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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.

PLEASE NOTE: This Guide should be used as general guidance only and should not be relied upon as legal advice. You are welcome to re-use the content of this Guide, provided you credit Hunton & Williams using the copyright notice set out on page 2, and any use is limited to within your organisation. Please also note that the Directive and (to a lesser extent) the Regulation, are subject to national interpretation. This Guide is not designed to provide analysis of national requirements. For advice on these issues, and other more detailed questions, please contact: EUregulation@hunton.com
## Progress of the Regulation

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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 unharmonised. 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 those 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.

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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 those 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.

Why is this issue important for businesses?

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 unharmonised. 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.

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Going forward: The Regulation is likely to require organisation-wide changes for many businesses. In-house lawyers should start to consider the impact of those 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).

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**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.

- **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.
<table>
<thead>
<tr>
<th><strong>The Directive</strong></th>
<th><strong>The Regulation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Art.2</strong></td>
<td><strong>Art.4</strong></td>
</tr>
<tr>
<td>&quot;consent&quot;: 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.</td>
<td>&quot;consent&quot;: any freely given, specific, informed and explicit indication of his or her wishes by which the data subject, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to him or her being processed.</td>
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<td>&quot;controller&quot;: the person or body that, alone or jointly with others, determines the purposes and means of the processing of personal data.</td>
<td>&quot;controller&quot;: the person or body that, alone or jointly with others, determines the purposes, conditions (per the Commission Text) and means of the processing of personal data.</td>
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<tr>
<td>'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.</td>
<td>'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, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person.</td>
</tr>
<tr>
<td>'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.</td>
<td>'processing': any operation or set of operations performed upon personal data, or sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, erasure or destruction.</td>
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<td>'processor': a person or body that processes personal data on behalf of the controller.</td>
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<td>'genetic data': There is no definition of 'genetic data' in the Directive.</td>
<td>'genetic data': any data that relate to characteristics that are inherited or acquired during early prenatal development. Genetic data are sensitive personal data.</td>
</tr>
<tr>
<td><strong>Art.8(1)</strong></td>
<td><strong>Art.9</strong></td>
</tr>
<tr>
<td>'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.</td>
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</tr>
</tbody>
</table>
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 outside 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:
    1. equipment situated in the EU (e.g., a server) unless that equipment is only used for the purposes of simply transmitting data; or
    2. 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:
    1. offers goods or service to EU residents; or
    2. monitors the behaviour of EU residents,
      that entity will be subject to the Regulation.

- **For example:** A business established in the U.S. that markets its products directly to EU residents, but has no physical presence in the EU, is not subject to the requirements of the Directive, but will be subject to the requirements of the Regulation.

- **The obligation to appoint a Representative:** If the relevant entity is established outside the EU, and the Directive (as implemented into national law) applies to that entity, then it will be required to appoint a Representative in each Member State in which it is uses a 'means of processing'. The Regulation reduces this to an obligation to appoint a representative in a single Member State, but the principle is otherwise unchanged. The Representative functions as the entity's point of contact for DPAs / SAs (although DPAs and SAs are not obliged to contact the representative and may choose to deal directly with the relevant controller or processor).

- **Going forward:** Businesses established outside the EU that are not subject to the Directive should consider whether any of their entities are subject to the Regulation. If so, such a business should review the compliance obligations of its affected entities under the Regulation, as set out in this Guide.

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.
The Directive

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

Yes
No

Outcome: It must comply with the Directive as implemented by the national laws of each Member State in which it is established.

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

Yes
No

Outcome: The entity must comply with the Directive as implemented by any national law(s) that apply to it by virtue of Public International Law.

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

Yes
No

Does the entity only use such 'means of processing' for the purposes of transmitting data?

No
Yes

Outcome: The entity must comply with the Directive as implemented by the national laws of each Member State in which it uses a 'means of processing' personal data.

Outcome: The entity is not subject to the Directive.

