HM Government
UK TRANSITION

Manufactured goods regulation

Placing goods on the market in GB and NI

Speaker: Sam McGeever -Deputy Head of Goods Regulation
Department for Business, Energy and Industrial Strategy

Slides accurate as at 4th May 2021

Check
Change
Go

PLACING GOODS ON THE MARKET

What does my business need to know?

Check which regulations apply to your product: this presentation will focus on new approach goods. Guidance for other products can be found on gov.uk/transition

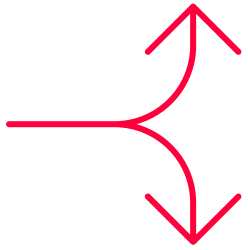
New Approach

Goods with a CE marking may be placed on the GB market until 1 January 2022 e.g. Toys, PPE, machinery.

It is longer in some cases e.g. medical devices. Different rules apply to NI.

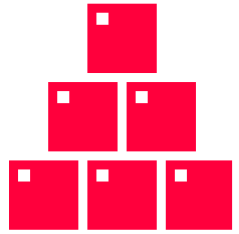
Old Approach

Rules under standalone regulation models depend on specific goods, e.g. Chemicals, Vehicles, Aerospace.



Non-Harmonised Goods

Mutual recognition no longer applies to non-harmonised goods, e.g. Furniture.



Other Goods

There are now special rules for some goods including medical devices, cosmetics, construction products, civil explosives, and products requiring eco-design and energy labelling.

ACT NOW AT
GOV.UK/TRANSITION

KEY ACTIONS FOR BUSINESSESS

Since 1 January 2021 the essential requirements and standards that can be used to demonstrate compliance have remained the same. However, there may be other changes you need to make. Separate guidance for specific sectors can be found on GOV.UK.

Check:

- Which regulations apply to your product
- If you need a new product approval and begin the process as soon as possible
- If you need to appoint a new representative to act on your behalf
- Your supply chains / distributors and understand new legal duties
- What marking / labelling changes apply to your product

ACT NOW AT
GOV.UK/TRANSITION

PLACING NEW APPROACH GOODS ON THE MARKET

What does my business need to know?

- If you had already placed CE marked goods on the EU or UK markets before 1 January 2021, you do not need to take any action for those goods. Placing on the market refers to individual goods, not types of goods.
- Businesses should take steps to comply with the new domestic regime.
- CE marked goods that meet EU and GB requirements can continue to be placed on the GB market in most cases until 1 January 2022.
- If you are placing manufactured goods on the EU market you must comply with EU requirements.

ACT NOW AT
GOV.UK/TRANSITION

ENSURE NEW APPROACH GOODS ARE LABELLED CORRECTLY

What does my business need to know?

CE Marking

- If businesses self-declare or use an EU Notified Body, they can still use the CE marking until 1 January 2022 for goods placed on the GB market (more in some cases). In this case, businesses can use their EU Declaration of Conformity until 1 January 2022.
- The CE marking is still required for products placed on the EU market.
- You can place the UKCA and CE marking on the same product if it is destined for both the GB and EU markets so long as the product meets the rules for both markets.

UKCA Marking

- New Approach goods assessed against GB rules by a GB 'Approved Body' will need the UKCA (UK Conformity Assessed) marking and a UK Declaration of Conformity.
- You can self-declare for the UKCA marking, as you can with the CE marking.
- Following 1 January 2021, the essential legal requirements that businesses must meet did not change. All harmonised standards became 'designated standards'.

ACT NOW AT
GOV.UK/TRANSITION

SCAN NOW FOR INFO ON: DESIGNATED STANDARDS

TIMELINE FOR UKCA

What does my business need to know?

Now (2021)

You can use the UKCA marking. In some cases, you need to use it right now.

From 1 January 2022

You will need to use UKCA for most goods* from 1 January 2022.

From 1 January 2023

The UKCA marking must, in most cases, be affixed directly to your product.

On 16 July 2021

Market Surveillance and Compliance of Products Regulation (EU) 2019/1020 comes into effect, which means you may need to appoint an EU representative if there is no other economic operator in place (when exporting to the EU and NI).

Until 1 January 2023

For most goods, you can affix the UKCA marking on a label affixed to the product or on an accompanying document.

