the Regulation. In the Parliament Text, consent expires once the specified purpose is fulfilled, and the controller is responsible for proving that consent was validly obtained.

- **Personal data of children**: The Regulation includes a requirement to obtain parental consent to the processing of personal data relating to a child under 13 years of age. It is important for businesses to consider how best to achieve this (particularly in an online context where identities can be difficult to verify).

- **Genetic data**: Genetic data are not explicitly mentioned in the Directive. Under the Regulation, genetic data are explicitly defined as sensitive personal data. Businesses that handle genetic data will need to consider whether changes to their business practices are required.

Please note: The comparison on page 9 (opposite) illustrates significant changes. However, in some cases, comparatively minor definition changes may still affect businesses. For example, the new definition of ‘personal data’ explicitly includes items such as online identifiers and location data. These items are often treated as personal data under the Directive, but some businesses have sought to argue that this is not the case. Under the Regulation, they will clearly be personal data, and affected business practices will need to be amended accordingly.

The Directive

**Art.2**

‘child’: There is no definition of a ‘child’ in the Directive.

**Art.4**


**Art.4**

‘consent’: any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed.

**Art.4**

‘controller’: the person or body that, alone or jointly with others, determines the purposes and means of the processing of personal data.

**Art.4**

‘personal data’: any information relating to an identified or identifiable natural person (a ‘data subject’); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

**Art.4**

‘processing’: any operation or set of operations performed upon personal data, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

**Art.5**

‘processor’: a person or body that processes personal data on behalf of the controller.

**Art.8(1)**

‘genetic data’: There is no definition of ‘genetic data’ in the Directive.

**Art.10**

‘sensitive personal data’: personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health or sex life. Several Member States have added actual or alleged criminal offences to this list.

**Art.9**

‘sensitive personal data’: personal data revealing race or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, genetic data, data concerning health or sex life, or criminal convictions or related security measures.

The Regulation

**Art.4**

‘controller’: the person or body that, alone or jointly with others, determines the purposes and means of the processing of personal data.

**Art.4**

‘personal data’: any information relating to a data subject.

‘data subject’: an identified natural person or a natural person who can be identified, directly or indirectly, by means reasonably likely to be used by the controller or by any other natural or legal person, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, genetic, mental, economic, cultural or social identity of that person.

‘processing’: any operation or set of operations performed upon personal data, or sets of personal data, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

‘processor’: a person or body that processes personal data on behalf of the controller.

‘genetic data’: any data that relate to characteristics that are inherited or acquired during early prenatal development. Genetic data are sensitive personal data.

Please note: The comparison on page 9 (opposite) illustrates significant changes. However, in some cases, comparatively minor definition changes may still affect businesses. For example, the new definition of ‘personal data’ explicitly includes items such as online identifiers and location data. These items are often treated as personal data under the Directive, but some businesses have sought to argue that this is not the case. Under the Regulation, they will clearly be personal data, and affected business practices will need to be amended accordingly.
Jurisdiction and Territorial Scope

Why is this issue important for businesses? Understanding whether the Regulation will apply to a business or not (particularly if that business is established outside the EU) is fundamental to identifying that business's compliance obligations.

Affected sectors: This issue is of particular relevance to businesses that are based outside the EU, but conduct business in the EU.

- For businesses in the EU, there are no material changes: If a given entity is established in any Member State, then it is subject to the Directive (as implemented in that Member State) and it will be subject to the Regulation.

- For businesses based in the EU, the requirements change: The test for determining whether EU data protection law applies to entities established in non-EU jurisdictions will change significantly:
  - Under the Directive: EU data protection law only applies to an entity established outside the EU if it uses a 'means of processing' (automated or otherwise) located in the EU. A 'means of processing' includes:
    (i) equipment situated in the EU (e.g., a server) unless that equipment is only used for the purposes of simply transmitting data; or
    (ii) a processor established in the EU.
  - Under the Regulation: The test set out in the Directive will fall away, and is replaced by a new test. If an entity is established outside the EU, and it either:
    (i) offers goods or service to EU residents; or
    (ii) monitors the behaviour of EU residents,
    that entity will be subject to the Regulation.

The Directive

Art.4(1)(a)
Is the relevant entity established as a controller in one or more Member States?

Yes
No

Art.4(1)(b)
Does the national law of any Member State apply to the entity by virtue of Public International Law?

Yes
No

Art.4(1)(c)
Does the entity use any 'means of processing' (automated or otherwise) located in any Member State?

Yes
No

Outcome: It is subject to the Directive as implemented in each Member State in which it is established.

Outcome: It must comply with the Regulation regardless of which Member State(s) it is established in.

The Regulation

Art.3(1)
Is the relevant entity established as a controller or a processor in one or more Member States?

Yes
No

Art.3(2)
Does the entity either: (i) offer goods or services to EU residents; or (ii) monitor EU residents' behaviour?

Yes
No

Art.3(3)
Does the national law of any Member State apply to the entity by virtue of Public International Law?

Yes
No

Outcome: The entity must use such 'means of processing' for the purposes of transmitting data?

Yes
No

Outcome: The entity must comply with the Directive as implemented by the national laws of each Member State in which it is subject to the Directive.

Outcome: The entity is not subject to the Directive.

Art.2(2)
Outcome: The entity must appoint a Representative in each such Member State.

Art.25(1)
Outcome: The entity must appoint a Representative in one of the Member States in which it either offers goods or services or monitors the behaviour of EU residents.

PLEASE NOTE: The flow-chart on page 11 is designed to assist with the analysis of these issues. This flowchart is designed on a per-entity basis – it does not work for corporate groups collectively. Under both the Directive and the Regulation, it is possible that some entities within a corporate group will have compliance obligations under EU data protection law, while other entities will not.
Enforcement, Sanctions and Penalties

Why is this issue important for businesses? The likelihood of enforcement and the magnitude of any applicable sanctions and penalties influence a business’ approach to compliance. The Regulation makes significant changes in this area.

Affected sectors: All business sectors will be subject to the new enforcement powers, sanctions and penalties that the Regulation imposes.

- Enforcement powers: Under the Directive, the powers of national DPs are not defined beyond high-level concepts of broad investigative and enforcement powers. Instead, the Directive leaves the detail of DPA enforcement powers to individual Member States. The Regulation will grant SAs (see page 14) specific enforcement powers, although these will still be subject to implementation into the national law of Member States.

- Sanctions and penalties: Under the Directive, the penalties and sanctions for breaches of national data protection law are not harmonised, and the maximum applicable penalties vary considerably across different Member States. The Regulation sets out the range of applicable administrative sanctions for breaches of certain aspects of the Regulation. Individual SAs will retain discretion to determine the particular sanction to be applied in a given case, but the maximum sanctions will be prescribed by the Regulation.

- Enforcement actions: Under the Directive, the circumstances in which DPs may take enforcement action are not prescribed. For example, in Spain, the DPA is required by law to investigate all complaints received, but this is typically not the case in other Member States. Under the Regulation, data subjects will be entitled to obtain a court remedy requiring the SA to investigate a complaint.

- Harmonisation: The Regulation will harmonise enforcement powers across the EU (including through the Consistency Mechanism – see page 14) although the procedures of individual SAs will still be subject to national implementation (see page 40).

- Significantly increased sanctions and penalties: The Regulation will prescribe the administrative sanctions applicable to breaches of the Regulation, and will harmonise the approach to enforcement across the EU. This will result in a substantial increase in the maximum possible fine. For example, the current maximum fine in the UK is £500,000 and the largest single fine issued to date is £250,000. Under the Regulation, the maximum fine will become the greater of €100 million, or 2-5% of annual worldwide turnover.