Art.25(1)
Outcome: The entity must appoint a Representative in each such Member State.

The Regulation

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

Yes
No

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

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

Yes
No

Outcome: The entity must comply with the Regulation.

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

Yes
No

Outcome: The entity must comply with the Regulation.

Art.3(4)
Does the entity either: (i) offer goods or services to EU residents; or (ii) monitor EU residents' behaviour?

Yes
No

Outcome: The entity is not subject to the Directive.

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.
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 DPAs 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 DPAs 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.

**Art.28**

**DPA enforcement powers:** DPAs 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.

### 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.

**Right to a remedy against a controller or processor:** Data subjects will have the right to a judicial remedy in respect of any processing of their personal data that infringes the Regulation.

**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.53**

**SA enforcement powers:** SAs will be given wide-ranging 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, SAs 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 fulfil 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, where a business has 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. Its tasks will include advising the EU institutions on data protection issues, including amendments to the Regulation; advising on the enforcement of the Regulation by SAs; overseeing the application of the Consistency Mechanism; and promoting cooperation between SAs.

- **Going forward:** For businesses that only operate within a single Member State, and only process the 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).
A guide for in-house lawyers

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.

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

The 'One Stop Shop': Under the Directive, a business is subject to enforcement by the local DPA of each Member State in which it operates.

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.28(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 to enforce the Regulation, 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.

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.

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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 compliance to SAs 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.
## The Directive

### Accountability

Controllers have direct compliance obligations under the Directive, but the concept of accountability is not directly addressed.

### Registration

Under the Directive, the national laws of most Member States require controllers (and in some cases processors) to register with the relevant DPA by providing information about their processing activities. This requirement, the applicable exemptions, and the precise contents of the registration application vary across the Member States.

### Appointment, position and role of a DPO

The Directive provides very little substance on the role of DPOs. It states that the role of the DPO is to ensure the internal application of applicable data protection law within a business. It also explains that DPOs can be internal or external appointments, and that the DPO must function independently of the controller. However, the precise role of the DPO varies across the Member States.

## The Regulation

### Accountability

Controllers must be able to ensure and demonstrate, through the adoption and implementation of appropriate data protection policies and notices, that their processing activities comply with the requirements of the Regulation.

### Internal records

In place of registrations, controllers and processors must maintain (and make available to data subjects and SAs upon request) internal records that cover all of their data processing activities, including:
- details of the controller and the DPO;
- the purposes of those processing activities;
- any legitimate interests pursued by the controller;
- the affected categories of personal data and data subjects;
- details of any recipients of the data; and
- the applicable retention periods.

The Parliament Text simplifies this list to an obligation to maintain documentation “necessary to fulfill the requirements” of the Regulation.

### Appointment of a DPO

All controllers or processors that employ 250 persons or more (or, per the Parliament Text, process the personal data of 5,000 persons or more in a year) are required to appoint a DPO. Corporate groups may appoint a central DPO. The DPO:
- must have expert knowledge of data protection law and be able to perform the DPO role;
- may be an employee or an external contractor;
- must be appointed for at least 4 years (if the DPO is an employee, per the Parliament Text) or 2 years (if the DPO is a contractor) and may be removed from this role only if he or she fails to fulfill the duties of a DPO; and
- must make his or her name and contact details available to SAs and data subjects.

**Position of the DPO:** The DPO must operate independently and not take instructions from the business as to the exercise of his or her functions. The DPO must also report to the management of the business.

**Role of the DPO:** The DPO must:
- advise the business on its compliance obligations;
- monitor compliance with those obligations;
- maintain internal records;
- ensure that suitable information is provided to data subjects (see page 18);
- monitor the implementation of privacy by design and DPIAs (see page 20); and
- act as a contact point for data subjects and SAs.
**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 much 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 \( \text{€500,000 or } 1\% \text{ of annual worldwide turnover}, \) 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.
The Directive

Art.10 & 11

General principle: Controllers must provide certain minimum information to data subjects.

