BIVDA
British In Vitro Diagnostics Association

UK Government no-deal Brexit advice for the IVD sector

Introduction

In preparation for a no-deal Brexit this document provides an overview of Government advice of relevance to the IVD sector, from regulation to the use of personal data. Of particular importance to our industry following a no-deal Brexit are the following key points:

- The EU Directive on in vitro diagnostics medical devices (IVDD) will continue to apply to the UK
- For a time-limited period, the UK Government will continue to allow devices to be placed on the UK market that are in conformity with the applicable EU Directive. Relevant labelling requirements will continue to apply including the requirement for products to carry a CE mark
- However, UK-based notified bodies will no longer be recognised by the EU, meaning the devices they have certified will no longer be in conformity with the applicable EU Directive. As such these products will not be able to be placed on the EU market and members will need to have an authorised representative in an EU country
- To support the continuity of supply of products to the UK market, the UK Government will give UK-based notified bodies an ongoing legal status and continue to recognise the validity of certificates that they issued prior to exit day
- Under UK legislation a new role, known as a UK Responsible Person, will be created for manufacturers based outside of the UK

Each of these points is expanded upon below, along with a detailed overview of the Guidance of relevance to our sector in the following categories:

- Regulations of IVDs
- Preparing your business
- Public sector procurement
- Changes to customs authorisation
- Intellectual property
- Trademarks and designs
- Horizon 2020 funding
- Employing of EU citizens
- Using personal data

In addition to this document, BIVDA will hold two members only webinars on 8 October and 14 October. These webinars will enable members to be taken through the relevant elements of the guidance, discuss examples of best practice from industry colleagues and ask any questions.

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Regulation of IVDs in a no-deal Brexit[1]

Full Government guidance on regulating IVDs in the event of a no-deal Brexit is available here.

1. *Regulation changes*

1.1. In a no-deal scenario the UK's current participation in the European regulatory network for medical devices and IVDs would end, and the MHRA would take on the responsibilities for the UK market currently undertaken through the EU system

1.2. The EU Directives on in vitro diagnostics medical devices (IVDD), active implantable medical devices (AIMDD) and medical devices (MDD) will continue to apply to the UK through the UK Medical Devices Regulations 2002

1.3. The Medical Devices (Amendment etc.) (EU exit) Regulations 2019 (UK MDR 2019) will amend the Medical Devices Regulations 2002, the UK will have a regulatory system in place on 1 November 2019, which will mirror all the key elements contained in the IVDR and MDR. This will be brought into force in line with the transitional timetable being followed by the EU for the full application of those two Regulations (2020 for MDR and 2022 for IVDR)

2. *The role of the MHRA*

2.1. The MHRA will continue to perform market surveillance of IVDs on the UK market and be able to take a decision over the marketing and supplying of a device in the UK, regardless of the position of the European regulatory network, or any post-exit decision of the European Court of Justice

3. *Role of those manufacturing and supplying devices*

3.1. In the event of a no-deal Brexit, from the day the UK leaves the EU the roles and responsibilities of those manufacturing and supplying IVDs will change

3.2. Based on the European Commission's Notice to Stakeholders of 22 January 2018, it is generally understood that UK-based Authorised Representatives will no longer be recognised in the EU. Under UK legislation a new role, known as a UK Responsible Person, will be created for manufacturers based outside of the UK *(details on this new role are set out below)*

3.3. The UK MDR 2002 sets out requirements that a manufacturer must meet. Manufacturers seeking conformity with the EU Directives transposed by that statutory instrument should continue to follow these criteria. A new Schedule (2A) has been inserted into the UK MDR 2002 which sets out how the Annexes to the Directives which are cross referenced in Parts II, III and IV of the UK MDR 2002 should be read in a UK specific context after the UK has left the EU

3.4. There are additional responsibilities for manufacturers wishing to comply with Part VIII or Part IX of the UK MDR 2002 (as amended by the UK MDR 2019), which transposes the relevant requirements from the EU MDR and the EU IVDR. These additional responsibilities include, but are not limited to:

[1] UK Government, Guidance – Regulating medical devices in the event of a no-deal Brexit, 26 February 2019 (Last updated 18 September 2019)

3.4.1. Correctly classifying the device against the new risk classification criteria
3.4.2. Meeting general safety and performance requirements, including for labelling and technical documentation and quality management systems
3.4.3. Meeting increased requirements for clinical evidence
3.4.4. Having a person responsible for regulatory compliance in place
3.4.5. Meeting the new vigilance reporting timescales and creating an annual periodic safety update report

