

Guidelines 3/2018 on the territorial scope of the GDPR (Article 3) - Version for public consultation

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The European Data Protection Board

Having regard to Article 70 (1)(e) of the Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

HAS ADOPTED THE FOLLOWING GUIDELINES:

INTRODUCTION

The territorial scope of General Data Protection Regulation¹ (the GDPR) is determined by Article 3 of the Regulation and represents a significant evolution of the EU data protection law compared to the framework defined by Directive 95/46/EC². In part, the GDPR confirms choices made by the EU legislator and the Court of Justice of the European Union (CJEU) in the context of Directive 95/46/EC. However, important new elements have been introduced. Most importantly, the main objective of Article 4 of the Directive was to define which Member State's national law is applicable, whereas Article 3 of the GDPR defines the territorial scope of a directly applicable text. Moreover, while Article 4 of the Directive made reference to the 'use of equipment' in the Union's territory as a basis for bringing controllers who were "not established on Community territory" within the scope of EU data protection law, such a reference does not appear in Article 3 of the GDPR.

Article 3 of the GDPR reflects the legislator's intention to ensure comprehensive protection of EU data subjects' rights and to establish, in terms of data protection requirement, a level playing field for companies active on the EU markets, in a context of worldwide data flows.

Article 3 of the GDPR defines the territorial scope of the Regulation on the basis of two main criteria: the "establishment" criterion, as per Article 3(1), and the "targeting" criterion as per Article 3(2). Where one of these two criteria is met, the relevant provisions of the GDPR will apply to the processing of personal data by the controller or processor concerned. In addition, Article 3(3) confirms the application of the GDPR to the processing where Member State law applies by virtue of public international law.

Through a common interpretation by data protection authorities in the EU, these guidelines seek to ensure a consistent application of the GDPR when assessing whether particular processing by a controller or a processor falls within the scope of the new EU legal framework. In these guidelines, the EDPB sets out and clarifies the criteria for determining the application of the territorial scope of the GDPR. Such a common interpretation is also essential for controllers and processors, both within and outside the EU, so that they may assess whether they need to comply with the GDPR.

As controllers or processors not established in the EU but engaging in processing activities falling within Article 3(2) are required to designate a representative in the Union, these guidelines will also provide

¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

² Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

clarification on the process for the designation of this representative under Article 27 and its responsibilities and obligations.

As a general principle, the EDPB asserts that where the processing of personal data falls within the territorial scope of the GDPR, all provisions of the Regulation apply to such processing. These guidelines will however specify the various scenarios that may arise, depending on the type of processing activities, the entity carrying out these processing activities or the location of such entities, and will detail the provisions applicable to each situation. It is therefore essential that controllers and processors, especially those offering goods and services at international level, do undertake a careful and *in concreto* assessment of their processing activities, in order to determine whether the related processing of personal data falls under the scope of the GDPR.

1 APPLICATION OF THE ESTABLISHMENT CRITERION - ART 3(1)

Article 3(1) of the GDPR provides that the "Regulation applies to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not."

Article 3(1) GDPR makes reference not only to an establishment of a controller, but also to an establishment of a processor. As a result, the processing of personal data by a processor may also be subject to EU law by virtue of the processor having an establishment located within the EU.

The following sections clarify the application of the establishment criterion, first by considering the definition of an 'establishment' in the EU within the meaning of EU data protection law, second by looking at what is meant by 'processing in the context of the activities of an establishment in the Union', and lastly by confirming that the GDPR will apply regardless of whether the processing carried out in the context of the activities of this establishment takes place in the Union or not.

Article 3(1) ensures that the GDPR applies to the processing by a controller or processor carried out in the context of the activities of an establishment of that controller or processor in the Union, regardless of the actual place of the processing. The EDPB therefore recommends a threefold approach in determining whether or not the processing of personal data falls within the scope of the GDPR pursuant to Article 3(1).

a) Consideration 1: "An establishment in the Union"

Before considering what is meant by "an establishment in the Union" it is first necessary to identify who is the controller or processor for a given processing activity. According to the definition in Article 4(7) of the GDPR, controller" means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data". A processor, according to Article 4(8) of the GDPR, is "a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller". As established by relevant CJEU case law and previous WP29 guidance³, the determination of whether an entity is a controller or processor for the purposes of EU data protection law is a key element in the assessment of the application of the GDPR to the personal data processing in question.

³ WP169 - Opinion 1/2010 on the concepts of "controller" and "processor", adopted on 16th February 2010.

While the notion of "main establishment" is defined in Article 4(16), the GDPR does not provide a definition of "establishment" for the purpose of Article 3⁴. However, Recital 22⁵ clarifies that an "[e]stablishment implies the effective and real exercise of activities through stable arrangements. The legal form of such arrangements, whether through a branch or a subsidiary with a legal personality, is not the determining factor in that respect."

This wording is identical to that found in Recital 19 of Directive 95/46/EC, to which reference has been made in several CJEU rulings broadening the interpretation of the term "establishment", departing from a formalistic approach whereby undertakings are established solely in the place where they are registered⁶. Indeed, the CJEU ruled that the notion of establishment extends to any real and effective activity — even a minimal one — exercised through stable arrangements⁷. In order to determine whether an entity based outside the Union has an establishment in a Member State, both the degree of stability of the arrangements and the effective exercise of activities in that Member State must be considered in the light of the specific nature of the economic activities and the provision of services concerned. This is particularly true for undertakings offering services exclusively over the Internet⁸. The threshold for "stable arrangement^{9"} can actually be quite low when the centre of activities of a controller concerns the provision of services online. As a result, in some circumstances, the presence of one single employee or agent of the non-EU entity may be sufficient to constitute a stable arrangement if that employee or agent acts with a sufficient degree of stability.

The fact that the non-EU entity responsible for the data processing does not have a branch or subsidiary in a Member State does not preclude it from having an establishment there within the meaning of EU data protection law. Although the notion of establishment is broad, it is not without limits. It is not possible to conclude that the non-EU entity has an establishment in the Union merely because the undertaking's website is accessible in the Union¹⁰.

Example 1: A car manufacturing company with headquarters in the US has a fully-owned branch and office located in Brussels overseeing all its operations in Europe, including marketing and advertisement.

The Belgian branch can be considered to be a stable arrangement, which exercises real and effective activities in light of the nature of the economic activity carried out by the car manufacturing company. As such, the Belgian branch could therefore be considered as an establishment in the Union, within the meaning of the GDPR.

⁴ The definition of "main establishment" is mainly relevant for the purpose of determining the competence of the supervisory authorities concerned according to Article 56 GDPR. See the WP29 Guidelines for identifying a controller or processor's lead supervisory authority (16/EN WP 244).