- Judicial remedies: The Regulation will grant data subjects the right to obtain a judicial remedy against an SA, requiring the SA to act on the data subject’s complaint. In practice, this will mean that SAs are obliged to investigate complaints that previously may not have received significant DPA attention.

- Going forward: Businesses that had not previously regarded non-compliance with EU data protection law as a serious risk will be forced to re-evaluate their positions in light of the substantial new fines, increased DPA enforcement powers and grounds for seeking judicial remedies under the Regulation.

The Directive

Art.22
Remedies: Under the Directive, Member States must provide every data subject with the right to a judicial remedy for breach of any of his or her data protection rights. In practice, the rights of data subjects differ across Member States.

Art.23
Compensation: Under the Directive, Member States must provide a right for data subjects to recover compensation from any controller who processes personal data unlawfully.

Art.24
Sanctions: Under the Directive, Member States are required to impose sanctions on controllers for breach of national data protection law. The Directive does not specify the sanctions to be imposed.

The Regulation

Art.74 & 75
Right to a remedy against an SA: Under the Regulation, all data subjects will have the right to seek a judicial remedy requiring the SA to act on a complaint by the data subject. In addition, the Regulation will provide businesses and data subjects with a right to seek a judicial remedy against a decision of the SA.

Art.77
Compensation: All data subjects will have the right to obtain compensation from the relevant controller or processor for damage suffered as a result of processing carried out in breach of the Regulation.

Art.79
Sanctions: The sanctions applicable for breaches of the Regulation include:
- for individuals and small businesses who commit a first, non-intentional breach of the Regulation, a written warning may be given;
- for a failure to provide an adequate mechanism for data subjects to exercise their rights, a fine of up to €250,000 or 0.5% of the controller’s annual worldwide turnover;
- for a failure to provide adequate information to data subjects or to allow subject access, or to comply with the right to be forgotten (amongst others), a fine of up to €500,000 or 1% of the controller’s annual worldwide turnover; or
- for processing personal data without a valid processing condition, failure to comply with the conditions relating to Profiling and other more serious breaches of the Regulation, a fine of up to €100 million or 2-5% of the controller’s annual worldwide turnover.

Art.28
DPA enforcement powers: DPs have the following minimum powers, under national law:
- investigative powers;
- powers of intervention (e.g., to order the blocking, erasure or destruction of data); and
- the power to commence legal proceedings.

Art.53
SA enforcement powers: SAs will be given widespread powers to enforce compliance with the Regulation (e.g., the power to compel a controller or processor to provide any information relevant to the performance of the SAs duties, and the power to impose a ban on processing).
Supervisory Authorities

Why is this issue important for businesses? The Directive is enforced by national DPAs, which have a significant degree of autonomy. Under the Regulation, SAIs will be obliged to enforce the law consistently across the EU.

Affected sectors: Businesses in all sectors will be subject to investigation of their processing activities, and enforcement of the Regulation, by SAs.

- The Directive: Under the Directive, each Member State has created a national DPA, tasked with enforcing the Directive, as implemented under the national law of that Member State. The DPA investigates breaches of national data protection law and brings enforcement actions in the event of a breach of that law. The DPA is generally the main forum to which data subjects may bring complaints.

- The Regulation: Under the Regulation, each Member State must create one or more SAs. SAs will broadly the same role that DPAs fulfil under the Directive, and most Member States will transition their existing DPA into the SA role when the Regulation comes into force. As with the position under the Directive, each SA will investigate breaches of the Regulation and bring enforcement action in the event of a breach. The SA will provide the main forum to which data subjects may bring complaints.

- The 'One Stop Shop': Under the Regulation, a business with multiple establishments in the EU, it will have a single SA as its "lead authority" based on the location of its 'main establishment' (i.e., the place where the main processing activities take place). The lead authority will act as a 'One Stop Shop' to supervise all the processing activities of that business throughout the EU. The precise rules by which this mechanism will operate are still subject to substantial questions, and the final position remains unclear (e.g., the Commission Text extends it to processors, but later texts do not).

- The Consistency Mechanism: In order to ensure that the Regulation is enforced uniformly across the EU (and that businesses face the same compliance obligations in each Member State) the Regulation will require the lead authority to consult with the other affected SAs and the EDPB in cases in which enforcement action by a lead authority affects processing activities in more than one Member State. A wide range of issues will fall under the Consistency Mechanism (e.g., multi-jurisdictional enforcement issues; BCRs; etc.).

- The EDPB: Under the Regulation, the EDPB will effectively replace the WP29. It will task with advising the EU institutions on data protection issues, including amendments to the Regulation; advising on the enforcement of the Regulation by SAs; overseeing the implementation of the Consistency Mechanism and promoting cooperation between SAs.

- Going forward: For businesses that only operate within a single Member State, and only process personal data of data subjects residing in that Member State, interaction with the local SA under the Regulation will be similar to interaction with the local DPA under the Directive. Businesses that operate in more than one Member State will see a substantial change, as the One Stop Shop will mean that they predominantly interact with a single SA as their lead authority (rather than multiple DPAs).

The Directive

Art. 28
Background and role: Each Member State must appoint one or more DPAs to oversee the implementation of the Directive, and to protect the rights and freedoms of data subjects.

Territorial scope: The DPA has oversight of processing activities taking place on the territory of its own Member State only.

Art. 28(3)
Powers: Each Member State must provide its DPA with investigative powers, the power to intervene, and the power to initiate legal proceedings.

Art. 29
Cooperation among DPAs: DPAs are obliged to cooperate with one another to the extent necessary to perform their duties.

Art. 28
The WP29: The WP29 comprises representatives of the DPAs, and serves in an advisory capacity.

Art. 51
The 'One Stop Shop': Under the Directive, a business with multiple establishments in the EU, it will have a 'lead authority', determined by the place of its 'main establishment' in the EU (i.e., the place where the main processing activities take place). The 'lead authority' effectively regulates that business across all Member States.

Art. 57-63
The Consistency Mechanism: Under the Directive, DPAs can (and frequently do) adopt enforcement positions that differ from the positions adopted by other DPAs. This means that businesses face inconsistent compliance obligations across the various Member States.

Art. 74(3)
Appeals: Actions of the DPA may be appealed through the national courts of the Member State.

The Regulation

Art. 46
Background and role: Each Member State must appoint one or more SAs to oversee the application of the Regulation, and to protect the rights and freedoms of data subjects.

Territorial scope: The SA is only entitled to exercise its powers in its own Member State but, under the One Stop Shop, the SA's regulatory actions may affect processing that occurs in other Member States.

Art. 53
Powers: The Regulation grants each SA the power for the Enforcement, to investigate breaches of the Regulation, and to initiate legal proceedings.

Art. 55 & 58
Cooperation among SAs: The SAs must provide one another with mutual assistance in the performance of their duties and may carry out joint operations.

The EDPB: The EDPB effectively replaces the WP29. As well as performing an advisory role, it is also actively involved in enforcement decisions.

Art. 51
The 'One Stop Shop': Where a business is established in more than one Member State, it will have a 'lead authority', determined by the place of its 'main establishment' in the EU (i.e., the place where the main processing activities take place). The 'lead authority' effectively regulates that business across all Member States.

Art. 57-63
The Consistency Mechanism: Under the Regulation, where a given processing activity affects data subjects in more than one Member State, the relevant SA must consult with all other affected SAs and the EDPB, to ensure that any enforcement action is consistent across the EU.

Art. 74(3)
Appeals: Actions of the SA may be appealed through the national courts of the Member State.
Accountability

Why is this issue important for businesses? The Regulation will require businesses to implement compliance programs to verify that their processing activities comply with the Regulation, and demonstrate that could reference to SAIs and data subjects.