4. *UK Responsible Person*

4.1. A new role – the UK Responsible Person – has been created under the UK MDR 2002 (as amended by the UK MDR 2019), applicable in a no-deal Brexit. The UK MDR 2019 defines the UK Responsible Person as *"a person established in the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer's obligations under these regulations"* [2]

4.2. The UK Responsible Person must be established in the UK and acts on behalf of a manufacturer established outside the UK, to carry out specified tasks in relation to the manufacturer's obligations. This includes registering with the MHRA before the device is placed on the UK market

4.3. Only a manufacturer or a designated UK Responsible Person can legally place a device on the UK market. This means that a single manufacturer may have several designated UK Responsible Persons. If you are a designated UK Responsible Person of a non-UK manufacturer, documentary evidence is required. This evidence should be in the form of a headed letter (letter of designation) or signed contract, which states the company name and address for both the overseas manufacturer and the UK Responsible Person

4.4. No labelling changes will be required to reflect the role of this UK Responsible Person

4.5. The requirement for a manufacturer to have in place a UK Responsible Person is in line with the grace period for registering your devices with the MHRA (IVD List A – 4 months / IVD List B – 8 months / General IVDs – 12 months / Class A IVDs complying with the EU IVDR 2017/746 – 12 months). Therefore, you must ensure that you are designated as a UK Responsible Person by the time you register with the MHRA

5. *Authorised Representatives*

5.1. For IVDs and medical devices, after the UK leaves the EU, any UK-based Authorised Representative will no longer be recognised under EU law. This means they will not be recognised as able to carry out tasks on the manufacturer's behalf for the purposes of placing products on the EU market

5.2. In order to place devices on the EU market, manufacturers with an Authorised Representative based in the UK will need to establish a new Authorised Representative in an EU country

[2] The term "person" refers to either an individual (i.e. a sole trader) or a legal person (i.e. a company)

6. *Importers*

6.1. If a person places a product on the market under Part VIII or Part IX of the UK MDR 2002 (as amended by the UK MDR 2019), a number of additional obligations will apply to importers, which will include, but are not limited to, verifying that:

6.1.1. The device has been CE marked
6.1.2. The manufacturer is identified and has a UK Responsible Person, if required
6.1.3. The device has been labelled correctly and a Unique Device Identifier (UDI) has been assigned to the device
6.1.4. The device is registered with the MHRA

7. *Parallel importers*

7.1. After the UK leaves the EU, parallel importing from the EU into the UK will not be possible. Any device that is imported from the EU and placed on the UK market will be treated as a new placing on the market, with all of the relevant manufacturer requirements applying to this importer, including the requirement to register the device with the MHRA. You will also need to ensure that there is a UK Responsible Person in place for this product

8. Conformity of products[3]

8.1. For a time-limited period, the UK Government will continue to allow devices to be placed on the UK market that are in conformity with the applicable EU Directive. Relevant labelling requirements will continue to apply including the requirement for products to carry a CE mark and devices which currently require conformity assessment by a Notified Body (NB) must have a valid CE certificate

8.2. If there's a no-deal Brexit, UK-based *NBs will no longer be recognised by the EU after Brexit*, meaning the devices they have certified will no longer be in conformity with the applicable EU Directive. As such these products will not be able to be placed on the EU market

8.3. To support the continuity of supply of products to the UK market, the UK Government will give UK-based NBs an ongoing legal status and continue to recognise the validity of certificates that they issued prior to exit day. This will allow products covered by certificates issued by UK-based notified bodies to continue to be placed on the UK market after exit day. UK law will not require any changes to the labelling of affected products. Furthermore, the UK will continue to accept labelling in the English language, which includes information from other jurisdictions (such as Ireland), on condition that information complies with all UK requirements

9. Market surveillance of devices

9.1. If there's no-deal, the MHRA would continue to perform market surveillance of medical devices on the UK market and be able to take a decision over the marketing of a device in the UK, regardless of the position of the European regulatory network, or any decision of the Court of Justice of the European Union (CJEU)

[3] MHRA, Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal, 3 January 2019 (Last updated 3 September 2019)

10. Registration of medical devices on the UK market

10.1. After exit day, all medical devices, active implantable medical devices, in vitro diagnostic medical devices (IVDs) and custom-made devices will need to be registered with the MHRA prior to being placed on the UK market. Given this is an extension of existing registration requirements, there will be a grace period to allow time for compliance with the new registration process as set out below:

4 months	Class III medical devices, Class IIb implantable medical devices, Active implantable medical devices, IVD List A
8 months	Class IIb non-implantable medical devices, Class IIa medical devices, IVD List B, Self-test IVDs
12 months	Class I medical devices, Self-certified IVDs, Class A IVDs

10.2. The registration requirements will be as follows:

10.3. Initially the MHRA will require most products to be registered at the level of Global Medical Device Nomenclature (GMDN) code meaning that groups of similar products can come under a single registration. The exception is class III devices, which must have individual product information registered

10.3.1. Once the MDR and IVDR fully apply (from May 2020 and May 2022 respectively), the UK will then mirror the new requirements within the legislation, which will mean individual registration of all products

Structure your business if there's a no-deal Brexit[4]

Full Government guidance on structuring your business if there's a no-deal Brexit is available here.

11. Cross border business operations

11.1. UK registered companies which operate in the EU should check they meet relevant EU countries' incorporation requirements. They may need to make adjustments to their structure

11.2. UK companies with an European Economic Area (EEA) corporate appointment and EEA companies registered with Companies House will need to provide some additional information to Companies House within 3 months of exit day

12. Cross border mergers

12.1. UK companies using the EU Cross Border Merger regime should be at an advanced stage of the process if they are to complete mergers before Brexit. These mergers must be completed by exit day. Companies may wish to seek professional advice

4 UK Government, Guidance – Structuring your business if there's a no-deal Brexit, 8 August 2019

Public-sector procurement after a no-deal Brexit[5]

Full Government guidance on public-sector procurement after a no-deal Brexit is available here.

13. If the UK leaves the EU without a deal, the public procurement regulations will remain broadly unchanged after Brexit. In March 2019 the Minister for the Cabinet Office made a Statutory Instrument (SI) which will amend the procurement regulations to ensure that they continue to operate effectively after exit day. The SI will come into force on exit day

14. For the most part the legal framework for public procurement and, in particular, the different procedures available to contracting authorities and entities will remain exactly the same. One key difference for contracting authorities will be the need to send notices to a new UK e-notification service instead of the EU Publications Office. The new service is called Find a Tender (FTS) and will be deployed at 11pm GMT on 31st October in the event that the UK leaves the EU without a deal

15. What will change for businesses?

15.1. Suppliers wishing to access UK contract opportunities from the UK public sector will need to access the new UK e-notification service, Find a Tender, instead of OJEU/TED. Access details will be provided in further updates

15.2. For procurements that have commenced before the UK leaves the EU (for example, they have been advertised in the OJEU already), contracting authorities will need to comply with the new regulations from that point, for example by posting subsequent contract award notices on the new UK eNotification service instead of OJEU TED. However, the effect of the former rules will be preserved in some circumstances to maintain fairness throughout the procurement

15.3. Contracting authorities which commence their procurements after the UK leaves the EU will need to follow the amended regulations

Changes to customs authorisations in a no-deal Brexit[6]

Full Government guidance on changes to customs authorisations in a no-deal Brexit is available here.

16. You should first check whether current authorisations to use special and simplified procedures (known as customs facilitations) still apply. Your business must be established in the UK to use most customs facilitations (with the exception of temporary admission). Depending on the type of facilitation, and whether HMRC or another EU customs authority gave you that authorisation, you should check that you can carry on using it and whether it will be more limited

Authorisation issued in the UK

17. If HMRC have authorised you to place goods into a customs special procedure in the UK, your authorisation will still be valid in the UK after Brexit and you'll also be able to use your authorisation to import goods from the EU along with any you already import from non-EU countries. You should write to your HMRC authorisation team to ask for an amendment to your authorisation if there are changes to the range of commodity codes, quantities, values and any other details specified in your current authorisation

[5] UK Government, Guidance – Public sector procurement after a no-deal Brexit, 14 January 2019 (Last updated 4 September 2019)
[6] UK Government, Guidance – Changes to your customs authorisations in a no-deal Brexit, 6 March 2019

Single authorisations issued in the UK for use in the EU

18. If HMRC have authorised you to place goods into a customs special procedure, including moving those goods into the EU, your authorisation will still be valid but in the UK only. This means that you can carry on importing goods into the UK under the authorised procedure after Brexit. You should write to your HMRC authorisation team to ask for an amendment to your authorisation if there are the same changes outlined in point 31