ACT NOW AT
GOV.UK/TRANSITION

* The CE marking will continue to be recognised in GB until 30 June 2023 for medical devices. Make sure you consult the sector specific guidance.

CHANGES TO CONFORMITY ASSESSMENT BODIES FOR NEW APPROACH GOODS

What does my business need to know?

- **NI market:** UK bodies approving for the NI market will remain 'Notified Bodies'. These 'Notified Bodies' can be based anywhere in the UK.
  EU bodies will continue to be recognised as competent to certificate for the NI market.
- **GB market:** All UK-based 'Notified Bodies' have automatically become UK 'Approved Bodies' for the GB market as of 1 January 2021. You can find details of UK bodies on the UKMCAB database.

- **EU market:** As of 1 January 2021, mandatory conformity assessments by UK bodies are not recognised in the EU.

ACT NOW AT
GOV.UK/TRANSITION

SCAN NOW FOR INFO ON: UKMCAB DATABASE

STATUS OF UK CABS IN THE EU AND VICE-VERSA

What does my business need to know?

- From now, UK bodies are not recognised as able to assess goods for the EU market. From 1 January 2022 (in most cases) EU bodies will not be able to assess goods for the GB market.

- Arrange for separate certificates for the UK and EU markets to be ready well in advance of 1 January 2022. There may be a requirement for a level of re-assessment before the second certificate is issued, so you should act now. Contact your conformity assessment body to understand your options.

ACT NOW AT
GOV.UK/TRANSITION

CHECK LEGAL RESPONSIBILITIES FOR NEW APPROACH GOODS

What does my business need to know?

The responsibilities of ‘economic operators’ who deal with CE or UKCA marked goods changed on 1 January 2021. Economic operators include manufacturers, importers, distributors and authorised representatives.

UK-based distributors of EU goods may become 'importers' - and vice-versa. Compared to distributors, importers have additional duties to ensure products are compliant with product standards and must ensure their address is on a product.

Authorised Representatives must be based in GB or NI for the GB market. GB-based Authorised Representatives aren't recognised in the EU.

On 16 July 2021, Regulation (EU) 2019/1020 – Market Surveillance and Compliance of Products Regulation – comes into effect, which means you may need to appoint an EU representative if there is no other economic operator in place (when exporting to the EU and NI).

ACT NOW AT
GOV.UK/TRANSITION

PLACING GOODS ON THE NI MARKET

What does my business need to know?

- The Ireland/Northern Ireland Protocol is now in force. For as long as it applies, goods placed on the market in NI will need to meet relevant EU rules.
- The CE marking will continue to be relevant marking for most goods. If you self-declare for CE, you can continue to do this when placing goods on the NI market.
- The CE marking will need to be accompanied by the UKNI marking if you use a UK Notified Body to assess against EU rules. This is now the case and this rule applies to existing stock that was not already placed on the market by the end of the 2020 (if that existing stock was assessed against relevant EU rules by a UK Notified Body). **Goods with the 'CE UKNI' marking are not valid for the EU market.**
- You never apply the UKNI marking on its own. It always accompanies the relevant EU conformity marking.
- If you use an EU Notified Body, you will only need to use the CE marking.
- The UKCA marking alone will not be valid for the NI market.

ACT NOW AT
GOV.UK/TRANSITION

UK
NI

PLACING QUALIFYING NI GOODS ON THE GB MARKET

What does my business need to know?

- The Government has guaranteed Unfettered Access* for qualifying Northern Ireland goods to the rest of the UK market.
- This means that qualifying Northern Ireland goods marked with the CE marking or CE plus UKNI marking can be placed on the GB market, even if EU and GB rules diverge.
- For highly regulated goods (e.g. chemicals and medicines), which pose a particular risk to the consumer, some basic information will need to be provided to the GB market regulator to place that good on the GB market. There is detailed guidance for these goods on gov.uk.
- Guidance is also available on gov.uk on how you can check whether your goods qualify for the arrangements in place to support NI's unfettered access to the rest of the UK market.

ACT NOW AT
GOV.UK/TRANSITION

* There will be only extremely limited exceptions to this for certain controlled products, for example the movement of radioactive waste.

IMPORTER RESPONSIBILITIES AND NI

Have my responsibilities changed?

There are now changes to the responsibilities of businesses importing goods within the UK.