Affected sectors: Businesses in all sectors will need to review their compliance programs and, where necessary, take remedial action.

- Accountability in general: The Regulation will require controllers to implement policies and procedures to ensure compliance with the Regulation. Controllers must verify the effectiveness of their compliance programs and, where proportionate, such verification should be carried out by an independent expert. In addition, controllers must demonstrate their compliance and (as noted on page 18) controllers must ensure that their data protection policies and information notices are transparent and easily accessible to data subjects. Elements of a compliance program include (but are not limited to):
  - appointing a DPO;
  - maintaining internal records;
  - implementing robust information security measures (see page 24); and
  - privacy by design and DPIAs (see page 20).

- Data protection registrations: Under the Directive, controllers are required to register their processing activities with the relevant DPA. In some Member States (e.g., Ireland and the UK) the controller need only provide the DPA with a high-level summary of its data processing activities. In other Member States (e.g., Austria and France) the controller must provide a very detailed explanation of its processing activities.

The Regulation will abolish the registration requirement, and replace it with an obligation to maintain internal records of data processing activities. The Regulation sets out a detailed list of information that must be included in these records and, in many cases, they are more detailed than the equivalent national registration requirements under the Directive.

- Data Protection Officers:
  - Under the Directive: There is no obligation to appoint a data protection officer (“DPO”) under the Directive, although some businesses choose to do so. In addition, some Member States (e.g., Germany and Sweden) have provided an exemption from the obligation to register if a DPO is appointed and maintains records of the controller’s processing activities.
  - Under the Regulation: The Commission Text states that all businesses with 250 or more employees must appoint a DPO. The Parliament Text amends this requirement so that any business that processes the personal data of more than 5,000 data subjects in a year must appoint a DPO. It is unclear how the final text of the Regulation will address this issue.

- Going forward: Businesses should:
  - Review their existing compliance programs. To the extent that a business’s existing compliance program does not fully address the requirements of the Regulation, that program should be updated and expanded as necessary. Ensure that they have clear records of all of their data processing activities. If this information has already been collated (e.g., as the result of a recent registration project) then producing internal records is likely to be straightforward. If the information has not yet been collated, or is not current, substantial work may be required.
  - Identify a suitable person to fulfil the role of the DPO. Businesses should be aware that if an employee is appointed as the DPO, that employee may have protected employment status.
Information Notices

Why is this issue important for businesses? In order to give effect to the rights of data subjects (see page 38), all businesses have a duty to provide certain minimum information about their data processing activities to data subjects.

Affected sectors: Businesses that act as controllers will be particularly affected by the requirement to provide notices to data subjects.

- The Directive: The Directive specifies a minimum set of information to be provided by controllers to data subjects. Some Member States have gone beyond the minimum requirements. Consequently, the precise information that must be provided in an information notice varies from one Member State to another. Businesses operating in several Member States are required to assess their notice obligations on a county-by-country basis and to amend their information notices accordingly. This can be a costly, difficult and time-consuming exercise.

- The Regulation: The Regulation sets a higher standard of notice than the Directive, by adding a significant number of new fields of information that must be provided in all information notices.
  - The primary advantage for businesses of the approach in the Regulation is that a single notice likely will be sufficient in all Member States (although translations into the relevant local language will still be necessary).
  - The primary disadvantage for businesses of the approach in the Regulation is that notices will have to be more detailed. This is a particular challenge for businesses that frequently share data intra-group, without tight restrictions on the purposes for which other group entities may use those data.

Penalties for failing to provide a valid information notice: The Regulation will increase both the detail to be provided in these notices and the penalties for failing to comply (see page 12). A negligent or intentional failure to provide a valid information notice will attract a fine of up to €500,000 or 1% of annual worldwide turnover, whichever is greater.

- Going forward: Businesses currently have an obligation to provide notice of their processing activities to data subjects, but not all such notices are compliant with the existing law. Before the Regulation comes into force, businesses should take the opportunity to review their existing information notices and identify any missing details that will need to be provided under the Regulation. Although this is likely to require substantial effort, businesses can build on their existing information notices, as the basic information required under the Directive is also required under the Regulation.

PLEASE NOTE: The Parliament Text proposes the use of standardised icons to indicate important features of the relevant data processing activities in simplified format.
Privacy by Design and by Default / DPIAs

Why is this issue important for businesses? These principles require businesses to take privacy and data protection issues into account from the start of any product design process, and to properly assess the risks before launching any new products.

Affected sectors: All business sectors will be affected by these requirements.

- Privacy by design: Whenever a business develops or designs a new technology, product or service, it should do so in a way that ensures compliance with data protection obligations. This approach is intended to ensure that a privacy-compliant approach is embedded in new technologies, products and services. Businesses should consider the entire lifecycle of the relevant processing activities, and plan for foreseeable uses of the new technology, product or service that may affect the data protection rights of data subjects.

- Privacy as a differentiator: DPIAs provide a tangible tool to which a business can point, to demonstrate that it takes the privacy concerns of its customers seriously, and that it has appropriately addressed those concerns. This, in turn, can help that business to differentiate its products and services from those of its competitors and reassure its customers that their personal data will be processed safely and responsibly.

- Limited economic impact: Although the principles of privacy by design and by default, and the requirement to perform DPIAs, impose a clear administrative burden on businesses, the overall cost of these measures will often be limited, once internal systems and procedures have been implemented to aid management of these issues. These costs are likely to be offset by the long-term benefits of compliance, bearing in mind the potentially significant cost of non-compliance (see page 12).

- Going forward: Under the Regulation, businesses are legally required to: (i) take data protection requirements into account from the inception of any new technology, product or service that involves the processing of personal data; and (ii) conduct DPIAs where appropriate. These steps will need to be planned into future product cycles.

PLEASE NOTE: The precise scope of the principles of privacy by design and by default is still under discussion. The Council has proposed a risk-based approach to compliance, which allows controllers to exercise greater discretion and flexibility in assessing how to address their compliance responsibilities in the context of their particular businesses. The Parliament has proposed significant amendments to the provisions concerning DPIAs, but whether these amendments will remain in the final text is not yet known.
Why is this issue important for businesses? Increasingly, businesses Profile their customers or engage third parties to do so. The Regulation will make it easier for data subjects to opt out of being Profiled.

Affected sectors: This issue is of particular relevance to businesses that provide or use services related to online marketing, analytics, customer tracking and ad conversion.

• Definition of 'Profiling': Under the Regulation, data subjects have the right not to be subject to automated processing of personal data intended to evaluate, analyse or predict any feature of their behaviour, preferences or identity ("Profiling"). Examples of Profiling activities include forms of customer tracking and ad conversion measurement that offer discounts to repeat customers.

• Technological advances: One of the key drivers behind the Regulation is the need to adapt EU data protection law to the risks and opportunities created by technological developments. In particular, Profiling allows businesses to analyse and predict aspects of a data subject's behaviour (such as consumption habits, interests, preferences, etc.), in many cases, without the data subject even being aware. While these advances have obvious advantages, they also carry inherent privacy risks, which the Regulation seeks to address.

• Protection for data subjects: The Regulation includes a provision to strengthen the protections available to data subjects against possible negative effects of Profiling. This replaces the outdated prohibition on automated decision-making set out in the Directive. The Regulation prohibits businesses from taking measures based on Profiling that: (i) produce 'legal effects' for data subjects; or (ii) significantly affect data subjects, without a lawful basis for doing so. This prohibition on Profiling is significantly broader than the existing prohibition in the Directive. As a result, many Profiling activities that are currently permitted may no longer be lawful under the Regulation.