19. Current guidance issued by the EU is that authorisations for customs simplifications or procedures, such as customs warehousing, issued by the UK will no longer be valid in the EU after Brexit

Authorisations given by another EU customs authority

20. If you are named on an authorisation issued by another EU customs authority to place goods into a customs special procedure in the UK, you will not be able to receive goods in the UK under that authorisation after Brexit

21. Where you've had goods under an authorisation from another EU customs authority, you'll have 12 months from the date the UK leaves the EU to discharge those goods from any customs special procedure

Guarantees and special procedures

22. After Brexit, in most cases you will not need a guarantee to cover your customs duty and import VAT. HMRC will give 12 months' notice before reintroducing guarantees

Transit simplifications

23. You can carry on using HMRC-issued authorisations for transit simplifications, including authorised consignor and consignee status, after Brexit

Customs freight simplified procedures

24. If you're already authorised by HMRC to use customs freight simplified procedures, after Brexit you'll be able to use your authorisation to make simplified declarations for goods imported from the EU as well as from non-EU countries

Authorised economic operator

25. If you're established in the UK and you already hold authorised economic operator status (issued by HMRC), your authorisation will be transferred automatically to the UK scheme after Brexit. This will be a new UK status and will replace your existing EU status for your UK customs operations. You'll be issued with a new certificate and logo which you should use in place of any existing certificate and logo after Brexit

26. Guidance issued by the EU is that economic operator status authorisations issued by the UK will no longer be valid in the EU after Brexit

27. If you currently hold authorised economic operator status issued by another EU customs authority, which covers your customs operations in the UK, the UK will not recognise this and it will not secure the benefits of the status in the UK after Brexit

Importing from the EU to the UK

28. The Government advises that business do the following to be ready to import from the EU to the UK after Brexit:

28.1. Make sure your business has an Economic Operator Registration and Identification (EORI) number that starts with GB [Get an EORI number here]
28.2. Decide who will make the import declarations (ie yourselves or a hired customs agent)
28.3. Apply to make importing easier via transitional simplified procedures [register here] and set up a duty deferment account if you import regularly [apply hire]
28.4. Check the rate of tax and duty you'll need to pay – rates of customs on import after Brexit are available here

Temporary rates of customs duty (tariffs) on imports after a no-deal Brexit

29. If the UK leaves the EU with no deal, you may need to pay different rates of customs duty (tariffs) on imports into the UK. These rates would only be applied if the UK were to leave the EU with no deal and would be in place for up to 12 months

30. If you need to pay customs duty, the rates (tariffs) could vary depending on where you import your good from. You can find the commodity codes here

VAT

31. If your business is registered for VAT in the UK you'll be able to account for import VAT on your VAT Return. This means you will pay import VAT on your VAT Return instead of when the goods arrive at the UK border

32. If you are not VAT-registered in the UK, you will not be able to account for import VAT in this way, you'll need to pay import VAT at the time you import the goods

Goods already in transit before Brexit

33. You must continue to treat goods already in transit from the EU as acquisitions and account for VAT on the return for the period in which the acquisition takes place

34. If you're bringing goods into the UK under customs freight simplified procedures and you've completed your simplified frontier declaration before Brexit, you will not be able to account for import VAT on your VAT Return even if you complete your supplementary declaration after this time

How to account for import VAT

35. You can still account for import VAT on your VAT Return, even if you cannot confirm the customs value of the goods that you import. You should declare the highest value for VAT and reclaim any eligible input tax under the normal rules

Changes to VAT IT systems

36. After Brexit, you will be able to check if a UK VAT number is valid by using the UK's VAT checking service (this service is not available yet)

37. You'll no longer be able to use the EU's VAT number validation service, to check the validity of a UK VAT number, or use the EU VAT refund electronic system to claim refunds of VAT incurred in the UK

Intellectual property

38. Patents if there's no Brexit deal[7]

Full Government guidance on patents if there's no Brexit deal is available here

38.1. The relevant EU legislation (or its domestic implementation) will be retained in UK law under the EU Withdrawal Act 2018. The existing systems will therefore remain in place, operating independently from the EU regime, with all the current conditions and requirements

38.2. Any UK legislation supporting the existing systems will also continue to function as normal. This means that the EU's legislation on supplementary protection certificates will be kept in UK law. This law, along with the existing supporting provisions in UK patents legislation, will form the UK's own supplementary protection certificate regime on exit