Format: There are no specific requirements concerning the format in which information notices must be provided.

Content: Information notices must:
- identify the controller (and any representative);
- state the purposes of the processing;
- identify recipients of the data;
- briefly explain the rights of access and rectification (see page 38); and
- provide any further information reasonably necessary to guarantee fair processing.

If the data are obtained directly from the data subject, the notice must state whether replies to questions are obligatory or voluntary, as well as the possible consequences of failure to reply. If the data are not obtained directly from the data subject, the notice must list the categories of data being processed.

Timing: Where data are collected from the data subject, there is no specific timing requirement for the notice, but DPAs typically take the view that it must be provided at the point of collection. Where data are not collected from the data subject, notice should be provided:
- at the time of collection; or
- in the event of a disclosure to a third party, no later than the first such disclosure.

Exemptions: Notice does not need to be provided if the data subject already has the relevant information. Member States can create additional exemptions (e.g., where the processing relates to the detection or prevention of crime). Where the data are not obtained from the data subject, notice is not required if:
- it is impossible or involves disproportionate effort;
- the processing is required by law; or
- an exemption applies (e.g., the processing is carried out for the purposes of national security, journalism, or artistic or literary expression).

The Regulation

Art.11 & 14

General principle: Controllers must provide certain minimum information to data subjects.

Format: Controllers are expected to:
- have transparent and easily accessible information notices; and
- provide information in an intelligible form, using clear and plain language, adapted to the data subject (in particular, if the notice is addressed specifically to children).

Content: In addition to the requirements of the Directive, information notices under the Regulation must also provide:
- the identity and contact details of the DPO (if any);
- if the processing relates to the performance of a contract, the relevant terms of that contract;
- if the processing is based on the controller’s legitimate interests, an explanation of those interests;
- the data retention period;
- a brief explanation of the rights to erasure and to object to processing (see page 38);
- the right to complain to the SA and the contact details of the relevant SA; and
- information on cross-border data transfers.

Where the personal data are not obtained directly from the data subject, the notice should also identify of the source of the data.

Timing: Where data are collected from the data subject, the information notice should be provided at the point of collection. Where data are not collected from the data subject, notice should be provided:
- at the time of collection; or
- in the event of a disclosure to a third party, no later than the first such disclosure.

Exemptions: Notice does not need to be provided if the data subject already has the relevant information. Member States can create additional exemptions (e.g., where the processing relates to the detection or prevention of crime). Where the data are not obtained from the data subject, notice is not required if:
- it is impossible or involves disproportionate effort;
- the processing is required by law;
- the provision of the notice would impair the rights and freedoms of others; or
- an exemption applies (e.g., the processing is carried out for the purposes of national security, journalism, or artistic or literary expression).
**Privacy by Design and by Default / DPIAs**

- **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 by default:** This principle is closely linked to the principle of 'privacy by design'. It requires businesses to implement mechanisms for ensuring that, by default, personal data are only processed in so far as necessary for the intended purposes, are not collected or kept beyond the minimum necessary for these purposes and are not made accessible to an indefinite number of individuals.

- **DPIAs:** DPIAs provide businesses with a mechanism designed to: (i) assess the privacy risks related to a proposed data processing activity; and (ii) identify measures to address these risks and demonstrate compliance with the Regulation.

**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 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.
## Privacy by design and by default – General Principle

**The Directive**

When designing a processing system, and when using that system to process data, controllers (and, per the Parliament Text, processors) must implement appropriate technical and organisational measures to protect the rights of data subjects and ensure compliance with the Regulation. Businesses must ensure that, by default, data processing activities are limited to the minimum necessary purposes.

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## DPIAs – General Principle

**The Directive**

DPIAs are not explicitly addressed in the Directive, although several national DPAs recommend that a DPIA be undertaken in certain circumstances.