• The need for consent: In practice, the only lawful basis for Profiling that will be available to businesses in most circumstances will be the consent of the data subject. The Regulation makes it more difficult for businesses to obtain valid consent (see pages 8 and 28). Consequently, lawful Profiling is likely to be substantially more difficult to achieve under the Regulation. For example, passive acquiescence of users to a general set of terms and conditions will not result in valid consent. Instead, it will be necessary to implement tick-boxes or similar mechanisms to secure the data subject's positive indication of consent to specific processing activities related to Profiling.

• Going Forward: The impact of the Regulation’s restrictions on Profiling on a given business will largely depend on how frequently that business engages in Profiling activities. For those businesses for which Profiling is a rare or occasional activity, it may simply be easier to cease such activities than to comply with the Regulation. Those businesses that regularly engage in Profiling activities (e.g., in the advertising or social media context) will need to consider how best to implement appropriate consent mechanisms in order to continue these activities.

The Directive

Art.15
General concept: The Directive does not explicitly define or refer to the concept 'Profiling'. However, it does regulate a similar (though narrower) practice of 'automated individual decisions' that produce 'legal effects' on them, or significantly affect them.

Restriction on ‘automated individual decisions’: Automated individual decision making is prohibited, unless:
• the decision is taken in the course of the performance of, or entering into, a contract, provided that: (a) the data subject asked to enter into the contract; or (b) there are suitable measures in place to protect the data subject’s legitimate interests;
• the decision-making is authorised by a Member State law that provides suitable safeguards for the data subject’s legitimate interests.

Rights of data subjects: As part of the right of access to data (see page 38), data subjects have the right to obtain information on the logic involved in any automated processing of data concerning them.

Automated processing of sensitive personal data: The Directive does not directly address the automated processing of sensitive personal data.

The Regulation

Art.20
General concept: Under the Regulation, data subjects have the right not to be subject to measures based on Profiling that produce 'legal effects' on them, or significantly affect them.

Restrictions on Profiling: Measures based on Profiling are only permissible if the Profiling:
• is carried out in the course of the performance of, or entering into, a contract, provided that: (a) the data subject asked to enter into the contract; or (b) there are suitable measures in place to protect the data subject’s legitimate interests;
• is expressly authorised by a Member State law that provides suitable safeguards for the data subject’s legitimate interests; or
• is carried out with the data subject’s consent.

Rights of data subjects: The information provided to data subjects in the information notice (see page 18) should include information about the Profiling and an explanation of how the Profiling is likely to affect the data subject.

Automated processing of sensitive personal data: Profiling performed solely on the basis of sensitive personal data is prohibited. (See the definition of 'sensitive personal data' on page 9).
Data Breach Reporting

Why is this issue important for businesses? In order to force businesses to take a more pro-active approach to data security, the Regulation introduces a general data breach reporting obligation.

Affected sectors: Any business that suffers a data breach will be subject to the new reporting requirements under the Regulation.

- **The Directive:*** Under the Directive, there is no general obligation on businesses to notify data breaches either to DPAs or to the affected data subjects. (Although there are some sector-specific breach reporting obligations in other areas of EU law – e.g., for providers of electronic communications services, there is a reporting obligation under the e-Privacy Directive 2002/58, as amended).

Some Member States have implemented breach reporting obligations in their national laws (e.g., Austria and Germany). Furthermore, the WP25 and certain local DPAs (e.g., Belgium, Denmark, Ireland and the United Kingdom) have issued guidance strongly urging businesses to voluntarily report serious data breaches. In instances where failed to report such breaches can result in increased penalties if the DPA later investigates the breach and discovers a failure to comply with national data protection law.

- **The Regulation:*** The Regulation will introduce a general data breach reporting obligation, requiring businesses in all sectors to report breaches. (e.g., cancel affected credit cards); and (iii) motivate businesses to implement robust information security measures in order to avoid data breaches.

- **Consequences of non-compliance:*** Businesses that fail to fulfil their data breach reporting obligations may be sanctioned by the SA with a fine of up to €1 million or, up to 2% of annual worldwide turnover, whichever is greater.

- **Going forward:*** Businesses will need to develop and implement a data breach response plan (including designating specific roles and responsibilities, training employees, and preparing template notifications) enabling them to react promptly in the event of a data breach.

Information security measures will need to be re-assessed to ensure that data breaches can be detected and managed promptly. Businesses should also consider implementing measures to ensure that any data that are subject to a breach are unintelligible to any person who is not authorised to access the data (e.g., by encrypting data wherever possible), as this may exempt the business from the obligation to report the breach to the affected data subjects, and may help prevent harm to the business’s reputation.

Complying with the data breach reporting obligations in the Regulation will also entail a significant administrative burden for businesses, which may increase costs. On the other hand, the harmonisation of the data breach reporting obligation will allow businesses operating across multiple Member States to have one pan-EU data breach response plan.
Obligations of Processors

Why is this issue important for businesses? Unlike the Directive (which generally places direct compliance obligations only on controllers), the Regulation will impose direct compliance obligations on processors as well.

Affected sectors: This issue primarily affects businesses that act as processors, but it may also affect any business that engages a processor to process data on its behalf.

- The Directive: Under the Directive, the primary obligation to comply with EU data protection law falls on controllers. If a DPA takes any enforcement action, it does so against the controller. The controller is required to impose certain compliance obligations on any processor it appoints, in a binding contract, but the DPA generally does not have direct enforcement powers against the processor.

- The Regulation: Rather than relying on controllers to contractually flow down compliance obligations to processors, the Regulation will impose a number of obligations directly on processors. These direct obligations include:
  - maintaining records of processing activities;
  - cooperating with the relevant SA;
  - implementing appropriate security measures;
  - appointing a DPO (see page 16);
  - informing the controller in the event of a data breach;
  - performing DPIAs;
  - obtaining prior authorisation from, or ensuring prior consultation with, the relevant SA before commencing certain types of processing; and
  - complying with the requirements of the Regulation regarding cross-border data transfers (see page 32).

The Regulation will also explicitly state that a processor will be considered a joint controller in the event that it processes personal data other than in accordance with the instructions of the controller.

- Contractual obligations: Much like the Directive, the Regulation will require that the outsourcing of data processing activities by a controller to a processor is governed by a written data processing agreement. Whereas the Directive does not specify the content of this data processing agreement, the Regulation will mandate in detail the terms that must be included in such an agreement.

- Penalties for failure to comply: Because processors will have direct compliance obligations under the Regulation, they will also face penalties for non-compliance. Deliberate or negligent breach by a processor of its obligations will attract a fine of up to €100 million or 2-5% of annual worldwide turnover, whichever is greater.

- Going forward: The Regulation is likely to substantially impact both processors and controllers that engage processors:
  - The increased compliance obligations and penalties for processors are likely to result in an increase in the cost of data processing services.
  - Negotiating data processing agreements may become more difficult, as processors will have a greater interest in ensuring the scope of the controller’s instructions is clear.
  - Some processors may wish to review their existing data processing agreements, to ensure that they have met their own compliance obligations under the Regulation.

The Directive

Art.4(1)(e)

Art.17
Appointing a processor: A controller must appoint a processor under a written data processing agreement.

Content of data processing agreements: The data processing agreement must specify that the processor shall:
- act only on instructions from the controller;
- implement appropriate technical and organisational information security measures.

Many Member States have implemented additional requirements that go beyond the requirements of the Directive.

The Regulation

Art.3(1)
Application of the law: Under the Regulation, EU data protection law applies directly to controllers and processors.

Art.26-28
Appointing a processor: A controller must appoint a processor under a written data processing agreement.