38.3. All other EU legislation relevant to patents and supplementary protection certificates will be kept in UK law. This will ensure UK law continues to work in respect of biotechnology patents and applications, compulsory licensing arrangements, and exceptions from infringement for the testing of pharmaceutical products. Issues relating to the unitary patent are covered elsewhere in this notice

38.4. Any existing rights and licences in force in the UK will remain in force automatically after the UK leaves the EU and no action is required from the right or licence holder. For UK, EU and third country businesses there will be no significant change to the legal requirements or the application processes. Pending applications will continue to be assessed on the same basis, and new applications can continue to be filed

39. Unified Patent Court

39.1. The Unified Patent Court will hear cases relating to European patents and the new unitary patent – both administered by the non-EU European Patent Office. The unitary patent is a new type of patent and will be a single patent covering a number of European states. The Unified Patent Court will be an international patent court established through an international agreement (the Unified Patent Court Agreement) between 25 EU countries. The Unified Patent Court is intended to provide businesses with a streamlined process for enforcing patents through a single court, rather than through multiple courts in multiple countries. The Unified Patent Court (UPC) is not yet in force, and will not be before the UK leaves the EU. The start date is dependent on ratification of the Unified Patent Court Agreement by Germany

[7] UK Government, Guidance – Patents if there's no Brexit deal, 24 September 2018

39.2. In the context of a no-deal there are two different scenarios for the Unified Patent Court:

[A] The Unified Patent Court does not come into force. The UK has ratified the Unified Patent Court Agreement but ratification by Germany is still outstanding. If the Unified Patent Court is never fully ratified, the domestic legislation to bring it into force will never take effect in the UK. In this scenario, there will be no changes for UK and EU businesses at the point that the UK exits the EU

Or

[B] Unified Patent Court comes into force. If the Unified Patent Court is ratified and comes into force, there will be actions that UK and EU businesses, organisations and individuals may need to consider. The UK will explore whether it would be possible to remain within the Unified Patent Court and unitary patent systems in a 'no deal' scenario

39.3. If the Unified Patent Court comes into force and the UK needs to withdraw from both the Unified Patent Court and unitary patent, businesses will not be able to use the Unified Patent Court and unitary patent to protect their inventions within the UK. UK business will still be able to use the Unified Patent Court and unitary patent to protect their inventions within the contracting EU countries. However, in the UK, businesses will only have the option of protecting their inventions using national patents (including patents available from the non-EU European Patent Office) and UK courts

39.4. UK business will still be open to litigation within the Unified Patent Court based on actions they undertake within the contracting EU countries if they infringe existing rights

39.5. EU business will not be able to use the Unified Patent Court and unitary patent to protect their inventions within the UK but will be able to apply for domestic UK rights as they can now, via the UK Intellectual Property Office and the non-EU European Patent Office

39.6. If the Unified Patent Court comes into force and the UK is unable to participate. UK, EU and third country businesses will still be able to use the Unified Patent Court and unitary patent to protect their inventions within the EU. UK, EU and third country businesses seeking protection in the UK for their inventions will need to use national patents (including patents available from the non-EU European Patent Office) and the UK court system

40. Correspondence addresses and confidentiality for UK patents

40.1. There will be no immediate changes to the UK address for service rules. Privilege for patent attorneys will remain unaffected as this is not determined by reference to EU membership. There will be no immediate implications for UK, EU or third country businesses. The current rules will remain in place at the point the UK exits the EU

Trade marks and designs if there's no Brexit deal[8]

Full Government guidance on trade marks and designs if there's no Brexit deal is available here.

41. The government will ensure that the property rights in all existing registered EU trade marks and registered Community designs will continue to be protected and to be enforceable in the UK by providing an equivalent trade mark or design registered in the UK

42. Right holders with an existing EU trade mark or registered Community design will have a new UK equivalent right granted that will come into force at the point of the UK's exit from the EU. The new UK right will be provided with minimal administrative burden. The trade mark or design will then be treated as if it had been applied for and registered under UK law. This means that these trade marks and designs:

42.1. Will be subject to renewal in the UK
42.2. Can form the basis for proceedings before the UK Courts and the Intellectual Property Office's Tribunal can be assigned and licensed independently from the EU right

Horizon 2020 funding[9]

Full Government guidance on Horizon 2020 funding after Brexit is available here.