**The Regulation**

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## DPIAs – Scope

**The Directive**

DPIAs are not explicitly addressed in the Directive.

**The Regulation**

DPIAs are not explicitly addressed in the Directive.

## DPIAs – Content

**The Directive**

The content of DPIAs is not explicitly addressed in the Directive, although some national DPAs have issued guidance, and the WP29 has issued DPIA frameworks for RFID applications and Smart Meters.

**The Regulation**

A DPIA should contain:

- a description of the processing activities being assessed;
- an assessment of the risks to data subjects; and
- a description of the measures the controller will take to address these risks, including the safeguards, security measures and mechanisms that the controller will implement to ensure compliance with the Regulation.
Profiling

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 Profileing 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.

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**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; or
- 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.

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**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; or
- 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 WP29 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 some cases, failure 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 inform the competent SA and, in certain cases, affected data subjects.

The purpose of implementing a general data breach reporting requirement is to: (i) make it easier for SAs to exercise their supervisory functions (see page 14); (ii) enable affected data subjects to take measures to mitigate the risks related to the data breach (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.
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<th><strong>The Directive</strong></th>
<th><strong>The Regulation</strong></th>
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**Data breach reporting obligations generally:** The Directive does not contain a general data breach reporting obligation. Some Member States have implemented data breach reporting obligations in their national law (e.g., Austria and Germany). In other Member States, local DPAs have issued non-binding guidance in which they strongly recommend controllers to notify personal data breaches (e.g., Belgium, Denmark, Ireland and the UK).

**Data breach reporting obligations generally:** The Regulation introduces a general obligation to report data breaches:
(a) to the competent SA (in all cases); and
(b) to the affected data subjects (if the breach is likely to affect the protection of personal data or privacy of the data subject).
If the breach is suffered by a processor, the processor must report it to the controller immediately after it is discovered.

**Reporting breaches to the competent DPA:** The Directive does not specify any requirements regarding the reporting of data breaches to DPAs.

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(a) to the competent SA (in all cases); and
(b) to the affected data subjects (if the breach is likely to affect the protection of personal data or privacy of the data subject).

**Reporting breaches to affected data subjects:** The Directive does not specify any requirements regarding the reporting of data breaches to affected data subjects.

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**Art.31 & 32**

**Reporting breaches to the competent SA:**
- **Timing:** Data breaches must be reported to the relevant SA without undue delay and where feasible no later than 72 hours after being discovered. If it is not possible to notify the SA within 72 hours, this delay must be justified to the SA.
- **Content:** The report to the SA should include: (i) a description of the nature of the data breach (including the number and categories of data subjects and volume of data affected); (ii) the name and contact details of the DPO or other contact point; (iii) a recommendation for measures to mitigate potential adverse effects; (iv) a description of consequences of the breach; and (v) a description of the measures proposed or taken to address the breach.
- **Exemptions:** None.

**Reporting breaches to affected data subjects:**
- **Timing:** Data breaches must be reported to the affected data subjects without undue delay, after being reported to the SA.
- **Content:** Data subjects should be told about the nature of the data breach, and given the contact details of the DPO or other contact point, and informed of any recommended measures to mitigate possible adverse effects of the breach.
- **Exemptions:** It is not necessary to inform affected data subjects if the controller can demonstrate, to the satisfaction of the SA, that it has implemented appropriate information security measures that render the data unintelligible to any person not authorised to access it (e.g., the lost data are protected by strong encryption).
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 direct obligations 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)(a)**

**Application of the law:** Under the Directive, EU data protection law applies directly to controllers.

**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; and
- implement appropriate technical and organisational information security measures.

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

**Direct legal obligations of processors:** The Directive does not impose direct legal obligations on processors.

**Direct enforcement against processors:** EU data protection law cannot be enforced directly against processors under 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.28-28**

**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; and
- implement appropriate technical and organisational information security measures.

