

LIFE SCIENCE BUSINESS ACTION CHECKLIST

NEW RULES WILL AFFECT YOU FROM 1 JANUARY 2021

A guide to help Life Science businesses identify the actions they need to take before the end of the Brexit transition period.





TO TAKE ACTION

The UK has left the EU and the transition period will end on **31 December**. As we transition to our new relationship with the EU, we all need to take action to prepare.

From 1 January 2021, there will be a series of guaranteed changes and opportunities for businesses.

Many of these changes will be required regardless of the agreement we reach with the EU on our future trade relationship, as the UK will be leaving the single market and customs union. You can be confident that your preparations for these changes will not be wasted.

You need to check what will change for your business from 1 January 2021 and take action now, to ensure you are not at risk.

We have put together a list of actions that are relevant to your sector to help you to start identifying what your business needs to do. We have provided a summary for each action, explaining why your business needs to act and where you can find further information.

These actions have been categorised into separate themes to help you decide which actions are relevant to your business.

There may be more actions that are relevant to your business. You should visit gov.uk/transition and use the simple checker tool to find out if your business needs to take any further actions.





Importing and Exporting Make sure you have a GR FORI number.

□ Make sure you have a GB EORI number
☐ Check the new rules on importing and exporting goods between the EU and Great Britain from 1 January 2021
☐ Get ready to make customs declarations
☐ Check if import VAT is due at the border
☐ Decide how you will account for import VAT when you make a customs declaration
Selling your goods
$\hfill \Box$ Use gov.uk to identify how your business can be ready to sell certain goods in the UK and EU
Trading with the EU
☐ Use the 'Check How to Export Goods' tool on gov.uk to look up information on overseas tariffs, rules and border formalities for trading your goods worldwide ☐ Use the new UK Global Tariff schedule to check what tariff will be payable on goods entering the UK from 1 January 2021
☐ Use gov.uk guidance to understand changes to trading with non-EU countries from 1 January 2021. Check if the UK has negotiated a trade agreement with the country you will be trading with
Northern Ireland Protocol ☐ Follow NI specific rules for trading between GB and Northern Ireland
Data
□ Be prepared on data protection and data transfers□ Replace .eu top level domain names
Workforce
☐ Signpost your current employees to the EU Settlement Scheme ☐ Check if a visa or work permit is required to travel to the EU for work purposes and apply if necessary
☐ If you are planning to recruit from overseas from 1 January 2021, you will need to register as a licensed visa sponsor
Providing Services ☐ Get your qualifications recognised now by EU regulators to be able to practise or service clients in the EU





Access to Research and Development Funding

☐ Find out more about Horizon 2020 on gov.uk

Chemicals Regulations

☐ Check what actions you need to take under UK REACH and EU REACH to continue to manufacture and place chemicals on the GB, NI and EU markets ☐ Regulatory systems – Apply for licences to trade drug precursor chemicals with the EU from 1 January 2021

Animal, Plant, Food, and Drink Regulations

 $\hfill\square$ Register for the UK's new Import of Products, Animals, Food and Feed System

☐ Register to submit Export health certificates and understand border checks on animals and animal products for export





Importing and Exporting

The process for importing and exporting goods from the EU will change. Businesses in Great Britain need to complete the following actions to continue importing and exporting with EU countries from 1 January 2021.

✓ Make sure you have a GB EORI number.

You will need a unique trader reference number, called an Economic Operator Registration and Identification (EORI) number, to complete customs declarations from 1 January 2021. If you do not yet have one, you can register for free by going to www.gov.uk/eori.

✓ Check the new rules on importing and exporting goods between the EU and Great Britain from 1 January 2021.

From 1 January 2021, if you send goods from Great Britain to customers in Europe, you must complete export declarations for those goods. If you import goods from Europe that are on the controlled goods list such as animal products, alcohol or tobacco, or firearms, you must also complete declarations. To check if your imported goods are on the Controlled goods list, go to www.gov.uk/transition.

If you import non-controlled goods into Great Britain from Europe, you may be able to defer import declarations for up to six months. Your business could face delays, disruption or administrative costs if you do not comply with new customs procedures from 1 January 2021. For more information go to www.gov.uk/transition.

✓ Get ready to make customs declarations.

Most businesses like yours will need to work with a specialist, like a freight forwarding company or fast parcel operator, to complete import and export declarations. Import and export declarations are complicated, requiring specialist skill, knowledge and IT. If you are not able to make declarations or provide the wrong information, your business could face delays, disruption or administrative costs. You can find a list of businesses that can help you at www.gov.uk/transition.