Content of data processing agreements: The data processing agreement must specify that the processor shall:
- act only on instructions from the controller;
- impose a duty of confidentiality on relevant staff; and
- implement the necessary security measures; and
- subcontract processing activities only with the controller’s prior permission;
- in so far as possible, make arrangements to enable the controller to fulfils the rights of data subjects (see page 38);
- assist the controller in complying with its obligations regarding data security and consultation with SAs;
- return all relevant personal data to the controller after the end of the processing and not process the relevant personal data further;
- make available to the controller and the relevant SA all necessary information regarding the processor’s data processing activities.

Art.28-31; 33-35; 40
Direct legal obligations of processors: The Regulation does not impose direct legal obligations on processors.

Direct legal obligations of processors: The Regulation requires processors to:
- maintain records of its processing activities;
- co-operate with the SA;
- implement appropriate technical and organisational information security measures;
- inform the controller immediately after discovering a data breach;
- perform DPIAs for high-risk processing activities;
- obtain prior authorisation or perform prior consultation with SAs, where required;
- appoint a DPO if required (see page 16); and
- comply with the restrictions regarding cross-border data transfers.

Direct enforcement against processors: EU data protection law cannot be enforced directly against processors under the Directive.

Direct enforcement against processors: The Regulation will be enforced by SAs directly against processors.
Processing Conditions

Why is this issue important for businesses? A 'processing condition' is a legal basis for processing personal data. Businesses must satisfy at least one processing condition for each data processing activity they undertake.

Affected sectors: Businesses in all sectors will need to ensure that they have valid processing conditions for their data processing activities.

The Directive: Under the Directive, all processing activities (including collecting, reviewing, deleting or merely storing personal data) require a 'processing condition'. A processing condition is a lawful ground on which personal data may be processed, and these are set out in the Directive (see page 29). A narrower set of processing conditions applies to the processing of sensitive personal data.

The Regulation: Under the Regulation, processing conditions are more onerous. In particular, consent will become significantly harder to rely on (see also the revised definition of consent, discussed on page 8).

Conditions for consent: Where consent is given in a document that also concerns other matters (e.g., a set of website Terms and Conditions that govern both use of the site and processing of personal data) the Regulation requires that consent must be presented in a manner that is clearly distinguishable from other subject matter (Art.7(1)). As a result, businesses will not be able to rely on a standard set of contractual terms to obtain consent for the processing of personal data.

'Significant imbalance': Under the Regulation, consent is not valid where there is a 'significant imbalance' between the data subject and the controller (Art.7(4)). Many DPAs already interpret the Directive to include such a requirement, and this will be explicitly set out in the Regulation. In particular, it is doubtful that employers will be able to rely on the consent of their employees in the majority of cases.

Legitimate interests: Under the Regulation, as with the Directive, the legitimate interests of the controller must be balanced against the rights of the data subject. Where data subjects require special protection (e.g., they are children) the balance tilts against the controller. Also, as noted on page 19, the controller's legitimate interests must be explained in the controller's information notice. In the Parliament Text, the legitimate interests processing condition is narrower and more difficult for controllers to rely on.

Sensitive personal data: In addition to narrowing the conditions on which sensitive personal data can be processed, the Regulation expands the categories of data that are deemed to be sensitive. As noted on page 9, the Regulation adds genetic data and data concerning criminal convictions or related security measures to the categories of sensitive personal data.

Additional requirements: Businesses that process sensitive data for health purposes, or for historical, statistical or scientific research, should be aware of the additional safeguards imposed on these types of processing (see Art. 81 and 83 of the Regulation).

Going forward: Businesses will need to carefully consider whether they have a lawful processing condition for all of their data processing activities. Where no processing condition applies, businesses will need to determine whether: (i) another processing condition might be available (e.g., by obtaining consent from affected data subjects) or (ii) that processing activity should cease.

Consent: Consent is a valid processing condition if the data subject has 'unambiguously' given his or her consent.

Legitimate Interests: Personal data may be processed for the purposes of legitimate interests pursued by the controller, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject.

Consent to process sensitive personal data: The processing of sensitive personal data usually requires the consent of the data subject.

Processing sensitive personal data without consent: Sensitive data may be processed if the processing is necessary:

- for the purposes of applicable employment law;
- to protect the vital interests of the data subject;
- for the purposes of a legal claim;
- the processing relates to data that have been deliberately made public by the data subject; or
- additional grounds created by Member States in their national laws.

Consent to process sensitive personal data: The processing of sensitive personal data is prohibited without the explicit consent of the data subject.

Processing sensitive personal data without consent: In addition to the conditions set out in the Directive, the grounds for processing sensitive personal data include cases where the processing:

- is carried out in the public interest, on the basis of EU law, subject to appropriate protections;
- of health data is necessary for health purposes, subject to appropriate protections; or
- is for historical, statistical or scientific purposes, subject to appropriate protections.
Anonymisation and Pseudonymisation

Why is this issue important for businesses? In many cases, businesses can use data that would otherwise be subject to EU data protection law if those data are anonymised, so that data subjects are no longer identifiable.

Affected sectors: This issue is particularly relevant to businesses that re-purpose or publish existing data (e.g., ‘big data’ businesses; CROs; data aggregators; etc.).

• Background: There are some cases in which a business may want to use information about people, without needing to identify data subjects from those data (e.g., in clinical trials, or statistical analysis). If the data can be structured in such a way that they do not enable the identification of data subjects, then the requirements of EU data protection law can be reduced, or may no longer apply. There are two ways to achieve this:
  • ‘Anonymous data’ are data from which no data subjects can be identified. Although not explicitly defined in either the Directive or the Regulation, ‘anonymous data’ are not personal data and are not subject to the requirements of EU data protection law.
  • ‘Pseudonymous data’ are data that are ‘coded’ (i.e., details such as a data subject’s name and address are replaced with pseudonyms) in such a way that the data cannot be attributed to a particular data subject without the use of additional information (i.e., a ‘key’ that can re-identify data subjects from the data). Under the Regulation, pseudonymous data will be treated as personal data, but pseudonymous data will likely be subject to less stringent protections. The Parliament Text requires that the ‘key’ necessary to identify data subjects from the coded data is kept separately, and is subject to technical and organisational security measures to prevent inadvertent re-identification of the coded data.

• Pseudonymous data and Profiling: Under the Parliament Text, there is a presumption that Profiling based on pseudonymous data will not adversely affect data subjects. In addition, Member States may (under the same Text) allow processing of certain health data without the consent of data subjects provided such data are anonymised, or if anonymisation is not possible, pseudonymised to the highest technical standards. However, where Profiling activities enable identification of data subjects from pseudonymous data, those data will no longer be considered pseudonymous.

• Going forward: Currently, national DPAs have differing approaches to anonymisation and pseudonymisation, and the criteria for determining whether data are truly anonymised or pseudonymised. Compliance with these divergent guidelines is often difficult for businesses that process anonymous or pseudonymous data in multiple Member States. EU-wide guidelines are expected to be produced under Art.38 of the Regulation once it enters into force, unifying the current disparate approaches.

The Directive

Recital 26
Anonymous data: The Directive recognises that the rules that apply to personal data do not apply to data that are anonymised (i.e., data that have been amended in such a way that data subjects are no longer identifiable).

Definitions: The concepts of anonymous data and pseudonymous data are not explicitly defined in the Directive.

The Regulation

Recital 23
Anonymous data: The Regulation recognises that the rules that apply to personal data do not apply to data that are anonymised (i.e., they are amended in such a way that data subjects are no longer identifiable).

Art.4
Definitions (Commission Text): The concepts of anonymous data and pseudonymous data are not explicitly defined in the Regulation.