**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:** The Regulation will be enforced by SAs directly against processors.
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 purposes, 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.
### The Directive

**Art.7(a)**

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

**Art.7(b-e)**

**General processing conditions:** Personal data may be processed if the processing is necessary:
- for the **performance of a contract** to which the data subject is party, or into which the data subject is seeking to enter;
- for **compliance with a legal obligation**;
- to protect the **vital interests** of the data subject;
- for the performance of a task carried out in the **public interest**.

**Art.7(f)**

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

**Art.8(1) & 8(2)**

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

**Art.8(2)(b), (c) and (e)**

**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.

### The Regulation

**Art.6(1)(a) – (e) & 6(3)**

**General processing conditions:** Personal data may be processed if the processing is necessary:
- for the **performance of a contract** to which the data subject is party, or into which the data subject is seeking to enter;
- for **compliance with an EU legal obligation**;
- to protect the **vital interests** of the data subject;
- for the performance of a task carried out in the **public interest**.

**Art.6(1)(a); 7**

**Consent:** To be valid, consent must relate to the processing of personal data for a specified purpose. Where consent is obtained in a document that also concerns another matter, the consent must be distinguishable from that other matter. Consent is invalid where there is a significant imbalance between the controller and the data subject. Under the Parliament Text, consent expires once the relevant purposes are fulfilled, and the controller bears the burden of proof that consent was validly obtained.

**Art.6(1)(f)**

**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.

**Art.9(1) & 9(2)(a)**

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

**Art.9(2)(g)-(i)**

**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.

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### The Directive

**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.

**Re-identification of anonymous and pseudonymous data:** The Directive is silent on this issue.

**Pseudonymous data and Profiling:** The Directive is silent on this issue.

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

### The Regulation

**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).

**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.

**Re-identification of anonymous and pseudonymous data:** 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 pseudonymous data, those data will no longer be considered pseudonymous.

**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, some DPAs insist 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-EU 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.
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<td><strong>General prohibition:</strong></td>
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<tr>
<td>Transfers of personal data to a third country are prohibited unless that third country ensures an adequate level of protection.</td>
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<tr>
<td><strong>Adequate Jurisdictions:</strong></td>
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<tr>
<td>The Commission can determine that a non-EU jurisdiction has adequate protections in place for personal data. Transfers to Adequate Jurisdictions do not require a separate transfer mechanism (such as Model Clauses).</td>
<td>Adequacy determinations made under the Directive will continue to apply under the Regulation.</td>
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<td><strong>Model Clauses:</strong></td>
<td><strong>Model Clauses:</strong></td>
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<td>Transfers of personal data to non-EU jurisdictions may lawfully be made on the basis of Model Clauses approved by the Commission under the Directive.</td>
<td>Model Clauses approved by the Commission under the Directive will remain a valid transfer mechanism under the Regulation.</td>
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<td><strong>Approval of Model Clauses:</strong></td>
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<td>Several Member States require DPA notification or approval prior to transfers made on the basis of Model Clauses.</td>
<td>Transfers made on the basis of Model Clauses will not require any specific authorisation from SAs.</td>
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<td><strong>Art.26</strong></td>
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<td><strong>Derogations:</strong></td>
<td><strong>Derogations:</strong></td>
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<tr>
<td>Transfers of personal data to non-adequate jurisdictions are permitted where:</td>
<td>The derogations under the Directive will continue to apply. In addition, transfers that are not frequent or massive may take place where:</td>
</tr>
<tr>
<td>• the data subject has unambiguously consented to the transfer;</td>
<td>• the transfer is necessary for the legitimate interests of the controller; and</td>
</tr>
<tr>
<td>• the transfer is necessary to perform or enter into a contract with the data subject;</td>
<td>• the controller has, based on the circumstances surrounding the transfer, adduced appropriate safeguards, where necessary.</td>
</tr>
<tr>
<td>• the transfer is necessary to conclude a contract with a third party in the data subject’s interest;</td>
<td><strong>Derogations (Parliament Text):</strong> The Parliament Text does not expand upon the derogations provided in the Directive.</td>
</tr>
<tr>
<td>• the transfer is in the public interest;</td>
<td><strong>Data Protection Seals (Parliament Text):</strong> Cross-border data transfers may lawfully be made if both the data exporter and the data importer hold valid ‘European Data Protection Seals’ (see page 36).</td>
</tr>
<tr>
<td>• the transfer is necessary to establish, exercise or defend legal claims;</td>
<td></td>
</tr>
<tr>
<td>• the transfer is necessary to protect the vital interests of the data subject; or</td>
<td><strong>Data Protection Seals:</strong> The Directive does not mention Data Protection Seals.</td>
</tr>
<tr>
<td>• the transferred data came from a public register. These derogations are implemented inconsistently across the Member States.</td>
<td></td>
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</tbody>
</table>
The Proposed EU General Data Protection Regulation