✓ Check if import VAT is due at the border.

If you import any goods from Europe into Great Britain, you may need to pay import VAT from 1 January 2021. Import VAT will not be due at the border in most cases if goods in a consignment are worth less than £135 in value. The only exception to this is consignments containing excise goods, where import VAT (along with Excise and Customs duties where applicable) will be due at the border. For more information, go to www.gov.uk/transition.

✓ Decide how you will account for import VAT when you make a customs declaration.

If you're business is VAT-registered, from 1 January 2021 you'll be able to use postponed VAT accounting to account for import VAT, for goods imported into the UK from anywhere in the world. This means you can account for VAT on goods imported through your VAT Return. For more information, go to www.gov.uk/transition.

Other useful links:

 How to import and export goods between Great Britain and the EU from 1 January 2021 www.gov.uk/transition.





Selling your goods

✓ Use gov.uk to identify changes affecting manufactured goods, such as new marking requirements or approvals needed, to ensure your business is ready to sell them in the UK and EU.

From 1 January 2021, there may be a number of changes that apply to your goods. You may need to review your product marking, labelling, and packaging. You may need additional approvals, certifications, or registrations. You may need to appoint a legal representative based in the UK or the EU. The legal responsibilities of you or your distributors may change. You may not be able to sell your goods in the UK and the EU from 1 January 2021.

- Check which regulations apply to your product to determine what steps you or others in your supply chain need to take, identify what EU regulations are relevant to you.
- Check if you need a new product approval and begin the process as soon as possible – if your product requires third-party approval, you may need a new approval especially if you sell in both UK and EU. Subject to negotiations, from 1 January 2021 the EU will stop recognising UK approvals.
- Check if you need to appoint a new authorised representative to act on your behalf – UK-based individuals and legal entities will no longer count as established in the EU, and vice-versa. You may need to appoint someone to undertake certain tasks in the EU or UK.
- Speak to your supply chains / distributors and understand new legal duties - make sure your suppliers/distributors/customers understand the actions they need to take. If you distribute EU goods, or have your goods distributed by someone in the EU, you may acquire new legal duties.
- Consider what marking / labelling changes apply to your product you
 may need to make changes to the information or regulatory markings that
 appear on your product, for example to reflect changes to product
 approvals or new representatives you appoint in the EU.

More information is available at www.gov.uk/transition.





Trading with the EU

After 31 December 2020, EU trade agreements will not apply to the UK. The UK is seeking to reproduce the effects of existing EU agreements for when they no longer apply to the UK. This will ensure continuity of trading arrangements for UK businesses. This means businesses will have to take action.

✓ Use the 'Check How to Export Goods' tool on gov.uk to look up information on overseas tariffs, rules and border formalities for trading your goods worldwide.

Use the 'Check How to Export Goods' service on gov.uk to check duties and customs procedures for exporting your goods worldwide. Failure to complete the proper documentation or follow the correct procedures may result in delays getting goods through customs as well as unexpected taxes on goods upon entry to the destination and country. From January 2021, there will be new requirements for how you export goods from the UK. Use the service at www.gov.uk/transition.

✓ Use the new UK Global Tariff schedule to check what tariff will be payable on goods entering the UK from 1 January 2021.

If you import goods into the UK, you should check the new UK Global Tariff schedule. From 1 January 2021, the UK Global Tariff schedule will apply to all goods imported into the UK unless an exception applies. Exceptions include goods you import from a country that has a trade agreement with the UK or from a developing country that pays less or no duty because it's part of the Generalised Scheme of Preferences. You can check the tariffs that will apply to goods you import at www.gov.uk/transition.

✓ Use gov.uk guidance to understand trading arrangements for non-EU countries from 1 January 2021. Check if the UK has negotiated a trade agreement with the country you will be trading with.

Trading with countries outside the EU may change from January 2021. Your business may face disruption when trading goods between the UK and the rest of world if you are not aware of trading arrangements with non-EU countries from 1 January 2021. Find out about trade agreements that the UK has signed or agreed in principle, and agreements that are still under discussion at www.gov.uk/transition.





- Check UK trade tariffs from 1 January 2021 www.gov.uk/transition.
- Search for 'UK global tariff' on www.gov.uk/transition.
- To find out what rules of origin apply to your exports, use the new UK's Check How to Export Goods system on www.gov.uk/transition.
- Contact us www.gov.uk/transition.





Northern Ireland Protocol

From 1 January 2021, the Northern Ireland Protocol will take effect. Businesses and individuals will be able to move goods from Northern Ireland into the rest of the United Kingdom on the same basis as now. However, the application of the Protocol will involve some changes for goods movements into Northern Ireland.