⁵ Recital 22 of the GDPR: "Any processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union should be carried out in accordance with this Regulation, regardless of whether the processing itself takes place within the Union. Establishment implies the effective and real exercise of activity through stable arrangements. The legal form of such arrangements, whether through a branch or a subsidiary with a legal personality, is not the determining factor in that respect."

⁶ See in particular Google Spain SL, Google Inc. v AEPD, Mario Costeja González (C-131/12), Weltimmo v NAIH (C-230/14), Verein für Konsumenteninformation v Amazon EU (C-191/15) and Wirtschaftsakademie Schleswig-Holstein (C-210/16).

⁷ Weltimmo, paragraph 31.

⁸ Weltimmo, paragraph 29.

⁹ Weltimmo, paragraph 31.

¹⁰ CJEU, Verein für Konsumenteninformation v. Amazon EU Sarl, Case C 191/15, 28 July 2016, paragraph 76 (hereafter "Verein für Konsumenteninformation").

Once it is concluded that a controller or processor is established in the EU, an *in concreto* analysis should then follow to determine whether the processing is carried out in the context of the activities of this establishment, in order to determine whether Article 3(1) applies. If a controller or processor established outside the Union exercises "a real and effective activity - even a minimal one" - through "stable arrangements", regardless of its legal form (e.g. subsidiary, branch, office...), in the territory of a Member State, this controller or processor can be considered to have an establishment in that Member State¹¹. It is therefore important to consider whether the processing of personal data takes place "in the context of the activities of" such an establishment as highlighted in Recital 22.

b) Consideration 2: Processing of personal data carried out "in the context of the activities of" an establishment

Article 3(1) confirms that it is not necessary that the processing in question is carried out "by" the relevant EU establishment itself; the controller or processor will be subject to obligations under the GDPR whenever the processing is carried out "in the context of the activities" of its relevant establishment. The EDPB recommends that determining whether an entity based in the EU is to be considered as an establishment of the controller or processor for the purposes of Article 3(1) is made on a case-by-case basis and based on an analysis *in concreto*. Each scenario must be assessed on its own merits, taking into account the specific facts of the case.

The EDPB considers that, for the purpose of Article 3(1), the meaning of "processing in the context of the activities of an establishment of a controller or processor" is to be understood in light of the relevant case law. On the one hand, with a view to fulfilling the objective of ensuring effective and complete protection, the meaning of "in the context of the activities of an establishment" cannot be interpreted restrictively¹². On the other hand, the existence of an establishment within the meaning of the GDPR should not be interpreted too broadly to conclude that the existence of any presence in the EU with even the remotest links to the data processing activities of a non-EU entity will be sufficient to bring this processing within the scope of EU data protection law. Some commercial activity led by a non-EU entity within a Member State may indeed be so far removed from the processing of personal data by this entity that the existence of the commercial activity in the EU would not be sufficient to bring that data processing within the scope of EU data protection law¹³.

i) Relationship between a data controller or processor outside the Union and a local establishment in the Union

The activities of a local establishment in a Member state and the data processing activities of a data controller or processor established outside the EU may be inextricably linked, and thereby may trigger the applicability of EU law, even if that local establishment is not actually taking any role in the data processing itself¹⁴. If a case by case analysis on the facts shows that

¹¹ See in particular para 29 of the Weltimmo judgment, which emphasizes a flexible definition of the concept of 'establishment' and clarifies that 'the degree of stability of the arrangements and the effective exercise of activities in that other Member State must be interpreted in the light of the specific nature of the economic activities and the provision of services concerned.'

¹² Weltimmo, paragraph 25 and Google Spain, paragraph 53.

¹³ WP 179 update - Update of Opinion 8/2010 on applicable law in light of the CJEU judgment in Google Spain, 16th December 2015

¹⁴ CJEU, Google Spain, Case C 131/12

there is an inextricable link between the activities of an EU establishment and the processing of data carried out by a non-EU controller, EU law will apply to that processing by the non-EU entity, whether or not the EU establishment plays a role in that processing of data¹⁵.

ii) Revenue raising in the Union

Revenue-raising in the EU by a local establishment, to the extent that such activities can be considered as "inextricably linked" to the processing of personal data taking place outside the EU and individuals in the EU, may be indicative of processing by a non-EU controller or processor being carried out "in the context of the activities of the EU establishment", and may be sufficient to result in the application of EU law to such processing¹⁶.

The EDPB recommends that non-EU organisations undertake an assessment of their processing activities, first by determining whether personal data are being processed, and secondly by identifying potential links between the activity for which the data is being processed and the activities of any presence of the organisation in the Union. If such a link is identified, the nature of this link will be key in determining whether the GDPR applies to the processing in question, and must be assessed against the elements listed above.

Example 2: An e-commerce website operated by a company based in China, whereas the data processing activities of which are exclusively carried out in China, has established a European office in Berlin in order to lead and implement commercial prospection and marketing campaigns towards EU markets.

In this case, it can be considered that the activities of the European office in Berlin are inextricably linked to the processing of personal data carried out by the Chinese e-commerce website, insofar as the commercial prospection and marketing campaign towards EU markets notably serve to make the service offered by the e-commerce website profitable. The processing of personal data by the Chinese company can therefore be considered as carried out in the context of the activities of the European office, as an establishment in the Union, and therefore be subject to the provisions of the GDPR as per its Article 3(1).

Example 3: A hotel and resort chain in South Africa offers package deals through its website, available in English, German, French and Spanish. The company does not have any office, representation or stable arrangement in the EU.

In this case, in the absence of any representation or stable arrangement of the hotel and resort chain within the territory of the Union, it appears that no entity linked to this data controller in South Africa can qualify as an establishment in the EU within the meaning of the GDPR. Therefore the processing at stake cannot be subject to the provisions of the GDPR, as per Article 3(1).

¹⁵ WP 179 update - Update of Opinion 8/2010 on applicable law in light of the CJEU judgment in Google Spain, 16th December 2015

¹⁶ This may potentially be the case, for example, for any foreign operator with a sales office or some other presence in the EU, even if that office has no role in the actual data processing, in particular where the processing takes place in the context of the sales activity in the EU and the activities of the establishment are aimed at the inhabitants of the Member States in which the establishment is located (WP179 update).

However, it must be analysed *in concreto* whether the processing carried out by this data controller established outside the EU can be subject to the GDPR, as per Article 3(2).

c) Consideration 3: application of the GDPR to the establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not

As per Article 3(1), the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union triggers the application of the GDPR and the related obligations for the data controller or processor concerned.