NI importers of GB goods - You are an importer if you bring goods into NI from GB or another non-EU country and place them on the NI market. This is due to the rules that apply in NI under the Protocol. You need to make sure goods are labelled with your details, among other responsibilities. The measure on providing address details on e.g. an accompanying document, does not apply to NI importers of goods from GB, due to the Protocol.

Placing goods on the GB market from outside the UK – You are an importer if you are an NI business placing goods from outside the UK on the GB market. This includes where they have come from the EU via NI and means they will need to be labelled with your details, for example. NI businesses benefit from Unfettered Access, meaning qualifying goods can use the CE or CE UKNI marking, for instance, even if EU and GB rules diverge.

ACT NOW AT
GOV.UK/TRANSITION

HM Government
UK TRANSITION

FURTHER GUIDANCE

Check
Change
Go

FIND OUT MORE ABOUT PLACING GOODS ON THE MARKET

Placing goods on the market

SCAN NOW FOR INFO ON: PLACING GOODS ON THE GB MARKET

SCAN NOW FOR INFO ON: PLACING GOODS ON THE EU MARKET

SCAN NOW FOR INFO ON: PLACING GOODS ON THE MARKET IN NORTHERN IRELAND

Product markings

SCAN NOW FOR INFO ON: USING THE UKNI MARKING

SCAN NOW FOR INFO ON: USING THE UKCA MARKING

ACT NOW AT
GOV.UK/TRANSITION

FIND OUT MORE ABOUT PLACING GOODS ON THE MARKET

Conformity assessment bodies and accreditation

SCAN NOW FOR INFO ON:
CONFORMITY ASSESSMENT
AND ACCREDITATION

SCAN NOW FOR INFO ON:
APPLYING TO BE A UK CONFORMITY ASSESSMENT
BODY FOR PRODUCT SAFETY AND METROLOGY

Moving goods into, out of, or through Northern Ireland

SCAN NOW FOR INFO ON:
MOVING GOODS BETWEEN
NI AND GB

ACT NOW AT
GOV.UK/TRANSITION

FIND OUT MORE ABOUT PLACING GOODS ON THE MARKET

Qualifying Northern Ireland goods

SCAN NOW FOR INFO ON:
HOW TO CHECK IF YOU QUALIFY FOR UNFETTERED ACCESS

Product safety and metrology regulations

SCAN NOW FOR INFO ON:
SPECIFIC PRODUCT SAFETY AND METROLOGY REGULATIONS

ACT NOW AT
GOV.UK/TRANSITION

FIND OUT MORE ABOUT PLACING GOODS ON THE MARKET

UK conformity assessment

SCAN NOW FOR INFO ON:
UK conformity assessment

ACT NOW AT
GOV.UK/TRANSITION

HM Government
UK TRANSITION

Step-by-step processes

Check
Change
Go

What marking must I use when placing goods subject to mandatory third-party conformity assessment on the market for the period between* 1 January 2021 and 1 January 2022?