Definitions (Parliament Text):
• “anonymous data” are not defined.
• “pseudonymous data” are personal data that cannot be attributed to a specific data subject without the use of an additional key, which is kept separately and stored securely.

Art.10
Re-identification of anonymous and pseudonymous data: Businesses are not obliged to collect further information in order to identify data subjects who are otherwise not identifiable.

Recital 38; 58a
Pseudonymous data and Profiling: The Directive is silent on this issue.

Pseudonymous data and Profiling (Commission Text): The Regulation is silent on this issue.

Pseudonymous data and Profiling (Parliament Text): Profiling based on pseudonymised data will not be presumed to significantly affect the rights of data subjects. However, where Profiling activities enable identification of data subjects from pseudonymised data, those data will no longer be considered pseudonymous.

Art.81
Pseudonymous health data: The Directive is silent on this issue.

Pseudonymous health data (Commission Text): The Regulation is silent on this issue.

Pseudonymous health data (Parliament Text): Member States can provide exceptions to the requirement for consent to process health data, provided that such data are anonymised or, if that is not possible for research purposes, pseudonymised to the highest technical standards.
Cross-Border Data Transfers

Why is this issue important for businesses? The Directive and the Regulation both restrict the ability of businesses to transfer personal data out of the EEA. For any business with multinational operations, this is a significant issue.

Affected sectors: This issue affects all businesses that transfer personal data out of the EEA and, increasingly, businesses that use cloud platforms and remote IT services.

- The Directive: Under the Directive, businesses are prohibited from transferring personal data out of the EEA unless:
  - the transfer is to an Adequate Jurisdiction;
  - the transfer is made pursuant to a mechanism that ensures an adequate level of protection (e.g., Model Clauses); or
  - a derogation applies. These restrictions are not uniformly interpreted. When businesses rely on Model Clauses or the U.S.-EU Safe Harbor, they only invest upon prior notification (and, in a few cases, prior authorisation).

- The Regulation: Under the Regulation, the existing transfer restrictions will be preserved but, importantly, SAs will be prevented from requiring further notification or authorisation where the requirements are otherwise satisfied.

- Adequate Jurisdictions: The European Commission has the power to determine that a non-EEA jurisdiction (and, under the Regulation, a territory or processing sector within such a jurisdiction) offers an adequate level of protection for personal data, based on that country’s data protection laws and approach to enforcement. A current list of the Approved Jurisdictions is provided in the Glossary (see page 42).

- Safe Harbor: Under the Regulation, the U.S.-EU Safe Harbor framework will continue to provide a lawful mechanism for the transfer of personal data from the EU to the U.S.

- Model Clauses: Transfers of personal data out of the EEA may also be made based on Model Clauses that cover:
  - transfers from a controller in the EU to a controller outside the EEA; or
  - transfers from a controller in the EU to a processor outside the EEA. Although the WP29 has published proposals for a set of processor-to-processor Model Clauses, no such clauses have yet been approved by the Commission.

- Derogations: The Directive allows a number of derogations from the general prohibition on cross-border data transfers (e.g., where the data subject has unambiguously consented to the transfer). The Regulation retains these derogations, but also allows limited cross-border data transfers on the basis of the controller’s legitimate interests (provided that the controller puts adequate safeguards in place). If it remains in the final text of the Regulation, this provision will make a significant difference to businesses that occasionally need to transfer personal data out of the EU, but cannot reasonably obtain consent from data subjects.

- Binding Corporate Rules: BCRs are addressed separately on pages 34-35.

- Going forward: Businesses should review their data flows, and consider whether they have appropriate data transfer mechanisms in place. If not, it will be important to ensure that such transfer mechanisms are in place before the Regulation comes into force.
## Binding Corporate Rules

**Why is this issue important for businesses?** Businesses that transfer personal data out of the EEA require a valid transfer mechanism. BCRs are limited to intra-group transfers, but allow greater flexibility than some other transfer mechanisms.

**Affected sectors:** This issue affects businesses that engage in large, intra-group cross-border transfers of personal data (e.g., multinational businesses, or IT service providers).

- **The Directive:** Under the Directive, BCRs are not formally recognised as a valid data transfer mechanism. Many Member States require additional DPA approval for transfers, even if BCRs have been adopted. BCRs were first made available to controllers, and later to processors.
- **The Regulation:** The Regulation will, in principle, make the adoption of BCRs a simpler task. Member States will no longer require data exporters to obtain additional approval from SAs for transfers based on BCRs. In the Commission Text, BCRs remain available to both controllers and processors. However, in the Parliament Text, BCRs are available only to controllers.

- **Key elements of BCRs under the Regulation:** The Regulation stipulates that BCRs must include: (i) a mechanism to make the BCRs legally binding on relevant group entities; (ii) a mechanism to grant enforceable rights to data subjects; and (iii) a document that sets out:
  - the list of entities bound by the BCRs;
  - the data transfers covered by the BCRs;
  - the legally binding nature of the BCRs;
  - the general data protection principles applicable to transferred data, including in respect of onward transfers to entities outside the group;
  - the rights of data subjects and the means of exercising those rights;
  - the acceptance, by a group entity within the EU, of liability for any breaches of the BCRs committed by any group entity outside the EU;
  - an overview of how the information in the preceding points is conveyed to data subjects;
  - the mechanisms by which the relevant entities’ compliance with the BCRs will be checked; and
  - the mechanisms for reporting and recording changes to the applicable data protection policies and reporting these changes to the relevant SA.

- **Changes to the approval process:** Under the Directive, the BCR approval process has been simplified but may still involve discussions with multiple DPAs, each of which imposes slightly different procedural requirements. The Regulation is expected to clarify and further streamline the BCR approval process, by:
  - setting out a consistent list of requirements that applies across the whole of the EU; and
  - making approval of BCRs subject to the Consistency Mechanism (see page 14) rather than interpretation by national SAs, as is currently the case.

- **Going forward:** As noted above, the Regulation formally recognises BCRs as a lawful data transfer mechanism, and makes it easier for businesses to obtain approval from SAs of their BCRs. Once the Regulation comes into force, it is likely that there will be an increase in the number of businesses that seek to implement BCRs.

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### The Directive

- **Art.26**
  - Availability: BCRs are available as a data transfer mechanism to both controllers and processors.

### The Regulation

- **Art.26**
  - Approval requirements: The current approval requirements for BCRs are based on WP29 recommendations, which set out the necessary components and features for BCRs, to ensure an adequate level of protection for transferred data. These requirements have been interpreted differently by the different Member States, meaning that there is no single set of consistent, EU-wide requirements.

- **Art.42**
  - Availability (Commission Text): BCRs remain available as a data transfer mechanism to both controllers and processors.
  - Availability (Parliament Text): BCRs are only available to controllers.

- **Art.43**
  - Approval requirements: Under the Regulation, SAs must, in accordance with the Consistency Mechanism, approve BCRs that:
    - are legally binding on and enforceable against every member of the data exporter’s group that will receive the data, and their employees;
    - expressly confer enforceable rights on data subjects; and
    - fulfil the information requirements set out in the Regulation. Member States are not permitted to impose further approval requirements.

- **Art.42**
  - Existing BCRs: BCRs that have been approved by the relevant DPAs are, subject to the terms of any approval, a valid data transfer mechanism.

- **Art.43**
  - Existing BCRs (Commission Text): BCRs that have been approved under the Directive will continue to be a valid data transfer mechanism, until amended, replaced or repealed by the relevant SA. The Parliament Text suggests that BCRs may be subject to further reviews under the Regulation. The final position remains unclear at this stage.

- **Art.42**
  - Formal recognition: BCRs are not explicitly recognised in the Directive as a valid data transfer mechanism. The WP29 has recognised the validity of BCRs as a data transfer mechanism, but implementation requirements vary from one Member State to another.