✓ Follow NI specific rules for trading between GB and Northern Ireland.

There will be some changes for goods movements into Northern Ireland from Great Britain. The new Trader Support Service is available to support businesses with these movements.

The free Trader Support Service:

- will help if you move goods between Great Britain and Northern Ireland, or bring goods into Northern Ireland from outside the UK
- will be free to use and guide you through any changes to the way goods move between Great Britain and Northern Ireland
- can complete declarations on your behalf

Processes for Northern Ireland businesses moving goods to and from the European Union (including Ireland) will not change after the Transition Period.

More information is available at www.gov.uk/transition and www.gov.uk/transition.





Data

Personal data is any information that can be used to identify a living person, including names, delivery details, IP addresses, or HR data such as payroll details. Most organisations use personal data in their daily operations. If you receive personal data from the EU for business use, you may need to take action on data protection. Additionally, if you provide online service in the EU, you will have to ensure that you are compliant with relevant requirements in each EU country you operate in.

✓ Be prepared on data protection and data transfers.

If you're a business or organisation that receives personal data from the EU/EEA, you may need to take action on data protection as we transition to our new relationship with the EU. Check how you can legally continue to receive personal data such as names, addresses or payroll details from organisations in the EU or EEA from 1 January 2021. Your business may not be able to legally receive personal data from EEA if you have not put in place alternative safeguards to cover EU-UK personal data flows by 31 December 2020. To understand more about the steps you need to take, visit www.gov.uk/transition.

√ Replace .eu top level domain names.

If you hold a .eu domain, check if you need to replace it. From 1 January 2021, you'll no longer be able to register or renew .eu domain names if your organisation, business or undertaking is established in the UK but not in the EU/European Economic Area (EEA), or if you live outside of the EU/EEA and are not an EU/EEA citizen. Find out more at www.gov.uk/transition.

- ICO Website Data protection at the end of the transition period <u>www.ico.org.uk.</u>
- Legal aspects of information society services <u>www.eur-lex.europa.eu.</u>





Workforce

The UK has left the EU and from 31 December 2020, free movement of people between the UK and EU will end. Currently, EU citizens have the right to move freely into the UK to live, work and study here. This will come to an end after the transition period and the UK will introduce a points-based immigration system.

The new system will change the way you hire from the EU and it is important you take the necessary steps to prepare. Anyone you want to recruit from outside the UK, excluding Irish citizens, will need to apply for permission first, and you will need to be registered as a licensed sponsor. Further information can be found below.

The new system will not apply to EU employees already working for you in the UK. EU citizens and their family members living in the UK by 31 December 2020 can apply to the EU Settlement Scheme. Similarly, EU citizens who are employed, or self-employed in the UK, but live elsewhere, otherwise known as frontier workers, will be able to keep their status if they are frontier working in the UK by 31 December 2020, but they will need to apply for a permit. Irish citizens will not need a frontier worker permit but may apply for one if they wish. Additionally, EU citizens can continue to visit the UK for up to six months without applying for a visa and may also participate in a wide range of activities, including business-related activities, such as events and conferences.

✓ Signpost your current employees to the EU Settlement Scheme.

If you employ EU, EEA and Swiss citizens, you can signpost them to the information they need to apply to the EU Settlement Scheme, to protect their right to live, work and access benefits in the UK. The deadline for applying is 30 June 2021. Find out more at www.gov.uk/transition.

✓ Check if a visa or work permit is required to travel to the EU for work purposes and apply if necessary.

The country you are travelling to might ask you to arrange additional documentation depending on who you are, the activity you perform and how long you are travelling for. You may face delays or refusal at border when travelling for business if you do not comply with the immigration requirements of the EU27 if travelling after 31 December 2020. For more information visit www.gov.uk/transition.





✓ If you are planning to recruit from overseas from 1 January 2021, you will need to register as a licensed visa sponsor.

The way you hire from the EU is changing from 1 January 2021. To hire anyone new from outside the UK, you'll need to register as a licensed sponsor. Getting a license normally takes 8 weeks and fees apply. New employees from outside the UK will also need to meet new job, salary and language requirements. Irish citizens and those eligible under the EU Settlement Scheme are not affected.

If you are not already a licensed sponsor and you think you will want to sponsor migrants through the skilled worker route from January 2021, you should apply now. You may not be able to legally hire people from outside the UK, unless you are a licensed sponsor. Find out more at www.pbiseemployers.campaign.gov.uk.