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: (i) setting out a consistent list of requirements that applies across the whole of the EU; and (ii) 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.
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.

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.

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.

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.

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.

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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.
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.

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

Seals and certifications: Because there is no specific EU-wide law governing the creation of privacy seals, a number of different approaches have been taken. For example:
- EuroPriSe – an EU-wide scheme, aimed at the IT sector.
- National schemes – e.g., the French DPA operates a privacy seal scheme, available to businesses that provide data protection training and auditing services, and to businesses that provide software and computer systems.
- Private sector schemes – several private sector organisations, such as TRUSTe and the EDAA run privacy seal programs.

Seals and certifications (Commission Text): The Regulation empowers the Commission to set technical standards for certification mechanisms and seal schemes. It is anticipated 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.

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.

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: 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.

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.

1. The Directive: Under the Directive, data subjects are guaranteed certain basic rights in relation to their personal data, including the following:
   a. 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).
   b. The right of access: Data subjects are entitled to a copy of their personal data, and information about the processing of those data, upon payment of a small fee (if applicable) and without delay.
   c. 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.
   d. The right to rectification, erasure or blocking of data: The data subject may exercise these rights where the processing is not in compliance with the Directive.

2. 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:
   a. The right of data portability: The Commission had originally proposed a right for data subjects to be able to transfer their data to another service (e.g., from Facebook to Google+). However, the Parliament Text moves this concept to Recital 55 of the Regulation, and encourages organisations to facilitate portability, but does not make it an enforceable right.

3. Class actions: Where there has been a breach of the rights of data subjects, any association or body acting in the public interest will be able to bring a claim on behalf of affected data subjects under the Regulation (Art.73). Such claims will also be permitted for non-pecuniary loss or harm, such as distress (Art.77).

4. Going forward: In general, the rights of data subjects are expanded under the Regulation. As a result, businesses will need to devote additional time and resources to ensuring that these issues are appropriately addressed. In particular, businesses that rely on legitimate interests as a processing condition (see page 28) will need to consider in advance how they will respond to data subjects who exercise the right to object to processing carried out on that basis.
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).

The right of subject access: Data subjects have a right to obtain from the controller, without excessive delay or expense:
- a copy of his 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.

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 the controller's processing activities are not compliant with the Directive (e.g., because the data are outdated or incomplete).

The right to be forgotten and to erasure: Data subjects have a right to erasure of their data where:
- the data are no longer needed for their original purpose;
- the processing is based on consent, and the data subject withdraws that consent (or, per the Parliament Text, the consent expires);
- the data subject exercises the right to object;
- a court holds that the data must be erased; or
- the processing is unlawful.

The right to data portability: The Directive does not address this issue.

The right to object: Where 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 right to data portability: The Commission Text proposes a general right for data subjects to transfer their data to another service provider. The Parliament Text amends this to an encouragement to controllers to work towards interoperability.

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.
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.