The text of the GDPR specifies that the Regulation applies to processing in the context of the activities of an establishment in the EU "regardless of whether the processing takes place in the Union or not". It is the presence, through an establishment, of a data controller or processor in the EU and the fact that a processing takes place in the context of the activities of this establishment that trigger the application of the GDPR to its processing activities. The place of processing is therefore not relevant in determining whether or not the processing, carried out in the context of the activities of an EU establishment, falls within the scope of the GDPR.

Example 4: A French company has developed a car-sharing application exclusively addressed to customers in Morocco, Algeria and Tunisia. The service is only available in those three countries but all personal data processing activities are carried out by the data controller in France.

While the collection of personal data takes place in non-EU countries, the subsequent processing of personal data in this case is carried out in the context of the activities of an establishment of a data controller in the Union. Therefore, even though processing relates to personal data of data subjects who are not in the Union, the provisions of the GDPR will apply to the processing carried out by the French company, as per Article 3(1).

Example 5: A pharmaceutical company with headquarters in Stockholm has located all its personal data processing activities with regards to its clinical trial data in its branch based in Singapore. According to the company structure, the branch is not a legally distinct entity and the Stockholm headquarter determines the purpose and means of the data processing carried out on its behalf by its branch based in Singapore.

In this case, while the processing activities are taking place in Singapore, that processing is carried out in the context of the activities of the pharmaceutical company in Stockholm i.e. of a data controller established in the Union. The provisions of the GDPR therefore apply to such processing, as per Article 3(1).

In determining the territorial scope of the GDPR, geographical location will be important under Article 3(1) with regard to the place of establishment of:

- the controller or processor itself (is it established inside or outside the Union?);
- any business presence of a non-EU controller or processor (does it have an establishment in the Union?)

However, geographical location is not important for the purposes of Article 3(1) with regard to the place in which processing is carried out, or with regard to the location of the data subjects in question.

The text of Article 3(1) does not restrict the application of the GDPR to the processing of personal data of individuals who are in the Union. The EDPB therefore considers that any personal data processing in the context of the activities of an establishment of a controller or processor in the Union would fall under the scope of the GDPR, regardless of the location or the nationality of the data subject whose personal data are being processed. This approach is supported by Recital 14 of the GDPR which states that "[t]he protection afforded by this Regulation should apply to natural persons, whatever their nationality or place of residence, in relation to the processing of their personal data."

d) Application of the establishment criterion to controller and processor

As far as processing activities falling under the scope of Article 3(1) are concerned, the EDPB considers that such provisions apply to controllers and processors whose processing activities are carried out in the context of the activities of their establishment in the EU. While acknowledging that the requirements for establishing the relationship between a controller and a processor¹⁷ does not vary depending on the geographical location of the establishment of a controller or processor, the EDPB takes the view that when it comes to the identification of the different obligations triggered by the applicability of the GDPR, the processing by each entity must be considered separately.

The GDPR envisages different and dedicated provisions or obligations applying to data controllers and processors, and as such, should a data controller or processor be subject to the GDPR as per Article 3(1), the related obligations would apply to them respectively and separately. In this context, the EDPB notably deems that a processor in the EU should not be considered to be an establishment of a data controller within the meaning of Article 3(1) merely by virtue of its status as processor. The existence of a relationship between a controller and a processor does not necessarily trigger the application of the GDPR to both, should one of these two entities not be established in the Union.

An organisation processing personal data on behalf of, and on instructions from, another organisation (the client company) will be acting as processor for the client company (the controller). Where a processor is established in the Union, it will be required to comply with the obligations imposed on processors by the GDPR (the 'GDPR processor obligations'). If the controller instructing the processor is also located in the Union, that controller will be required to comply with the obligations imposed on controllers by the GDPR (the 'GDPR controller obligations').

i) Processing by a controller in the EU using a processor not subject to the GDPR

Where a controller subject to GDPR chooses to use a processor located outside the Union and not subject to the GDPR, it will be necessary for the controller to ensure by contract or other legal act that the processor processes the data in accordance with the GDPR. Article 28(3) provides that the processing by a processor shall be governed by a contract or other legal act. The controller will therefore need to ensure that it puts in place a contract with the processor addressing all the requirements set out in Article 28(3). In addition, it is likely that, in order to ensure that it has complied

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¹⁷ In accordance with Article 28, the EDPB recalls that processing activities by a processor on behalf of a controller shall be governed by a contract or other legal act under Union or Member State law, that is binding on the processor with regard to the controller, and that controllers shall only use processors providing sufficient guarantees to implement appropriate measures in such manner that processing will meet the requirement of the GDPR and ensure the protection of data subjects' rights.

with its obligations under Article 28(1) – to use only a processor providing sufficient guarantees to implement measures in such a manner that processing will meet the requirements of the Regulation and protect the rights of data subjects – the controller may need to consider imposing, by contract, the obligations placed by the GDPR on processors subject to it. That is to say, the controller would have ensure that the processor not subject to the GDPR complies will the obligations, governed by a contract or other legal act under Union or Member State law, referred to Article 28(3).

The processor not subject to the GDPR will therefore become indirectly subject to some obligations imposed by controllers subject to the GDPR by virtue of contractual arrangements under Article 28. Moreover, provisions of Chapter V of the GDPR may apply.

Example 6: A Finnish research institute conducts research regarding the Sami people. The institute launches a project that only concerns Sami people in Russia. For this project the institute uses a processor based in Canada.

While the GDPR would not formally apply directly to the Canadian processor, the Finnish controller has a duty to only use processors that provide sufficient guarantees to implement appropriate measures in such manner that processing will meet the requirement of the GDPR and ensure the protection of data subjects' rights. The Finnish controller needs to enter into a data processing agreement with the Canadian processor, and the processor's duties will be stipulated in that legal act.

ii) Processing in the context of the activities of an establishment of a processor in the Union

Whilst case law provides us with a clear understanding of the effect of processing being carried out in the context of the activities of an EU establishment of the controller, the effect of processing being carried out in the context of the activities of an EU establishment of a processor is less clear.

The EDPB emphasises that it is important to consider the establishment of the controller and processor separately.

The first question is whether the controller itself has an establishment in the Union, and is processing in the context of the activities of that establishment. Assuming the controller is not considered to be processing in the context of its own establishment in the Union, that controller will not be subject to GDPR controller obligations by virtue of Article 3(1) (although it may still be caught by Article 3(2)). Unless other factors are at play, the processor's EU establishment will not be considered to be an establishment in respect of the controller.