Key

CAB – conformity assessment body

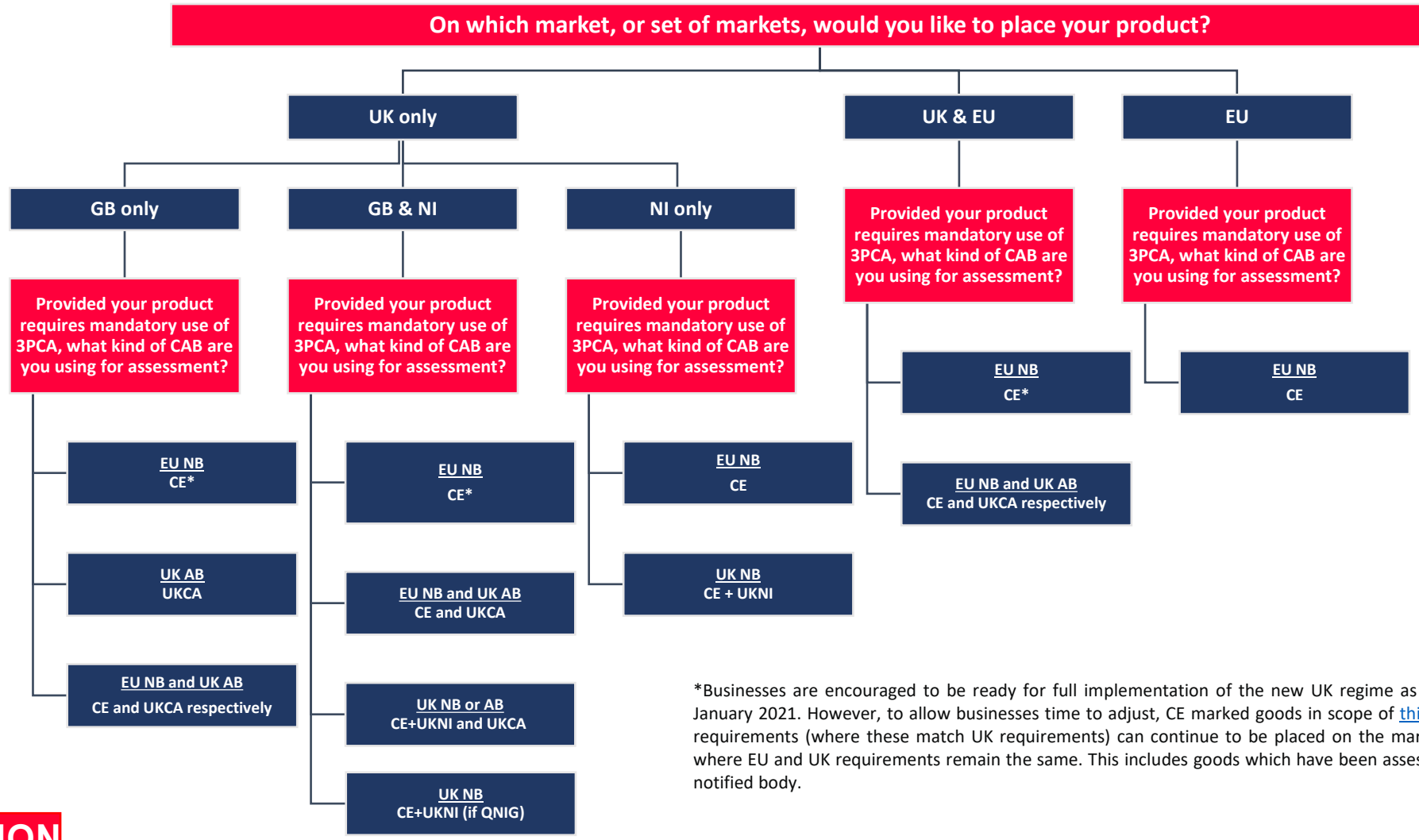
3PCA – Third party conformity assessment

EU NB – EU Notified Body (notified as competent to apply the CE marking)

UK AB – UK Approved Body (approved as competent to apply the UKCA marking)

UK NB – UK Notified Body (notified as competent to apply the CE+UKNI marking

QNIG – Qualifying Northern Ireland Good (see this guidance for further information on qualification)



*Businesses are encouraged to be ready for full implementation of the new UK regime as soon as possible after 1 January 2021. However, to allow businesses time to adjust, CE marked goods in scope of this guidance that meet EU requirements (where these match UK requirements) can continue to be placed on the market until 1 January 2022 where EU and UK requirements remain the same. This includes goods which have been assessed by an EU recognised notified body.

ACT NOW AT
GOV.UK/TRANSITION

***Please note:** recognition of the CE marking will apply to some goods for longer than 12 months. These goods include medical devices, pressure equipment, marine equipment and some others. We are not able to provide advice on your specific circumstances and would encourage you to seek external advice, such as from your solicitor or trade association, if needed.*

What marking must I use when placing goods subject to mandatory third-party conformity assessment on the market for the period between* 1 January 2021 and 1 January 2022?