- Travel Advice www.gov.uk/transition.
- Entry Requirements for providing services and travelling for business to the EU www.gov.uk/transition.
- Further Guidance on visiting Europe from 1 January 2021 www.gov.uk/transition.
- Checking passport validity <u>www.gov.uk/transition.</u>
- EU Settlement Scheme <u>www.gov.uk/transition.</u>
- Employer resources for understanding the new points-based immigration system www.gov.uk/transition.
- Further guidance on frontier working in the UK www.gov.uk/transition.





Providing Services

If you're a UK business or professional providing services in the EU or EFTA region, you will need to check the national regulations of the country you're doing business in to understand how best to operate. You will also need to have your UK professional qualification officially recognised if you want to work in a profession that is regulated in the EU or EFTA.

✓ Get your professional qualifications recognised now by EU regulators to be able to practise or service clients in the EU.

If you have a UK professional qualification you will need to have this officially recognised by the appropriate regulator for your profession in each country where you intend to work. You will need to do this even if you are only providing short-term or occasional professional services. If you do not do this, you may be unable to practise your profession or service clients in the EU from 1 January 2021. There are different rules if you are a lawyer or an auditor. For more information, visit www.gov.uk/transition.

- European Commission's Regulated Professions Database <u>www.ec.europa.eu.</u>
- Single Point of Contact www.eu.europa.eu.





Access to Research and Development Funding

Organisations can apply for a funding opportunity. Each opportunity has its own eligibility criteria and scope. UK scientists, researchers and businesses can continue to participate in Horizon 2020 programmes.

✓ Find out more about Horizon 2020 on gov.uk.

You can continue to apply for Horizon 2020 grant funding. Although the UK has left the EU, you'll continue to get any EU funding you've already been awarded. UK scientists, researchers and businesses can continue to participate in Horizon 2020 programmes and receive EU grant funding for the lifetime of individual projects. This includes projects finishing after 1 January 2021. Apply now to Horizon 2020 to secure your funding. For more information, visit www.gov.uk/transition.

Other useful links:

Horizon 2020 and EU Exit Q&A can be found on www.ukri.org.





Chemicals Regulations

UK REACH, the UK's independent chemicals regulatory framework, starts on 1 January 2021. Anyone making, selling or distributing chemicals in the UK and the EU needs to follow UK REACH and EU REACH rules. You will also need to apply for an import and export licence when trading drug precursor chemicals with EU countries.

✓ Check what actions you need to take under UK REACH and EU REACH to continue to manufacture and place chemicals on the GB, NI and EU markets.

If you want to place new chemicals on both the EU/EEA (including Switzerland) and UK markets from 1 January 2021, you must follow both EU REACH and UK REACH rules. You must register new chemicals you want to sell on the UK market from 1 January 2021 with the Health and Safety Executive. Your business may face delay, disruption or administrative costs to trading goods between UK and EU if you do not comply with chemicals regulations by 31 December 2020. More information is available at www.gov.uk/transition.

✓ Regulatory systems - Apply for licences to trade drug precursor chemicals with the EU from 1 January 2021.

If you trade drug precursor chemicals from 1 January 2021 you may need import or export licences to trade drug precursor chemicals with the EU. You need a domestic licence or registration before you can apply for import or export licences, this depends on the chemical you are trading. Applications usually take 12 to 16 weeks to process. More information is available at www.gov.uk/transition.





Animal, Plant, Food, and Drink Regulations

You will have to follow new processes to import and export animals, animal products, high-risk food and feed between UK and EU from 1 January 2021. Food and drink producers, manufacturers, retailers and suppliers will have to change labels from 1 January 2021.

✓ Register for the UK's new Import of Products, Animals, Food and Feed System.

If you import animals or animal products to the UK, you will need to register for the new Import of Products, Animals, Food and Feed System. To register for the system, you will need to create a Government Gateway account for the business or organisation you represent. More information is available at www.gov.uk/transition.

✓ Register to submit Export health certificates and understand border checks on animals and animal products for export.

If you export animals or animal products from Great Britain to the EU or from Great Britain to Northern Ireland, you'll need an Export Health Certificate from 1 January 2021. An Export Health Certificate is an official document that confirms your export meets the health requirements of the destination country. You need to apply for an Export Health Certificate in advance and get your goods checked at a Border Control Post in the first EU country they enter. You will not be able to export these goods from 1 January 2021 if you do not apply in time. Register for the new Export Health Certificate Online system to be ready from 1 January 2021. More information is available at www.gov.uk/transition.