The separate question then arises of whether the processor is processing in the context of an establishment in the Union. If so, the processor will be subject to GDPR processor obligations. However, this does not cause the non-EU controller to become subject to the GDPR controller obligations. That is to say, a "non-EU" controller (as described above) will not become subject to the GDPR simply because it chooses to use a processor in the Union.

By instructing a processor in the Union, the controller not subject to GDPR is not carrying out processing "in the context of the activities of the processor in the Union". The processing is carried out in the context of the controller's own activities; the processor is merely providing a processing service¹⁸

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¹⁸ The offering of a processing service in this context cannot be considered either as an offer of a service to data subjects in the Union.

which is not "inextricably linked" to the activities of the controller. As stated above, in the case of a data processor established in the Union and carrying out processing on behalf of a data controller established outside the Union and not subject to the GDPR as per Article 3(2), the EDPB considers that the processing activities of the data controller would not be deemed as falling under the territorial scope of the GDPR merely because it is processed on its behalf by a processor established in the Union. However, even though the data controller is not established in the Union and is not subject to the provisions of the GDPR as per Article 3(2), the data processor, as it is established in the Union, will be subject to the relevant provisions of the GDPR as per Article 3(1).

Example 7: A processor established in Spain has entered in a contract with a Mexican retail company, the data controller, for the processing of its clients' personal data. The Mexican company offers and directs its services exclusively to the Mexican market and its processing concerns exclusively data subjects located outside the Union.

In this case, the Mexican retail company does not target persons on the territory of the Union through the offering of goods or services, nor it does monitor the behaviour of person on the territory of the Union. The processing by the data controller, established outside the Union, is therefore not subject to the GDPR as per Article 3(2).

While the provisions of the GDPR does not apply to the data controller, the data processor, as a processor established in Spain, will be required to comply with the processor obligations imposed by the regulation for any processing carried out in the context of its activities.

When it comes to a data processor carrying out processing on behalf of a data controller established outside the Union and which does not fall under the territorial scope of the GDPR as per Article 3(2), the processor will be subject to the following relevant GDPR provisions directly applicable to data processors:

- The obligations imposed on processors under Article 28 (2), (3), (4), (5) and (6), on the duty to enter into a data processing agreement, with the exception of those relating to the assistance to the data controller in complying with its (the controller's) own obligations under the GDPR.
- The processor and any person acting under the authority of the controller or of the processor, who has access to personal data, shall not process those data except on instructions from the controller, unless required to do so by Union or Member State law, as per Article 29 and Article 32(4).
- Where applicable, the processor shall maintain a record of all categories of processing carried out on behalf of a controller, as per Article 30(2).
- Where applicable, the processor shall, upon request, cooperate with the supervisory authority in the performance of its tasks, as per Article 31.
- The processor shall implement technical and organisational measures to ensure a level of security appropriate to the risk, as per Article 32.
- The processor shall notify the controller without undue delay after becoming aware of a personal data breach, as per Article 33.
- Where applicable, the processor shall designate a data protection officer as per Articles 37 and 38.
- The provisions on transfers of personal data to third countries or international organisations, as per Chapter V.

In addition, since such processing would be carried out in the context of the activities of an establishment of a processor in the Union, the EDPB recalls that the processor will have to ensure its processing remains lawful with regards to other obligations under EU or national law. Article 28(3) also

specifies that "the processor shall immediately inform the controller if, in its opinion, an instruction infringes this Regulation or other Union or Member State data protection provisions."

In line with the positions taken previously by the Article 29 Working Party, the EDPB takes the view that the Union territory cannot be used as a "data haven", for instance when a processing activity entails inadmissible ethical issues¹⁹, and that certain legal obligations beyond the application of EU data protection law, in particular European and national rules with regard to public order, will in any case have to be respected by any data processor established in the Union, regardless of the location of the data controller. This consideration also takes into account the fact that by implementing EU law, provisions resulting from the GDPR and related national laws, are subject to the Charter of Fundamental Rights of the Union. However, this does not impose additional obligations on controllers outside the Union not falling under the territorial scope of the GDPR as per Article 3(2).

2 APPLICATION OF THE TARGETING CRITERION – ART 3(2)

The absence of an establishment in the Union does not necessarily mean that a data controller or processor established in a third country would be excluded from the scope of the GDPR, since Article 3(2) sets out the circumstances in which the GDPR applies to a controller or processor not established in the Union, depending on their processing activities.

In this context, the EDPB confirms that in the absence of an establishment in the Union, a controller or processor cannot benefit from the one-stop shop mechanism provided for in Article 56 of the GDPR. Indeed, the GDPR's cooperation and consistency mechanism only applies to controllers and processors with an establishment, or establishments, within the European Union²⁰.

While the present guidelines aims at clarifying the territorial scope of the GDPR, the EDPB also wish to stress that controllers and processors will also need to take into account other applicable texts, such as for instance EU or Member States' sectorial legislation and national laws. Several provisions of the GDPR indeed allow Member States to introduce additional conditions and to define a specific data protection framework at national level in certain areas or in relation to specific processing situations. Controllers and processors must therefore ensure that they are aware of, and comply with, these additional conditions and frameworks which may vary from one Member State to the other. Such variations in the data protection provisions applicable in each Member State are particularly notable in relation to the provisions of Article 8 (providing that the age at which children may give valid consent in relation to the processing of their data by information society services may vary between 13 and 16), of Article 9 (in relation to the processing of special categories of data), Article 23 (restrictions) or concerning the provisions contained in Chapter IX of the GDPR (freedom of expression and information; public access to official documents; national identification number; employment context; processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes; secrecy; churches and religious associations).

Article 3(2) of the GDPR provides that "this Regulation applies to the processing of personal data of data subjects who are in the Union by a controller or processor not established in the Union, where the processing activities are related to: (a) the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the Union; or (b) the monitoring of their behaviour as far as their behaviour takes place within the Union."

¹⁹ WP169 - Opinion 1/2010 on the concepts of "controller" and "processor", adopted on 16th February 2010

²⁰ WP244, 13th December 2016, Guidelines for identifying a controller or processor's lead supervisory authority.

The application of the "targeting criterion" towards data subjects who are in the Union, as per Article 3(2), can be triggered by two distinct and alternative types of activities carried out by a controller or processor not established in the Union. In addition to being applicable only to a controller or processor not established in the Union, the targeting criteria largely focus on what the "processing activities" are "related to", which is to be considered on a case-by-case basis.