Key

CAB – conformity assessment body

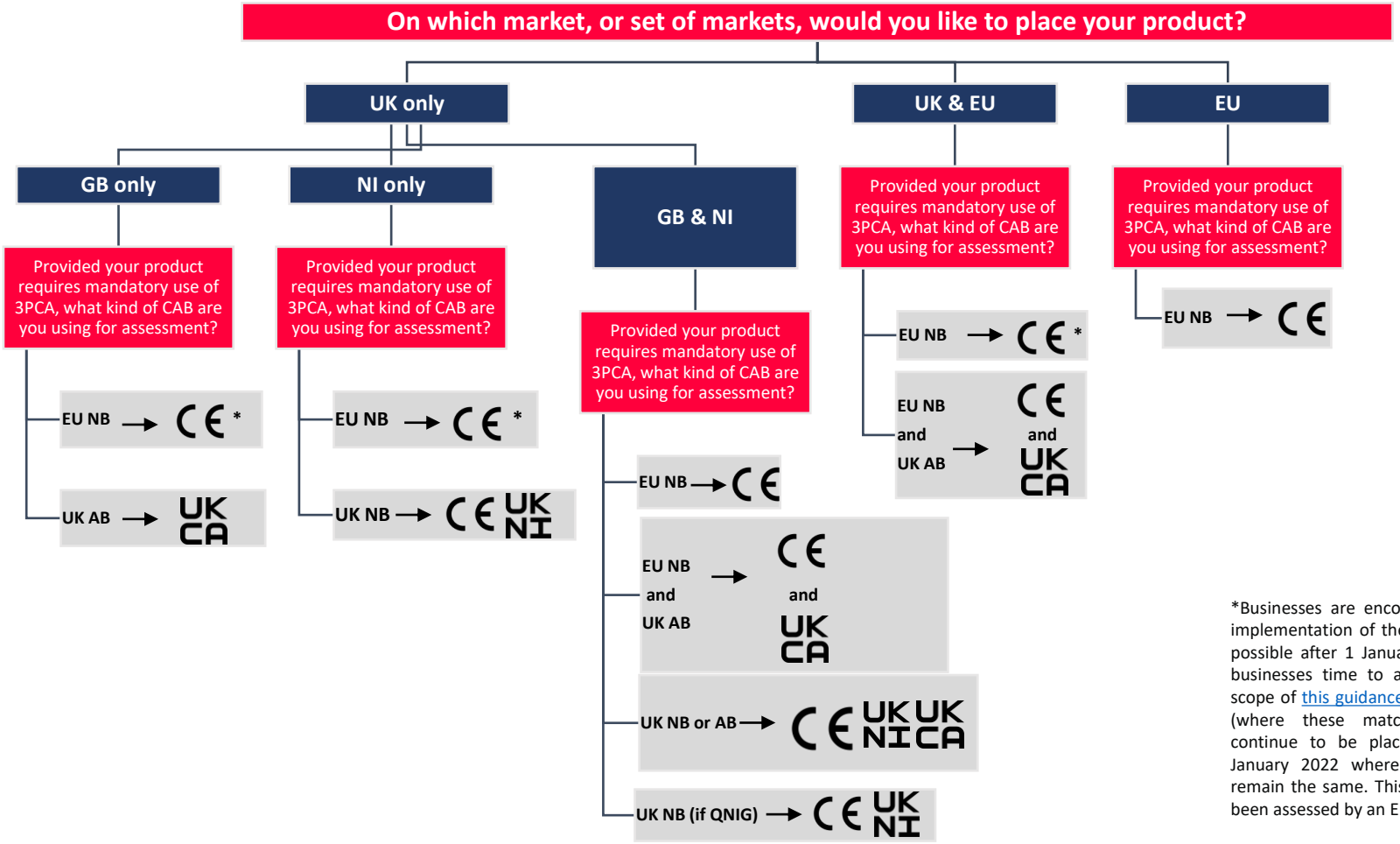
EU NB – EU Notified Body (notified as competent to apply the CE marking)

UK AB – UK Approved Body (approved as competent to apply the UKCA marking)

UK NB – UK Notified Body (notified as competent to apply the CE+UKNI marking

QNIG – Qualifying Northern Ireland Good (see this guidance for further information on qualification)

3PCA – Third party conformity assessment



*Businesses are encouraged to be ready for full implementation of the new UK regime as soon as possible after 1 January 2021. However, to allow businesses time to adjust, CE marked goods in scope of this guidance that meet EU requirements (where these match UK requirements) can continue to be placed on the market until 1 January 2022 where EU and UK requirements remain the same. This includes goods which have been assessed by an EU recognised notified body.