- **Art.43**
  - Formal recognition: The Regulation explicitly recognises BCRs as a valid data transfer mechanism. Member States are not entitled to impose further authorisation requirements for transfers based on BCRs.

- **Art.42**
  - Content and structure: The required content and structure of BCRs is set out in a series of guidance documents produced by the WP29.

- **Art.43**
  - Content and structure: The content and structure set out by the WP29 is largely unchanged in the Regulation.
Seals, Certifications and Codes of Conduct

Why is this issue important for businesses? Seals, certifications and codes of conduct provide a way for businesses to demonstrate to their customers that they take their data protection compliance responsibilities seriously.

Affected sectors: All businesses will be able to apply for seals and certifications, to give data subjects confidence that those businesses are compliant with the Regulation.

- **Background:** Privacy seals and certifications typically consist of a badge or other visual device that organisations are entitled to display if their data processing activities satisfy certain criteria. Businesses can then publicly display the seal or certification to help assure customers that the business is taking a responsible approach to privacy requirements.

Codes of Conduct are generally specific to particular industries or categories of data processing activities, and are often used by businesses to demonstrate compliance with industry best practice.

- **The Directive:** Privacy seals and certifications are not explicitly recognised in the Directive, although there is an existing privacy seal scheme, known as 'EuroPriSe', which is available on an EU-wide basis to companies in the IT sector.

The Directive creates a framework for the assessment of codes of conduct by national DPAs and the WP29 against compliance with the Directive and national implementing laws.

- **The Regulation:** The Regulation will explicitly recognise privacy seals, and set out a framework for the adoption by the European Commission of EU-wide rules relating to privacy seals and certifications.

Under the Regulation, codes of conduct may be submitted to national SAs, or to the European Commission for assessment against compliance with the Regulation.

As noted on page 33, the Parliament Text proposes that transfers of personal data out of the EEA will be justifiable if the data exporter and the data importer both hold valid European Data Protection Seals.

- **Going forward:** Existing privacy seal schemes drawn up by Member States and the EuroPriSe scheme are expected to be harmonised after the Regulation enters into force. In the meantime, businesses should review the status of existing privacy seal certifications and, once EU-wide rules are adopted, review their compliance with those requirements. Depending on the rules adopted, businesses may be required to re-apply under the revised rules.

The Regulation will provide a framework for the adoption of EU-wide codes of conduct, rather than the current adoption system for codes of conduct, which predominantly occurs at a national level. The adoption of such codes of conduct is expected to provide clarity to businesses as to how they can ensure compliance with the Regulation.

The Directive

- **Art.39**
  - **Formal recognition:** The Directive does not address seals or certifications. Some Member State DPAs, and EuroPriSe at a pan-EU level, have proposed privacy seal initiatives.

The Regulation

- **Art.39**
  - **Formal recognition:** The Regulation explicitly recognises, and encourages the adoption of certification mechanisms and privacy seals at an EU level.

- **Seals and certifications (Commission Text):** The Regulation empowers the Commission to set technical standards for certification mechanisms and seal schemes. It is intended that existing privacy seal schemes of all kinds will gradually be harmonised under the Regulation.

- **Seals and certifications (Parliament Text):** SAs can certify compliance with the Regulation under a "European Data Protection Seal". SAs can accredit third party auditors to certify compliance. The Commission, together with the EDPB, may issue further relevant requirements and technical standards.

- **Art.27**
  - **Codes of conduct:** The Directive requires Member States and the Commission to encourage the drawing up of codes of conduct intended to help ensure compliance with EU data protection law.

- **Approval of codes of conduct:** The Directive states that codes of conduct “may” be submitted to the WP29 for review, but does not specify a formal approval process or requirements.

- **Art.38**
  - **Codes of conduct:** The Regulation requires Member States, SAs and the Commission to encourage the drawing up of codes of conduct intended to help ensure compliance with EU data protection law.

- **Approval of codes of conduct:** Interested parties are entitled to submit draft codes of conduct to either a local SA (for in-country codes) or the Commission (for codes covering multiple Member States), which will then confirm whether the draft code is sufficient to ensure compliance with the Regulation.
Rights of Data Subjects

Why is this issue important for businesses? The Directive and the Regulation both grant rights to data subjects regarding the processing of their personal data. In order to give effect to these rights, businesses need to be aware of their compliance obligations.

Affected sectors: All business sectors will need to enable data subjects to exercise their rights.

- The Directive: Under the Directive, data subjects are guaranteed certain basic rights in relation to their personal data, including the following:
  - The right to certain minimum information: Data subjects are entitled to receive certain minimum information from the controller about the processing of their personal data (see page 18).
  - The right of access: Data subjects are entitled to object to processing of their personal data, and information about the processing of those data, upon payment of a small fee (if applicable) and without delay.
  - Right to object: Data subjects are entitled to object to processing of their personal data that is performed: (i) in the public interest; (ii) on the basis of the legitimate interests of the controller; or (iii) for the purposes of direct marketing.
  - The right to rectification, erasure or blocking of data: Data subjects may exercise these rights where the processing is not in compliance with the Directive.

- The Regulation: Under the Regulation, the rights of data subjects set out in the Directive continue to apply (subject to minor amendments and clarifications) and the following rights are added:
  - The right to be forgotten: The Commission initially proposed a wide-ranging right to be forgotten. In light of developments following the CJEU’s decision in Costeja v Google, more recent texts of the Regulation have recast this as a ‘right to erasure’.

The Directive

Art. 10 & 11
The right to certain minimum information: Controllers are required to provide data subjects with certain minimum information about the processing of their personal data (see page 18).

Art. 12
The right of subject access: Data subjects have a right to obtain from the controller, without excessive delay or expense:
- a copy of its or her personal data processed by or on behalf of the controller;
- the purposes of the processing;
- the recipients to whom the data are disclosed;
- information on the source of the data; and
- an explanation of the logic involved in any automatic processing of his or her personal data.

Art. 13
The right to rectification, erasure or blocking of data: Data subjects have a right to obtain from the controller the rectification, erasure or blocking of their data if their controller’s processing activities are not compliant with the Directive (e.g., because the data are outdated or incomplete).

Art. 14
The right to object: The controller’s legal basis for processing the personal data is either that the processing is in the public interest, or in the legitimate interests of the controller, the data subject may object to that processing “on compelling legitimate grounds”.

The Regulation

Art. 11 & 14
The right to certain minimum information: Controllers are required to provide data subjects with certain minimum information about the processing of their personal data (see page 18).

Art. 15, 16 & 17
The right of subject access: Data subjects have a right to obtain from the controller at any time, on request:
- the purposes of the processing;
- the categories of personal data processed;
- the recipients to whom the data are disclosed;
- the applicable retention period;
- information on the source of the data; and
- a copy of his or her personal data processed by or on behalf of the controller.

Art. 18; Recital 55
The right to data portability: The Directive does not address this issue.

Art. 19(1) & (2)
The right to object: Where the controller’s legal basis for processing the personal data is either that the processing is in the vital interests of the data subject or the public interest the data subject may object to that processing unless the controller demonstrates compelling legitimate grounds for the processing. If the legal basis is the legitimate interests of the controller, the data subject may object without the need for further justification.
Areas Remaining Unharmonised

Why is this issue important for businesses? Although the Regulation will largely harmonise data protection law across all Member States, there remain a number of areas in which businesses may face different requirements in each Member State.

Affected sectors: All businesses that operate in more than one Member State may be affected by the areas of law that will remain unharmonised under the Regulation.