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The Proposed EU General Data Protection Regulation

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' but 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.

- 'EDPB' – the European Data Protection Board (an EU-level body that will oversee implementation and enforcement of the Regulation and issue guidance, created under Section 3 of Chapter VII of the Regulation).

- '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

Lisa J. Sotto, Partner in the New York office of Hunton & Williams
+1 (212) 309 1223; Isotto@hunton.com
Lisa is the global head of the Privacy and Cybersecurity team and is based in the firm’s New York office. She was named among The National Law Journal’s “The 100 Most Influential Lawyers in America,” and was rated the “No. 1 privacy expert” for the past three consecutive years by Computerworld magazine. She was ranked as a “Star Individual” for Privacy and Data Security by Chambers and Partners. Appointed by Secretaries Johnson and Napolitano, Lisa serves as Chairperson of the U.S. Department of Homeland Security’s Data Privacy and Integrity Advisory Committee.

Bridget Treacy, Partner in the London office of Hunton & Williams
+44 (0)20 7220 5731; btreacy@hunton.com
Bridget heads the firm’s UK Privacy and Cybersecurity practice and has more than 14 years of extensive experience in privacy law. Her practice focuses on all aspects of privacy, data protection and information governance, particularly for multi-national companies. She was ranked by Computerworld magazine as one of the top 10 privacy lawyers globally and is ranked as a “Star Individual,” the highest honour, by Chambers and Partners.

Wim Nauwelaerts, Partner in the Brussels office of Hunton & Williams
+32 (0)2 643 58 14, wnauwelaerts@hunton.com
Wim heads our Brussels Privacy and Cybersecurity practice. With more than 15 years of experience, he advises companies on all aspects of EU and international data protection and privacy compliance, including implementation of data security measures, compliance training, data transfer strategies, and representations before data protection authorities. Wim is recognized as a leading privacy practitioner by Chambers Global, Chambers Europe, The Legal 500 (Belgium), The International Who’s Who of Technology Lawyers, and by Global Law Experts.

Aaron P. Simpson, Partner in the New York office of Hunton & Williams
+1 (212) 309 1126; asimpson@hunton.com
Aaron is a partner in the firm’s New York office. He has more than 10 years of experience assisting clients with a broad range of complex privacy and cybersecurity matters, including U.S. and international privacy and data security requirements and the remediation of large-scale data security incidents. Aaron was ranked as a “Rising Star” by Chambers USA and New York Super Lawyers, and was recognised in The Legal 500 United States.

Rosemary Jay, Senior Attorney in the London office of Hunton & Williams
+44 (0)20 7220 5753; rjay@hunton.com
Rosemary has practised in privacy law for over 25 years and is recognised as one of the top lawyers in the area of data protection in the UK, with Chambers and Partners recognising her as a “Star Individual,” the highest honour. Rosemary is the author of Sweet & Maxwell’s Data Protection Law & Practice, a contributing editor to The White Book on privacy and an editor of the Encyclopedia of Data Protection and Privacy.

Dr. Jörg Hladjk, Counsel in the Brussels office of Hunton & Williams
+32 (0)2 643 58 28; jhladjk@hunton.com
Jörg advises multinational companies of all industry sectors on all aspects of EU data protection and cybersecurity law. He has more than 9 years of experience and regularly represents clients before the German state and federal data protection authorities. Jörg was recognised as one of the world’s leading practitioners by The International Who’s Who of Information Technology and Internet, E-Commerce and Data Protection Lawyers.
Our EU Team

Tim Hickman, Associate in the London office of Hunton & Williams
+44 (0)20 7220 5708; hickmant@hunton.com
Tim advises a broad range of UK and international clients on all areas of data protection law, from general compliance issues to more focused advice on issues such as social media advertising, cross-border data transfers, rights of data subjects and data retention obligations. He also provides guidance on managing interactions with data protection regulators.