ACT NOW AT

GOV.UK/TRANSITION

***Please note:** recognition of the CE marking will apply to some goods for longer than 12 months. These goods include medical devices, pressure equipment, marine equipment and some others. We are not able to provide advice on your specific circumstances and would encourage you to seek external advice, such as from your solicitor or trade association, if needed.*

What marking must I use when placing goods subject to mandatory third-party conformity assessment (not voluntary use) on the market from 1 January 2022?*

Key

CAB – conformity assessment body

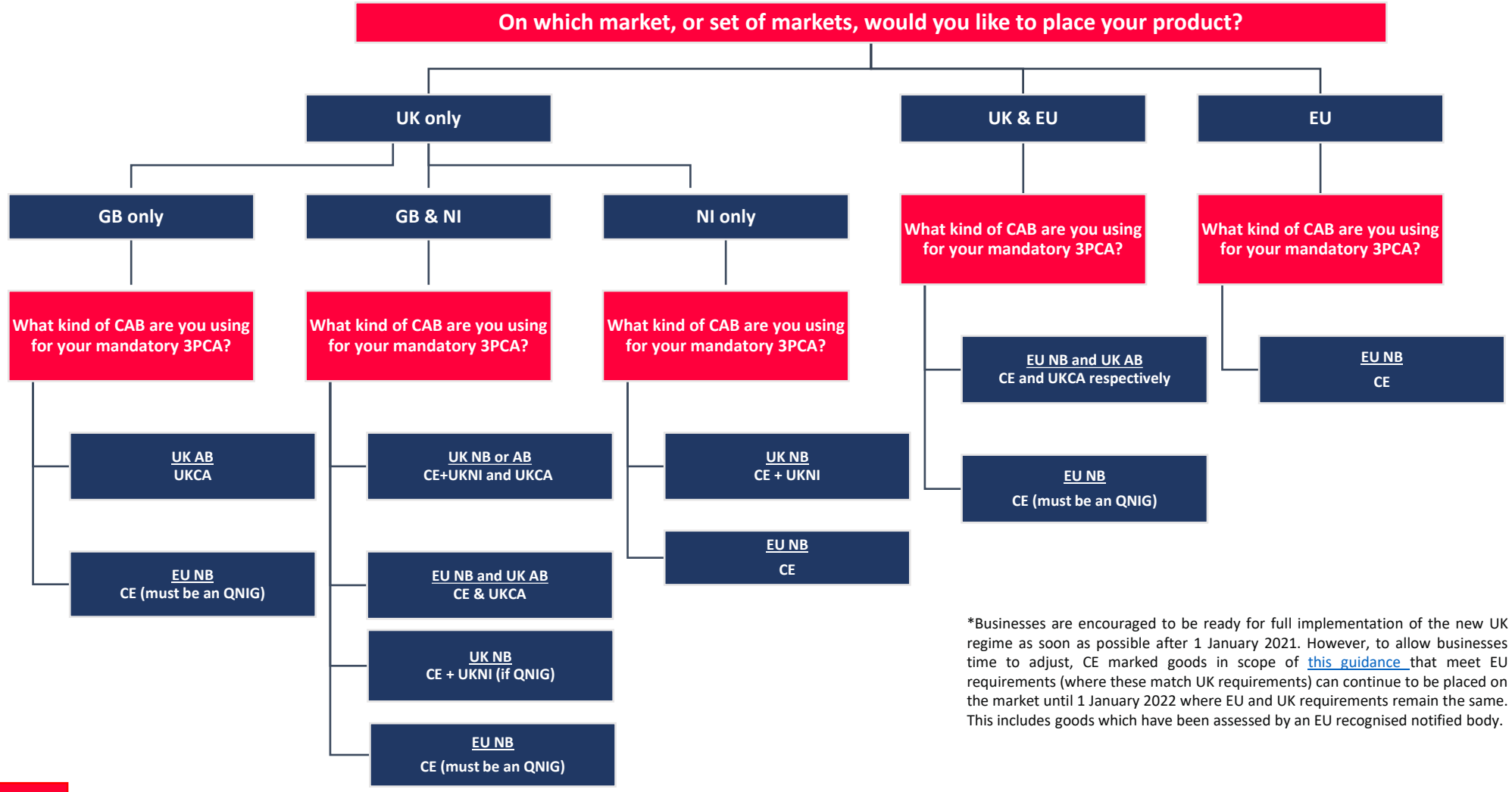
3PCA – Third party conformity assessment

