

## **Quality and safety of organs, tissues and cells if there's no EU exit deal**

### **Summary**

If the UK leaves the EU with 'no deal', the UK could still import and export organs, tissues and cells from and to EU countries.

### **Detail**

If the UK leaves the EU in March 2019 without a deal, find out how this would affect:

- safety and quality standards for organ transplantation, and tissues and cells for human use
- importing and exporting organs, tissues and cells

A scenario in which the UK leaves the EU without agreement (a 'no deal' scenario) remains unlikely given the mutual interests of the UK and the EU in securing a negotiated outcome.

Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it's our duty as a responsible government to prepare for all eventualities, including 'no deal', until we can be certain of the outcome of those negotiations.

For two years, the government has been implementing a significant programme of work to ensure the UK will be ready from day 1 in all scenarios, including a potential 'no deal' outcome in March 2019.

It has always been the case that as we get nearer to March 2019, preparations for a no deal scenario would have to be accelerated. Such an acceleration does not reflect an increased likelihood of a 'no deal' outcome. Rather it is about ensuring our plans are in place in the unlikely scenario that they need to be relied upon.

This series of technical notices sets out information to allow businesses and citizens to understand what they would need to do in a 'no deal' scenario, so they can make informed plans and preparations.

This guidance is part of that series.

Also included is an overarching framing notice explaining the government's overarching approach to preparing the UK for this outcome in order to minimise disruption and ensure a smooth and orderly exit in all scenarios.

We are working with the devolved administrations on technical notices and we will continue to do so as plans develop.

## **Purpose**

The purpose of this notice is to set out to organisations, businesses and members of the public the actions they should consider taking, to ensure continued access to and use of organs, tissues and cells, including reproductive cells, in the unlikely event that the UK leaves the EU in March 2019 with no agreement in place.

Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it's our duty as a responsible government to prepare for all eventualities, including 'no deal', until we can be certain of the outcome of those negotiations.

Organisations may also wish to consider other relevant notices, including 'Ensuring blood and blood products are safe if there's no Brexit deal', 'Batch testing medicines if there's no Brexit deal', 'How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal' and 'Submitting regulatory information on medical products if there's no Brexit deal'.

## **Before March 2019**

The EU has a common set of standards to ensure the quality and safety of:

- organs for transplantation, and
- tissues and cells for human use, including reproductive cells

The UK regulatory frameworks set high standards and are taken from a number of EU directives. These regulations cover issues such as obtaining, testing, processing, storing and tracing organs, tissues and cells.

UK organisations such as hospitals, stem cell laboratories, tissue banks and fertility clinics that undertake licensable activities working in this area are regulated by

- the Human Tissue Authority (HTA) for organs, tissues and cells other than reproductive tissues and cells
- the Human Fertilisation and Embryology Authority (HFEA) for reproductive tissues and cells

At present some organs, tissues and cells move between the UK and EU countries, but also between the UK and non-EU countries (third countries).

Only a small number of organs are shared with EU and non-EU countries:

- 22 organs from deceased donors came into the UK from the EU in 2017/18,
- 26 organs left the UK in 2017/18, with 19 going to the EU and 7 to non-EU countries.

Tissues and cells (for example bone, heart valves and corneas) are imported from and exported to EEA countries less often than they're imported and exported from and to countries outside the EEA.

The UK imports donated sperm, primarily from commercial sperm banks in the USA and Denmark. Approximately 4,000 samples were imported from the USA and 3,000 samples from Denmark in 2017, as well as a small number from other EU countries. Imports of eggs and embryos are far less common (usually fewer than 500 a year) and come mostly from EU countries.

### **After March 2019 if there's no deal**

If there's no deal, the EU Organ Directives and EU Tissues and Cells Directives would no longer apply to the UK. UK law already implements the EU directives, so the safety standards would not change. The UK would, however, become a 'third country' and the law would be amended under the EU (Withdrawal) Act to reflect this change.

UK licensed establishments working in this area, such as hospitals, stem cell laboratories, tissue banks and fertility clinics would continue to work to the same quality and safety standards as they did before exit but some would need new written agreements with relevant EU establishments. UK licensed establishments that import or export tissues or cells from EEA establishments would need to make written agreements with those EEA establishments to continue importing or exporting these products post-exit. However, this will for the most part be a minimum burden on industry.

For example, UK licensed establishments that already hold an import licence to import tissues and cells from third countries will be able to use their existing written agreements with third country organisations as a template.

### **What you would need to do**

#### **Members of the public**

These changes will not affect the availability of organs or the safety or quality of organs, tissues and cells in the UK as the current standards will be maintained.

### **Organs for transplantation**

NHS Blood and Transplant (NHSBT), which is the organisation responsible for organ donation and transplantation in the UK, is currently working with the UK regulator for organs, the HTA, to ensure that appropriate written agreements are in place with EU organisations to allow organ exchange to continue post-exit. Transplant centres do not need to take any further action.

If there's no deal, on 29 March 2019 the UK would meet the current EU safety and quality standards for organs, and these would be traceable from donor to recipient and from recipient to donor.

After exit day, the UK and EU countries would consider each other as third countries. The EU directive 2010/53/EU allows for organ exchange between EU countries and third countries. Organisations that currently exchange organs can make written arrangements to ensure organs can still move between the UK and EU countries.

### **Tissues and cells for human use, including reproductive cells**

If there's no deal, on 29 March 2019 tissues and cells from the UK would meet the current EU safety and quality standards.

After exit day, the UK and EU countries would consider each other as third countries. The EU directives 2004/23/EC and 2015/566 allow for written agreements to be made to import and export tissues and cells for human use between EU countries and third countries. The details of what these written agreements cover are set out in EU directive 2015/566. Licensed establishments that import or export tissues or cells would need written agreements with the relevant EU licensed establishments to continue importing and exporting. UK licensed establishments that already hold an import licence to import tissues and cells from third countries can use their existing written agreements with third country organisations as a template. Licensed establishments are recommended to consult the HTA and HFEA for more information. Further information on the agreement process will be published in November.

The government continues to plan for all negotiation outcomes, and will make the necessary changes to national regulations to maintain day one operability for the import and export of organs, tissues and cells in the unlikely event there is no agreement between the UK and the EU.

## **More information**

We'll be publishing more information and instructions on putting written agreements in place in November 2018. The aim is to give organisations, businesses and individuals as much certainty as possible, as soon as possible, and to ensure that any new requirements are not unduly burdensome.

This notice is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations.

It is part of the government's ongoing programme of planning for all possible outcomes. We expect to negotiate a successful deal with the EU.

The UK government is clear that in this scenario we must respect our unique relationship with Ireland, with whom we share a land border and who are co-signatories of the Belfast Agreement. The UK government has consistently placed upholding the Agreement and its successors at the heart of our approach. It enshrines the consent principle on which Northern Ireland's constitutional status rests. We recognise the basis it has provided for the deep economic and social cooperation on the island of Ireland. This includes North-South cooperation between Northern Ireland and Ireland, which we're committed to protecting in line with the letter and spirit of Strand two of the Agreement.

The Irish government have indicated they would need to discuss arrangements in the event of no deal with the European Commission and EU Member States. The UK would stand ready in this scenario to engage constructively to meet our commitments and act in the best interests of the people of Northern Ireland, recognising the very significant challenges that the lack of a UK-EU legal agreement would pose in this unique and highly sensitive context.

It remains, though, the responsibility of the UK government, as the sovereign government in Northern Ireland, to continue preparations for the full range of potential outcomes, including no deal. As we do, and as decisions are made, we'll take full account of the unique circumstances of Northern Ireland.