Anita Bapat, Associate in the London office of Hunton & Williams
+44 (0)20 7220 5729; abapat@hunton.com
Anita advises multinational clients on general European data protection compliance across a range of sectors, including on employee and customer data issues and electronic commerce. She has extensive knowledge of data protection and privacy legislation from her previous experience as a government lawyer.

Claire François, Associate in the Brussels office of Hunton & Williams
+32 (0)2 643 58 04; cfrancois@hunton.com
Claire’s practice focuses on EU data protection law with an emphasis on French law. She advises clients on a variety of French and international data compliance projects, including implementation of global data management strategies and international data transfers. Claire also represents clients before the French Data Protection Authority.

David Dumont, Associate in the Brussels office of Hunton & Williams
+32 (0)2 643 58 18; ddumont@hunton.com
David assists a broad range of clients with all aspects of Belgian and EU data protection law, including HR and customer data privacy issues, implementation of cross-border data transfer strategies and completing registrations with national data protection authorities.

James Henderson, Associate in the London office of Hunton & Williams
+44 (0)20 7220 5704; jhenderson@hunton.com
James advises a broad range of clients on all areas of UK and EU data protection law, from general compliance issues and cross-border data transfers to cutting-edge technology issues, such as social media, online behavioural advertising, geolocation and other technology, media and telecommunications matters.

Stephanie Johnson, Associate in the London office of Hunton & Williams
+44 (0)20 7220 5608; sljohnson@hunton.com
Stephanie advises clients on all areas of UK and EU data protection law. She also works on multi-jurisdictional data protection projects, including data breach incidents, employee monitoring and data retention, cross-border data transfers and other technology, media and telecommunications matters.
Bojana Bellamy, President of the Centre for Information Policy Leadership at Hunton & Williams
+44 (0)20 7220 5703; bbellamy@hunton.com
Bojana brings more than 20 years of experience and a deep knowledge of global data privacy and cybersecurity law and policy. Bojana was a board member of the International Association of Privacy Professionals (IAPP) from 2008-2013, and was elected chair from 2011-2012. Bojana was recently elected to participate in a new transatlantic initiative, the “Privacy Bridge Project,” that seeks to develop practical solutions to bridge the gap between European and U.S. privacy regimes.

Markus Heyder, Vice President and Senior Policy Counselor of the Centre for Information Policy Leadership at Hunton & Williams
+1 (202) 419 2005; mheyder@hunton.com
Markus has extensive experience in global data privacy and information security law and policy, including representing the Federal Trade Commission in developing the APEC Cross-Border Privacy Rules, helping to create and manage the Global Privacy Enforcement Network, and working on matters relating to the U.S.-EU Safe Harbor Framework. Prior to joining Hunton & Williams, Markus served for over 10 years as Counsel for International Consumer Protection in the Office of International Affairs at the FTC and nearly two years in the FTC’s Division of Marketing Practices.

Fred H. Cate, Senior Policy Advisor and Director of the Centre for Information Policy Leadership at Hunton & Williams
+1 (812) 855 1161; fcate@hunton.com
A distinguished professor and director of the Center for Applied Cybersecurity Research at Indiana University, Professor Cate is a leading authority on privacy, security and other information law and policy issues. He is actively engaged in advising government and industry leaders. He is a member of BNA’s Privacy & Security Law Report Advisory Board, and he leads the American Law Institute’s project on Principles of the Law on Government Access to and Use of Personal Digital Information.

Richard Thomas, CBE LLD, Global Strategy Advisor of the Centre for Information Policy Leadership at Hunton & Williams
+44 (0)20 7220 5601; rthomas@hunton.com
Richard has nearly 40 years of experience working across the private and public sectors. He was the Information Commissioner for the UK from November 2002 until his retirement at the end of June 2009. In 2008, he was awarded “Privacy Leader of the Year” by the IAPP and was voted third in Silicon.com’s global “IT Agenda Setters” poll.