EU NB – EU Notified Body (notified as competent to apply the CE marking)

UK AB – UK Approved Body (approved as competent to apply the UKCA marking)

UK NB – UK Notified Body (notified as competent to apply the CE+UKNI marking

QNIG – Qualifying Northern Ireland Good (see this guidance for further information on qualification)



*Businesses are encouraged to be ready for full implementation of the new UK regime as soon as possible after 1 January 2021. However, to allow businesses time to adjust, CE marked goods in scope of this guidance that meet EU requirements (where these match UK requirements) can continue to be placed on the market until 1 January 2022 where EU and UK requirements remain the same. This includes goods which have been assessed by an EU recognised notified body.

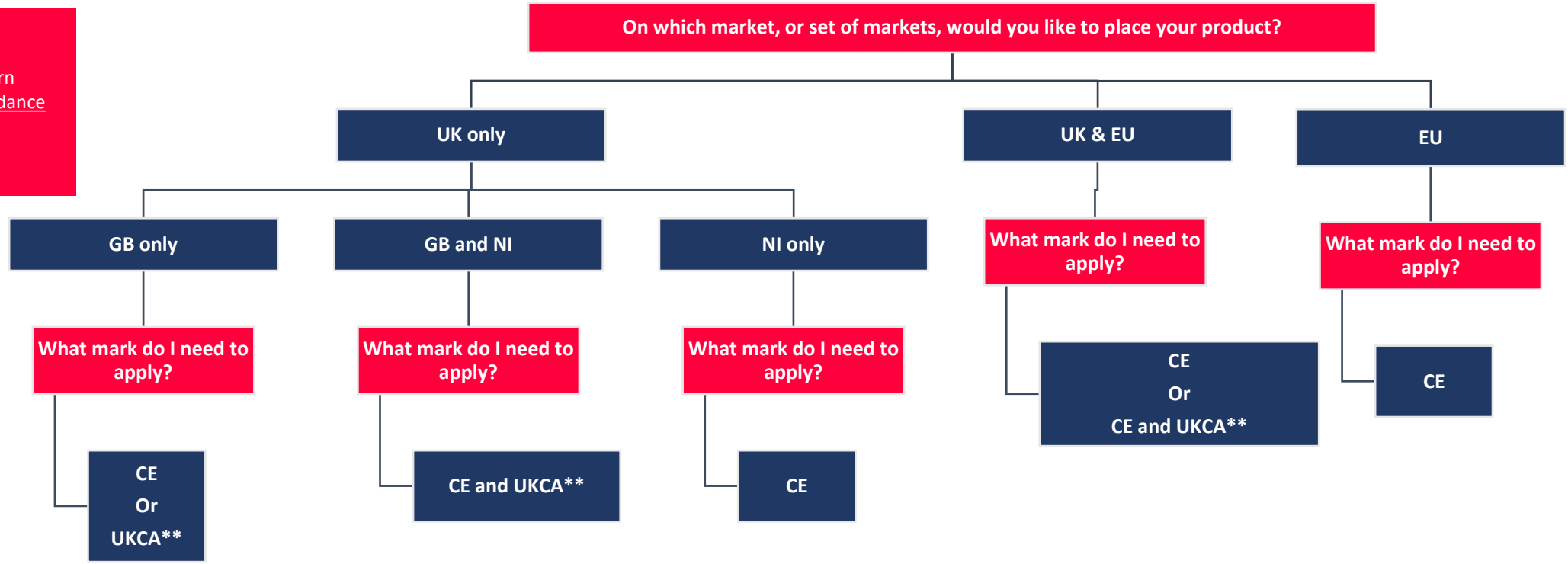
ACT NOW AT
GOV.UK/TRANSITION

Please note: recognition of the CE marking will apply to some goods for longer than 12 months. These goods include medical devices, pressure equipment, marine equipment and some others. We are not able to provide advice on your specific circumstances and would encourage you to seek external advice, such as from your solicitor or trade association, if needed.

What marking must I use when placing goods subject to self assessment or voluntary testing on the market between 1 January 2021 and 1 January 2022?*

Key

QNIG – Qualifying Northern Ireland Good (see this guidance for further information on qualification)



*Businesses are encouraged to be ready for full implementation of the new UK regime as soon as possible after 1 January 2021. However, to allow businesses time to adjust, CE marked goods in scope of this guidance that meet EU requirements (where these match UK requirements) can continue to be placed on the market until 1 January 2022 where EU and UK requirements remain the same. This includes goods which have been assessed by an EU recognised notified body.