In assessing the conditions for the application of the criteria, the EDPB therefore recommends a twofold approach, in order to determine first that the processing relates to personal data of data subjects who are in the Union, and second whether it relates to the offering of goods or services or to the monitoring of data subjects' behaviour in the Union.

a) Consideration 1: Data subjects in the Union

The wording of Article 3(2) refers to "personal data of data subjects who are in the Union". The application of the targeting criteria is therefore not limited by the citizenship, residence or other type of legal status of the data subject whose personal data are being processed. Recital 14 confirms this interpretation and states that "[t]he protection afforded by this Regulation should apply to natural persons, whatever their nationality or place of residence, in relation to the processing of their personal data".

This provision of the GDPR reflects EU primary law which also lays down a broad scope for the protection of personal data, not limited to EU citizens, with Article 8 of the Charter of Fundamental Rights providing that the right to the protection of personal data is not limited but is for "everyone"²¹.

While the location of the data subject in the territory of the Union is a determining factor for the application of the targeting criterion as per Article 3(2), the EDPB considers that the nationality or legal status of a data subject who is in the Union cannot limit or restrict the territorial scope of the Regulation.

The requirement that the data subject be located in the Union must be assessed at the moment when the relevant trigger activity takes place, i.e. at the moment of offering of goods or services or the moment when the behaviour is being monitored, regardless of the duration of the offer made or monitoring undertaken.

Example 8: A start-up established in the USA, without any business presence or establishment in the EU, provides a city-mapping application for tourists. The application processes personal data concerning the location of customers using the app (the data subjects) once they start using the application in the city they visit, in order to offer targeted advertisement for places to visits, restaurant, bars and hotels. The application is available for tourists while they visit New York, San Francisco, Toronto, London, Paris and Rome.

The US start-up, via its city mapping application, is offering services to individuals in the Union (specifically in London, Paris and Rome). The processing of the EU-located data subjects' personal data in connection with the offering of the service falls within the scope of the GDPR as per Article 3(2).

²¹ Charter of Fundamental Right of the European Union, Article 8(1), « Everyone has the right to the protection of personal data concerning him or her".

The EDPB also wishes to underline that the fact of processing personal data of an individual in the Union alone is not sufficient to trigger the application of the GDPR to processing activities of a controller or processor not established in the Union. The element of "targeting" individuals in the EU, either by offering goods or services to them or by monitoring their behaviour (as further clarified below), must always be present in addition.

Example 9: A U.S. citizen is travelling through Europe during his holidays. While in Europe, he downloads and uses a news app that is offered by a U.S. company. The app is exclusively directed at the U.S. market. The collection of the U.S. tourist's personal data via the app by the U.S. company is not subject to the GDPR.

Moreover, it should be noted that the processing of personal data of EU citizens or residents that takes place in a third country does not trigger the application of the GDPR, as long as the processing is not related to a specific offer directed at individuals in the EU or to a monitoring of their behaviour in the Union.

Example 10: A bank in Taiwan has customers that are residing in Taiwan but hold German citizenship. The bank is active only in Taiwan; its activities are not directed at the EU market. The bank's processing of the personal data of its German customers is not subject to the GDPR.

Example 11: The Canadian immigration authority processes personal data of EU citizens when entering the Canadian territory for the purpose of examining their visa application. This processing is not subject to the GDPR.

b) <u>Consideration 2a: offering of goods or services, irrespective of whether a payment of the data subject is required, to data subjects in the Union</u>

The first activity triggering the application of Article 3(2) is the "offering of goods or services", a concept which has been further addressed by EU law and case law, which should be taken into account when applying the targeting criterion. The offering of services also includes the offering of information society services, defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 as "any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services".

Article 3(2)(a) specifies that the targeting criterion concerning the offering of goods or services applies irrespective of whether a payment by the data subject is required. Whether the activity of a controller or processor not established in the Union is to be considered as an offer of a good or a service is not therefore dependent whether payment is made in exchange for the goods or services provided²².

Another key element to be assessed in determining whether the Article 3(2)(a) targeting criterion can be met is whether the offer of goods or services is directed at a person in the Union, or in other words,

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²² See, in particular, CJEU, C-352/85, Bond van Adverteerders and Others vs. The Netherlands State, 26 April 1988, par. 16), and CJEU, C-109/92, Wirth [1993] Racc. I-6447, par. 15

whether the conduct on the part of the controller or processor demonstrates its intention to offer goods or a services to a data subject located in the Union. Recital 23 of the GDPR indeed clarifies that "in order to determine whether such a controller or processor is offering goods or services to data subjects who are in the Union, it should be ascertained whether it is apparent that the controller or processor envisages offering services to data subjects in one or more Member States in the Union."

The recital further specifies that "whereas the mere accessibility of the controller's, processor's or an intermediary's website in the Union, of an email address or of other contact details, or the use of a language generally used in the third country where the controller is established, is insufficient to ascertain such intention, factors such as the use of a language or a currency generally used in one or more Member States with the possibility of ordering goods and services in that other language, or the mentioning of customers or users who are in the Union, may make it apparent that the controller envisages offering goods or services to data subjects in the Union."

Processing activities which are "related" to the activity which triggered application of Article 3(2) also fall within the territorial scope of the GDPR. The EDPB considers that there needs to be a connection between the processing activity and the offering of good or service, but both direct and indirect connections are relevant and to be taken into account.

The elements listed in Recital 23 echo and are in line with the CJEU case law based on Regulation 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, and in particular its Article 15(1)(c). In *Pammer v Reederei Karl Schlüter GmbH & Co and Hotel Alpenhof v Heller* (Joined cases C-585/08 and C-144/09), the Court was asked to clarify what it means to "direct activity" within the meaning of Article 15(1)(c) of Regulation 44/2001 (*Brussels I*). The Court held that, in order to determine whether a trader can be considered to be "directing" its activity to the Member State of the consumer's domicile, within the meaning of Article 15(1)(c) of Brussels I, the trader must have manifested its intention to establish commercial relations with such consumers. In this context, the Court considered evidence able to demonstrate that the trader was envisaging doing business with consumers domiciled in a Member State.

While the notion of "directing an activity" differs from the "offering of goods or services", the EDPB deems this case law in in *Pammer v Reederei Karl Schlüter GmbH & Co and Hotel Alpenhof v Heller (Joined cases C-585/08 and C-144/09)*²³ might be of assistance when considering whether goods or services are offered to a data subject in the Union. When taking into account the specific facts of the case, the following factors could therefore *inter alia* be taken into consideration, possibly in combination with one another:

- The EU or at least one Member State is designated by name with reference to the good or service offered:
- The data controller or processor pays a search engine operator for an internet referencing service in order to facilitate access to its site by consumers in the Union; or the controller or processor has launched marketing and advertisement campaigns directed at an EU country audience
- The international nature of the activity at issue, such as certain tourist activities;
- The mention of dedicated addresses or phone numbers to be reached from an EU country;

²³ It is all the more relevant that, under Article 6 of Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I), in absence of choice of law, this criterion of "directing activity" to the country of the consumer's habitual residence is taken into account to designate the law of the consumer's habitual residence as the law applicable to the contract.