43. The government has committed to guarantee funding for all successful competitive UK bids to Horizon 2020 that are submitted before we leave the EU, if there's a no-deal Brexit

44. The guarantee also covers all successful competitive UK bids to Horizon 2020 calls open to third-country participation submitted between Brexit and the end of 2020. Both the guarantee and extension commit funding to UK Horizon 2020 participants for the lifetime of projects

45. UK Research and Innovation (UKRI) will also manage the independent assessment of UK applications to European Research Council (ERC), Marie Skłodowska-Curie Actions (MSCA) and SMEi grants that have been submitted before Brexit, if they are not assessed by the European Commission. Successful applications will be funded for the lifetime of the project

46. Current UK recipients of Horizon 2020 funding need to provide initial information about their projects on the UKRI portal: https://apply-for-innovation-funding.service.gov.uk/eu-grant/overview?_ga=2.58637674.1390812493.1568644626-1901264398.1565631622

Employing EU citizens[10]

[8] Department for Business, Energy & Industrial Strategy, Guidance – Trade marks and designs if there's no Brexit deal, 17 January 2019
[9] UK Government, Guidance – Horizon 2020 funding after Brexit, 9 August 2019
[10] UK Government, Guidance – Right to work checks on EU citizens if the UK leaves the EU without a deal, 1 April 2019 (Last updated 5 September 2019)

Full Government guidance on right to work checks on EU citizens if the UK leaves the EU without a deal is available here.

47. Duty of employers

47.1. There will be no change to the right to work of EU, EEA and Swiss citizens and their family members living in the UK until 31 December 2020 if the UK leaves the EU without a deal

47.2. Employers will need to check a job applicant's right to work in the same way as now until 1 January 2021

47.3. A new immigration system will apply to people arriving on or after 1 January 2021. You will not be required to undertake retrospective checks on existing EU, EEA or Swiss employees

48. EU Settlement Scheme

48.1. EU, EEA or Swiss citizens and their family members who are living in the UK before the UK leaves the EU can apply to the EU Settlement Scheme to continue living in the UK after 31 December 2020

49. European temporary leave to remain

49.1. If EU, EEA and Swiss citizens arrive in the UK after the UK leaves the EU and before 1 January 2021, they can apply for European temporary leave to remain. The deadline for applications is 31 December 2020

Personal data

50. .eu domain names – what members need to do if there's no Brexit deal[11]

Full Government guidance on .eu domain names if the UK leaves the EU without a deal is available here.

50.1. If there's no Brexit deal you'll no longer be able to register or renew .eu domain names if:

50.1.1. Your organisation, business or undertaking is established in the UK but not in the EU/European Economic Area (EEA) or

50.1.2. You live outside of the EU/EEA and are not a EU/EEA citizen

50.2. You may still satisfy the eligibility criteria if you have your registered office, central administration, or principal place of business within the EU/EEA, are established within the EU/EEA, or are a natural person resident in the EU/EEA

50.3. The European Commission and EURid have confirmed that EU/EEA citizens who are resident in the UK will be able to retain their .eu addresses. If you are an EU/EEA citizen living in the UK and have

[11] UK Government, Guidance – .eu domain names – what you need to do if there's no Brexit deal, December 2018 (Last updated 5 April 2019)

registered a .eu domain name, discuss with your registrar whether you will need to provide proof of eligibility

51. Using personal data in your business or organisation if there's no Brexit deal[12]

Full Government guidance on using personal data in your business or organisation if there's no Brexit deal is available here.

51.1. If your organisation receives personal data from the EU/EEA, you should review your contracts and, where absent, include Standard Contractual Clauses (SCC) or other Alternative Transfer Mechanisms (ATM) to ensure that you can continue to legally receive personal data from the EU/EEA

51.2. Businesses that are part of a multinational group may be able to rely on binding corporate rules (BCRs), for intra-group transfers as an appropriate safeguard

51.3. If the UK leaves the EU without a deal, UK businesses and organisations will still need to be compliant with data protection law

51.4. There will be no immediate change to the UK's data protection standards. The General Data Protection Regulation (GDPR) will be brought into UK law and the Information Commissioner would remain the UK's independent supervisory authority on data protection

Further information and next steps

Further Government guidance is available here and if you have any further questions the Business Support Helpline may be worth contacting at enquiries@businesssupporthelpline.org.

This document will be updated as any additional Guidance is published by the Government and will also incorporate elements from the member webinars being undertaken in early October.

September 2019

[12] UK Government, Guidance - Using personal data in your business or organisation if there's no Brexit deal, 6 February 2019