**The UKCA marking would only be required in if UK and EU rules diverge over time. In the meantime, a manufacturer may choose to apply the UKCA marking, but if there is a CE marking on the product, they won't need to. In either situation, if you are placing a QNIG on the GB market, the UKCA marking is not required.

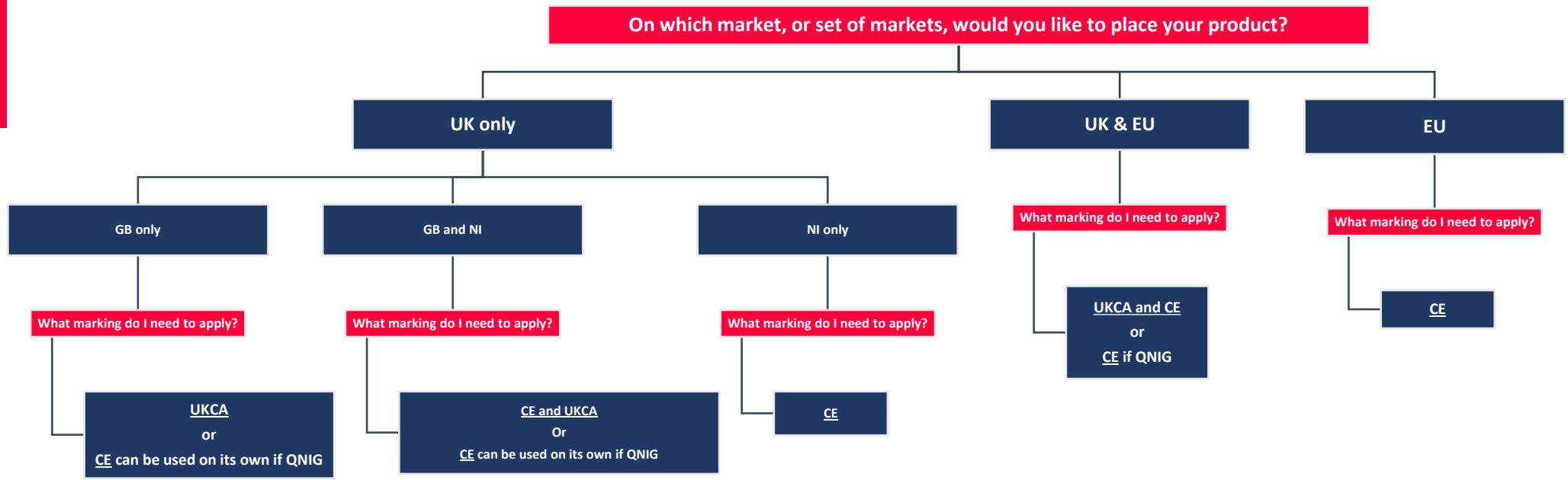
ACT NOW AT
GOV.UK/TRANSITION

***Please note:** recognition of the CE marking will apply to some goods for longer than 12 months. These goods include medical devices, pressure equipment, marine equipment and some others. We are not able to provide advice on your specific circumstances and would encourage you to seek external advice, such as from your solicitor or trade association, if needed.*

What marking must I use when placing goods subject to self assessment or voluntary testing on the market from 1 January 2022?*

Key

QNIG – Qualifying Northern Ireland Good (see this guidance for further information on qualification)



*Businesses are encouraged to be ready for full implementation of the new UK regime as soon as possible after 1 January 2021. However, to allow businesses time to adjust, CE marked goods in scope of this guidance that meet EU requirements (where these match UK requirements) can continue to be placed on the market until 1 January 2022 where EU and UK requirements remain the same. This includes goods which have been assessed by an EU recognised notified body.

ACT NOW AT
GOV.UK/TRANSITION

***Please note:** recognition of the CE marking will apply to some goods for longer than 12 months. These goods include medical devices, pressure equipment, marine equipment and some others. We are not able to provide advice on your specific circumstances and would encourage you to seek external advice, such as from your solicitor or trade association, if needed.*