- The use of a top-level domain name other than that of the third country in which the controller or processor is established, for example ".de", or the use of neutral top-level domain names such as ".eu";
- The description of travel instructions from one or more other EU Member States to the place where the service is provided;
- The mention of an international clientele composed of customers domiciled in various EU Member States, in particular by presentation of accounts written by such customers;
- The use of a language or a currency other than that generally used in the trader's country, especially a language or currency of one or more EU Member states;
- The data controller offers the delivery of goods in EU Member States.

As already mentioned, several of the elements listed above, if taken alone may not amount to a clear indication of the intention of a data controller to offer goods or services to data subjects in the Union, however, they should each be taken into account in any *in concreto* analysis in order to determine whether the combination of factors relating to the data controller's commercial activities can together be considered as an offer of goods or services directed at data subjects in the Union.

It is however important to recall that Recital 23 confirms that the mere accessibility of the controller's, processor's or an intermediary's website in the Union, the mention on the website of its e-mail or geographical address, or of its telephone number without an international code, does not, of itself, provide sufficient evidence to demonstrate the controller or processor's intention to offer goods or a services to a data subject located in the Union.

Example 12: A website, based and managed in Turkey, offers services for the creation, edition, printing and shipping of personalised family photo albums. The website is available in English, French, Dutch and German and payments can be made in Euros or Sterling. The website indicates that photo albums can only be delivered by post mail in the UK, France, Benelux countries and Germany.

In this case, it is clear that the creation, editing and printing of personalised family photo albums constitute a service within the meaning of EU law. The fact that the website is available in four languages of the EU and that photo albums can be delivered by post in six EU Member States demonstrates that there is an intention on the part of the Turkish website to offer its services to individuals in the Union.

As a consequence, it is clear that the processing carried out by the Turkish website, as a data controller, relates to the offering of a service to data subjects in the Union and is therefore subject to the obligations and provisions of the GDPR, as per its Article 3(2)(a).

In accordance with Article 27, the data controller will have to designate a representative in the Union.

Example 13: A private company based in Monaco processes personal data of its employees for the purposes of salary payment. A large number of the company's employees are French and Italian residents.

In this case, while the processing carried out by the company relates to data subjects in France and Italy, it does not takes place in the context of an offer of goods or services. Indeed human resources management, including salary payment by a third-country company cannot be considered as an offer

of service within the meaning of Art 3(2)a. The processing at stake does not relate to the offer of goods or services to data subjects in the Union (nor to the monitoring of behaviour) and, as a consequence, is not subject to the provisions of the GDPR, as per Article 3.

This assessment is without prejudice to the applicable law of the third country concerned.

Example 14: A Swiss University in Zurich is launching its Master degree selection process, by making available an online platform where candidates can upload their CV and cover letter, together with their contact details. The selection process is open to any student with a sufficient level of German and English and holding a Bachelor degree. The University does not specifically advertise to students in EU Universities, and only takes payment in Swiss currency.

As there is no distinction or specification for students from the Union in the application and selection process for this Master degree, it cannot be established that the Swiss University has the intention to target students from a particular EU member states. The sufficient level of German and English is a general requirement that applies to any applicant whether a Swiss resident, a person in the Union or a student from a third country. Without other factors to indicate the specific targeting of students in EU member states, it therefore cannot be established that the processing in question relates to the offer of an education service to data subject in the Union, and such processing will therefore not be subject to the GDPR provisions.

The Swiss University also offers summer courses in international relations and specifically advertise this offer in German and Austrian universities in order to maximise the courses' attendance. In this case, there is a clear intention from the Swiss University to offer such service to data subjects who are in the Union, and the GDPR will apply to the related processing activities.

c) Consideration 2b: monitoring of data subjects' behaviour

The second type of activity triggering the application of Article 3(2) is the monitoring of data subject behaviour as far as their behaviour takes place within the Union.

Recital 24 clarifies that "[t]he processing of personal data of data subjects who are in the Union by a controller or processor not established in the Union should also be subject to this Regulation when it is related to the monitoring of the behaviour of such data subjects in so far as their behaviour takes place within the Union."

For Article 3(2)(b) to trigger the application of the GDPR, the behaviour monitored must first relate to a data subject in the Union and, as a cumulative criterion, the monitored behaviour must take place within the territory of the Union.

The nature of the processing activity which can be considered as behavioural monitoring is further specified in Recital 24 which states that "in order to determine whether a processing activity can be considered to monitor the behaviour of data subjects, it should be ascertained whether natural persons are tracked on the internet including potential subsequent use of personal data processing techniques which consist of profiling a natural person, particularly in order to take decisions concerning her or him or for analysing or predicting her or his personal preferences, behaviours and attitudes." While Recital 24 exclusively relates to the monitoring of a behaviour through the tracking of a person on the internet, the EDPB considers that tracking through other types of network or technology involving personal data

processing should also be taken into account in determining whether a processing activity amounts to a behavioural monitoring, for example through wearable and other smart devices.

As opposed to the provision of Article 3(2)(a), neither Article 3(2)(b) nor Recital 24 introduce a necessary degree of "intention to target" on the part of the data controller or processor to determine whether the monitoring activity would trigger the application of the GDPR to the processing activities. However, the use of the word "monitoring" implies that the controller has a specific purpose in mind for the collection and subsequent reuse of the relevant data about an individual's behaviour within the EU. The EDPB does not consider that any online collection or analysis of personal data of individuals in the EU would automatically count as "monitoring". It will be necessary to consider the controller's purpose for processing the data and, in particular, any subsequent behavioural analysis or profiling techniques involving that data. The EDPB takes into account the wording of Recital 24, which indicates that to determine whether processing involves monitoring of a data subject behaviour, the tracking of natural persons on the Internet, including the potential subsequent use of profiling techniques, is a key consideration.

The application of Article 3(2)(b) where a data controller or processor monitors the behaviour of data subjects who are in the Union could therefore encompass a broad range of monitoring activities, including in particular:

- Behavioural advertisement
- Geo-localisation activities, in particular for marketing purposes
- Online tracking through the use of cookies or other tracking techniques such as fingerprinting
- Personalised diet and health analytics services online
- CCTV
- Market surveys and other behavioural studies based on individual profiles
- Monitoring or regular reporting on an individual's health status

Example 15: A marketing company established in the US provides advice on retail layout to a shopping centre in France, based on an analysis of customers' movements throughout the centre collected through Wi-Fi tracking.