- **The Directive:** Under the Directive, Member States have broadly similar data protection laws, but there remain significant differences between the relevant national laws. There are two key reasons for this:
  - There are issues that affect data protection, but fall outside the scope of the Directive. For example, the issue of national security falls outside the EU's legislative competence, and so each Member State takes its own approach to the question of what processing activities are necessary for national security (and are therefore exempt from the provisions of the Directive).
  - Even where the Directive addresses a particular issue, Member States have often implemented the requirements of the Directive differently. For example, the Directive sets out a minimum set of fair processing information to be provided to data subjects (see page 18) but Member States are free to insist on additional requirements.

  For these reasons, businesses currently face inconsistent data protection compliance requirements across the EU.

- **The Regulation:** Under the Regulation, the first issue identified above remains largely unchanged, as the limits on the EU’s legislative competence have not changed. However, because the Regulation removes the need for national implementation, the second issue will (for the most part) fall away, resulting in a more consistent set of data protection compliance obligations across the EU.

- **Examples of areas remaining unharmonised:** Notwithstanding the greater harmonisation introduced by the Regulation, there will still be several issues that differ from one Member State to another. For example:
  - **National Security (Art.2(2)(a)):** Data processed for the purposes of the national security of a Member State are exempt from the Regulation. Member States have different conceptions of national security.
  - **Journalism and freedom of speech (Art.80):** The concepts of ‘journalism’ and ‘freedom of expression’ vary from one Member State to another (although Recital 121 of the Regulation states that ‘journalism’ should be interpreted broadly).
  - **Employment law (Art.82):** Member States may adopt their own rules regarding the processing of personal data in an employment context.
  - **Professional secrecy laws (Art.84):** Some Member States have laws on professional secrecy that prevent the processing of certain data, even where the Regulation would otherwise permit that processing.
  - **Laws on interception of communications:** Member States have interception laws under the e-Privacy Directive 2002/58/EC, which are not uniform across the EU.

- **Going forward:** Although the Regulation increases harmonisation of data protection law across the EU, there remain areas in which the applicable requirements vary among the Member States. Businesses should keep these areas in mind when reviewing their obligations under the Regulation.

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**A guide for in-house lawyers**

**The Directive**

- **Art.3**
  - Member States retain discretion in some areas: Member States retain flexibility to create exemptions to certain requirements of the Directive.

- **Art.3: 9 & 13**
  - Issues governed by national law: Under the Directive, exemptions and derogations, the scope of which is governed by national law, include the following:
    - purely personal or household activity;
    - journalistic purposes, and artistic or literary expression;
    - national security, defence and public security;
    - the prevention, investigation, detection and prosecution of criminal offences;
    - important national economic interests;
    - protection of data subjects;
    - employment law; and
    - professional secrecy laws.

**The Regulation**

- **Art.2**
  - Member States retain discretion in some areas: Although the Regulation introduces greater harmonisation, Member States still retain discretion in a number of areas.

- **Art.2: 21; 80; 82 & 84**
  - Issues that continue to be governed by national law: Under the Regulation, exemptions and derogations, the scope of which is governed by national law include the following:
    - national security;
    - exclusively personal or household activity;
    - the prevention, investigation, detection or prosecution of criminal offences;
    - important national economic interests;
    - protection of data subjects;
    - journalism and freedom of speech, and artistic or literary expression;
    - employment law; and
    - professional secrecy laws.

- **Art.8. 18-19 & 24**
  - Issues governed by national law: Under the Directive, examples of issues governed by national law include:
    - Sensitive personal data – Member States retain some flexibility to lay down additional exemptions to the prohibition on processing sensitive personal data.
    - Registration with the local DPA – Member States retain considerable flexibility in relation to exemptions from registration and the content of registration forms.
    - Sanctions – Member States determine the sanctions to be imposed for breaches of national data protection law.

- **Art.15 & 78-79**
  - Issues no longer governed by national law: Under the Regulation, examples of issues that will no longer be governed by national law include:
    - Sensitive personal data – the conditions for processing sensitive personal data are harmonised under the Regulation.
    - Registration with the local SA – registration will no longer be required under the Regulation (see page 16).
    - Sanctions – Member States will still be required to lay down rules on the application of sanctions, but the sanctions themselves will be harmonised.
Glossary

The following terms and abbreviations are used in this Guide:

- ‘Adequate Jurisdictions’ – those jurisdictions that have been formally recognised by the Commission as providing an adequate level of data protection (i.e., Andorra, Argentina, Canada (for commercial entities subject to the Personal Information and Protection of Electronic Documents Act), Switzerland, the Faeroe Islands, Guernsey, Israel, Isle of Man, Jersey, New Zealand, Uruguay and the U.S./EU Safe Harbor).
- ‘BCRs’ – Binding Corporate Rules (see page 34).
- ‘CJEU’ – the Court of Justice of the European Union.
- ‘Codes of Conduct’ – codes to which companies adhere in order to demonstrate their compliance with their data protection obligations (see page 36).
- ‘the Commission’ – the European Commission (an EU institution).
- ‘Consistency Mechanism’ – the mechanism by which national SAs are required to achieve consistent decisions across the EU under the Regulation (see page 14).
- ‘controller’ – the entity that determines the purposes for which and means by which personal data are processed (see page 9).
- ‘the Council’ – the Council of Ministers of the European Union (an EU institution).
- ‘CROs’ – Clinical Research Organisations.
- ‘data breach’ – any accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data, usually as the result of a breach of security.
- ‘data exporter’ – a controller or processor that transfers personal data out of the EEA.
- ‘data importer’ – a controller or processor outside the EEA that receives personal data from the data exporter.
- ‘data subject’ – the individual to whom the personal data relate (see page 9).
- ‘DPA’ – a Data Protection Authority under the Directive (see page 14). (The Directive uses the term ‘Supervisory Authority’ over most Member States, and the WP29, use the term ‘DPAs’ (when using English)).
- ‘DPIA’ – Data Protection Impact Assessment (see page 20).
- ‘DPO’ – Data Protection Officer (see page 16).
- ‘EDAA’ – the European Digital Advertising Alliance.
- ‘EDPS’ – the European Data Protection Supervisor (an independent supervisory authority tasked with ensuring that EU institutions abide by the requirements of EU data protection law).
- ‘EEA’ – the European Economic Area (which is made up of the Member States, plus Iceland, Liechtenstein and Norway).
- ‘Member States’ – the Member States of the European Union (i.e., Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the UK).
- ‘Model Clauses’ – the European Commission’s Standard Contractual Clauses for the transfer of personal data to third countries (note that there are several versions).
- ‘personal data’ – information relating to an identified or identifiable individual (see page 9).
- ‘processing’ – any operation that is performed upon personal data (see page 9).
- ‘processor’ – an entity that processes personal data on behalf of the controller (see pages 9 and 26).
- ‘Profiling’ – automated processing intended to evaluate information about a person or to analyse or predict his or her behaviour (e.g., performance at work, location, or preferences).
- ‘the Regulation’ – the proposed EU General Data Protection Regulation (see page 3).
- ‘SA’ – a Supervisory Authority under the Regulation (see page 14).
- ‘Sensitive Personal Data’ – personal data, revealing race or ethnicity, political opinions, religion or beliefs, trade-union membership, physical or mental health or sex life. The Regulation adds genetic data and criminal convictions or related security measures (see page 9).
- ‘U.S.-EU Safe Harbor’ – a data transfer mechanism agreed between the U.S. and the EU and ratified pursuant to Commission Decision 2000/520/EC.
- ‘WP29’ – the Article 29 Working Party (an advisory body comprising representatives of the DPAs from each of the 28 Member States and the EDPS).

Our Privacy Leaders

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