The analysis of a customers' movements within the centre through Wi-Fi tracking will amount to the monitoring of individuals' behaviour. In this case, the data subjects' behaviour takes place in the Union since the shopping centre is located in France. The marketing company, as a data controller, is therefore subject to the GDPR in respect of the processing of this data for this purpose as per its Article 3(2)(b).

In accordance with Article 27, the data controller will have to designate a representative in the Union.

Example 16: An app developer established in Canada with no establishment in the Union monitors the behaviour of data subject in the Union and is therefore subject to the GDPR, as per Article 3(2)b. The developer uses a processor established in the US for the app optimisation and maintenance purposes.

In relation to this processing, the Canadian controller has the duty to only use appropriate processors and to ensure that its obligations under the GDPR are reflected in the contract or legal act governing the relation with its processor in the US, pursuant to Article 28.

3 PROCESSING IN A PLACE WHERE MEMBER STATE LAW APPLIES BY VIRTUE OF PUBLIC INTERNATIONAL LAW

Article 3(3) provides that "[t]his Regulation applies to the processing of personal data by a controller not established in the Union, but in a place where Member State law applies by virtue of public international law". This provision is expanded upon in Recital 25 which states that "[w]here Member State law applies by virtue of public international law, this Regulation should also apply to a controller not established in the Union, such as in a Member State's diplomatic mission or consular post."

The definitions and status of diplomatic missions and consular posts are laid down in international law, respectively in the Vienna Convention on Diplomatic Relations of 1961 and the Vienna Convention on Consular Relations of 1963.

The EDPB considers that the GDPR applies to personal data processing carried out by EU Member States' embassies and consulates, insofar as such processing falls within the material scope of the GDPR, as defined in its Article 2. A Member State's diplomatic or consular post, as a data controller or processor, would then be subject to all relevant provisions of the GDPR, including when it comes to the rights of the data subject, the general obligations related to controller and processor and the transfers of personal data to third countries or international organisations.

Example 17: The Dutch consulate in Kingston, Jamaica, opens an online application process for the recruitment of local staff in order to support its administration.

While the Dutch consulate in Kingston, Jamaica, is not established in the Union, the fact that it is a consular post of an EU country where Member State law applies by virtue of public international law renders the GDPR applicable to its processing of personal data, as per Article 3(3).

Example 18: A German cruise ship travelling in international waters is processing data of the guests on board for the purpose of tailoring the in-cruise entertainment offer.

While the ship is located outside the Union, in international waters, the fact that it is German-registered cruise ship means that by virtue of public international law the GDPR shall be applicable to its processing of personal data, as per Article 3(3).

4 REPRESENTATIVE OF CONTROLLERS OR PROCESSORS NOT ESTABLISHED IN THE UNION

Data controllers or processors subject to the GDPR as per its Article 3(2) are under the obligation to designate a representative in the Union. A controller or processor not established in the Union but subject to the GDPR failing to designate a representative in the Union would therefore be in breach of the Regulation.

This provision is not entirely new since Directive 95/46/EC already provided for a similar obligation. Under the Directive, this provision concerned controllers not established on Community territory that, for purposes of processing personal data, made use of equipment, automated or otherwise, situated on the territory of a Member State. The GDPR imposes an obligation to designate a representative in

the Union to any controller or processor falling under the scope of Article 3(2), unless they meet the exemption criteria as per Article 27(2). In order to facilitate the application of this specific provision, the EDPB deems it necessary to provide further guidance on the designation process, establishment obligations and responsibilities of the representative in the Union as per Article 27.

It is worth noting that a controller or processor not established in the Union who has designated in writing a representative in the Union, in accordance with article 27 of the GDPR, does not fall within the scope of article 3(1), meaning that the presence of the representative within the Union does not constitute an "establishment" of a controller or processor by virtue of article 3(1).

a) Designation of a representative

Recital 80 clarifies that "[t]he representative should be explicitly designated by a written mandate of the controller or of the processor to act on its behalf with regard to its obligations under this Regulation. The designation of such a representative does not affect the responsibility or liability of the controller or of the processor under this Regulation. Such a representative should perform its tasks according to the mandate received from the controller or processor, including cooperating with the competent supervisory authorities with regard to any action taken to ensure compliance with this Regulation."

The written mandate referred to in Recital 80 shall therefore govern the relations and obligations between the representative in the Union and the data controller or processor established outside the Union, while not affecting the responsibility or liability of the controller or processor. The representative in the Union may be a natural or a legal person established in the Union able to represent a data controller or processor established outside the Union with regard to their respective obligations under the GDPR.

In practice, the function of representative in the Union can be exercised based on a service contract concluded with an individual or an organisation, and can therefore be assumed by a wide range of commercial and non-commercial entities, such as law firms, consultancies, private companies, etc... provided that such entities are established in the Union. One representative can also act on behalf of several non-EU controllers and processors.

When the function of representative is assumed by a company or any other type of organisation, it is recommended that a single individual be assigned as a lead contact and person "in charge" for each controller or processor represented. It would generally also be useful to specify these points in the service contract.

The EDPB does not consider the function of representative in the Union as compatible with the role of an external data protection officer ("DPO") which would be established in the Union. Article 38(3) establishes some basic guarantees to help ensure that DPOs are able to perform their tasks with a sufficient degree of autonomy within their organisation. In particular, controllers or processors are required to ensure that the DPO "does not receive any instructions regarding the exercise of [his or her] tasks". Recital 97 adds that DPOs, "whether or not they are an employee of the controller, should be in a position to perform their duties and tasks in an independent manner"²⁴. Such requirement for a sufficient degree of autonomy and independence of a data protection officer does not appear to be compatible with the function of representative in the Union, which subject to a mandate by a controller

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²⁴ WP29 Guidelines on Data Protection Officers ('DPOs'), WP 243 rev.01

or processor and will be acting on its behalf and therefore under its direct instruction²⁵. Furthermore, and to complement this interpretation, the EDPB recalls the position already taken by the WP29 stressing that "a conflict of interests may also arise for example if an external DPO is asked to represent the controller or processor before the Courts in cases involving data protection issues". Given the possible conflict of obligation and interests in cases of enforcement proceedings, the EDPB does not consider the function of a data controller representative in the Union as compatible with the role of data processor for that same data controller.

While the GDPR does not foresee any obligation to data controller or the representative itself to notify the designation of the latter to a supervisory authority, the EDPB recalls that, in accordance with Articles 13(1)a and 14(1)a, as part of their information obligations, controllers shall provide data subjects information as to the identity of their representative in the Union. This information shall for example be included in the privacy notice or upfront information provided to data subjects at the moment of data collection. A controller not established in the Union but falling under Article 3(2) and failing to inform data subjects who are in the Union of the identity of its representative would be in breach of its transparency obligations as per the GDPR. Such information should furthermore be easily accessible to supervisory authorities in order to facilitate the establishment of a contact for cooperation needs.

Example 19: The website referred to in example 12, based and managed in Turkey, offers services for the creation, edition, printing and shipping of personalised family photo albums. The website is available in English, French, Dutch and German and payments can be made in Euros or Sterling. The website indicates that photo albums can only be delivered by post mail in the UK, France, Benelux countries and Germany. This website being subject to the GDPR, as per its Article 3(2)(a), the data controller must designate a representative in the Union.

The representative must be established in one of the Member States where the service offered is available, in this case either in the UK, France, Belgium, Netherlands, Luxembourg or Germany. The name and contact details of the data controller must be part of the information made available online to data subjects once they start using the service by creating their photo album. It must also appear in the website general privacy notice.

b) Exemptions from the designation obligation²⁶

While the application of Article 3(2) triggers the obligation to designate a representative in the Union for controllers or processors established outside the Union, Article 27(2) foresees derogation from the mandatory designation of a representative in the Union, in two distinct cases:

• processing is "occasional, does not include, on a large scale, processing of special categories of data as referred to in Article 9(1) or processing of personal data relating to criminal convictions and offences referred to in Article 10", and such processing "is unlikely to result in a risk to the rights and freedoms of natural persons, taking into account the nature, context, scope and purposes of the processing". While the GDPR does not define what constitutes large-scale processing, the WP29 has previously recommended in its guidelines WP243 on data

²⁵ An external DPO also acting as representative in the Union could for example be in a situation where he is instructed to communicate to a data subject a decision or measure taken by the controller or processor which he or she had deemed uncompliant with the provisions of the GDPR and advised against.

²⁶ Part of the criteria and interpretation laid down in WP243 (Data Protection Officer) can be used as a basis for the exemptions to the designation obligation.

protection officers (DPOs) that the following factors, in particular, be considered when determining whether the processing is carried out on a large scale: the number of data subjects concerned - either as a specific number or as a proportion of the relevant population; the volume of data and/or the range of different data items being processed; the duration, or permanence, of the data processing activity; the geographical extent of the processing activity²⁷.

Or

processing is carried out "by a public authority or body".

c) Establishment in one of the Member States where the data subjects whose personal data are processed are

Article 27(3) foresees that "the representative shall be established in one of the Member States where the data subjects, whose personal data are processed in relation to the offering of goods or services to them, or whose behaviour is monitored, are". In cases where a significant proportion of data subjects whose personal data are processed are located in one particular Member State, the EDPB recommends, as a good practice, that the representative is established in that same Member State. However, the representative must remain easily accessible for data subjects in Member States where it is not established and where the services or goods are being offered or where the behaviour is being monitored.

The EDPB confirms that the criterion for the establishment of the representative in the Union is the location of data subjects whose personal data are being processed. The place of processing, even by a processor established in another Member State, is here not a relevant factor for determining the location of the establishment of the representative.

Example 20: An Indian pharmaceutical company, with neither business presence nor establishment in the Union and subject to the GDPR as per Article 3(2), sponsors clinical trials carried out by investigators (hospitals) in Belgium, Luxembourg and the Netherlands. The majority of patients participating to the clinical trials are situated in Belgium.

The Indian pharmaceutical company, as a data controller, shall designate a representative in the Union established in one of the three Member States where patients, as data subjects, are participating to the clinical trial (Belgium, Luxembourg or the Netherlands). Since most patients are Belgian residents, it is recommended that the representative is established in Belgium. Should this be the case, the representative in Belgium should however be easily accessible to data subjects and supervisory authorities in the Netherlands and Luxembourg.

In this specific case, the representative in the Union could be the legal representative of the sponsor in the Union, as per Article 74 of Regulation (EU) 536/2014 on clinical trials, provided it is established in one of the three Member States, and that both functions are governed by and exercised in compliance with each legal framework.

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²⁷ Article 29 Working Party guidelines on data protections officers (DPOs), adopted on 13th December 2016, as last revised on 5th April 2017, WP 243 rev.01.

d) Obligations and responsibilities of the representative

The representative in the Union acts on behalf of the controller or processor it represents with regards to the controller or processor's obligations under the GDPR. This implies notably the obligations relating to the exercise of data subject rights, and in this regard and as already stated, the identity and contact details of the representative must be provided to data subjects in accordance with articles 13 and 14. While not itself responsible for complying with data subject rights, the legal representative must facilitate the communication between data subjects and the controller or processor represented, in order to make the exercise of data subjects' rights are effective.

As per Article 30, the controller or processor's representative shall in particular maintain a record of processing activities under the responsibility of the controller or processor. The EDPB considers that the maintenance of this record is a joint obligation and that the controller or processor not established in the Union must provide to its representative with all accurate and updated information so that the record can be maintained and made available by the representative.

As clarified by recital 80, the representative should also perform its tasks according to the mandate received from the controller or processor, including cooperating with the competent supervisory authorities with regard to any action taken to ensure compliance with this Regulation. In practice, this means that a supervisory authority would contact the representative in connection with any matter relating to the compliance obligations of a controller or processor established outside the Union, and the representative shall be able to facilitate any informational or procedural exchange between a requesting supervisory authority and a controller or processor established outside the Union.

With the help of a team if necessary, the representative in the Union must therefore be in a position to efficiently communicate with data subjects and cooperate with the supervisory authorities concerned. This means that this communication must take place in the language or languages used by the supervisory authorities and the data subjects concerned. The availability of a representative is therefore essential in order to ensure that data subjects and supervisory authorities will be able to establish contact easily with the non-EU controller or processor.

In line with Recital 80 and Article 27(5), the designation of a representative in the Union does not affect the responsibility and liability of the controller or of the processor under the GDPR and shall be without prejudice to legal actions which could be initiated against the controller or the processor themselves.

It should however be noted that the concept of the representative was introduced precisely with the aim of ensuring enforcement of the GDPR against controllers or processors that fall under Article 3(2) of the GDPR. To this end, it was the intention to enable enforcers to initiate enforcement action against a representative in the same way as against controllers or processors. This includes the possibility to impose administrative fines and penalties, and to hold representatives liable.

For the European Data Protection Board
The Chair
(Andrea Jelinek)