



Department
for Business
Innovation & Skills

DIRECTIVE 2015/1535/EU

Guidance for Officials

JANUARY 2016

Withdrawn

This publication was withdrawn on 1 January 2021.

Contents

| | |
|---|----|
| The Directive | 3 |
| 1. What is the purpose of the Directive?..... | 3 |
| 2. What is in scope of the Directive? | 4 |
| 3. Where does the Directive apply?..... | 4 |
| 4. Does your proposed Regulation or standard need to be notified? | 4 |
| 5. What are the consequences of not notifying?..... | 5 |
| 6. Process Overview | 5 |
| 7. The Technical Regulations Information System (TRIS)..... | 5 |
| 8. The role of the Department for Business, Innovation & Skills (BIS) | 5 |
| How the notification procedure works | 6 |
| 9. Introduction | 6 |
| 10. How to submit a notification | 7 |
| 11. Standstill periods..... | 7 |
| 12. Standstill period variations | 7 |
| 13. Standstill Exemptions..... | 8 |
| 14. Comments and Detailed Opinions..... | 9 |
| 15. What happens once the standstill period has ended | 11 |
| 16. Publication of the Final Text..... | 11 |
| 17. Additional Information | 11 |
| 18. Useful links | 14 |
| Annex A: Process Flowchart..... | 15 |

EU Notification Requirements: A Guide

DIRECTIVE 2015/1535/EU

“A procedure for the provision of information in the field of technical standards and regulations & rules on Information Society services”.

The Directive

1. What is the purpose of the Directive?

1a. Underlying philosophy

The basic principles of the EU include the freedom to provide services and to prohibit quantitative restrictions on the movement of goods. The Directive aims to support these principles, and the smooth functioning of the single market, by delivering transparency in respect of national initiatives for the establishment of new technical standards or regulations, in order to prevent creating new barriers to trade within the EU.

Directive (EU) 2015/1535 is a codified replacement for Directive 98/34/EC and came into force on 7 October 2015. It does not need to be implemented (transposed) into UK law as the UK already fulfils the legal requirements of the new Directive through its existing procedures. The new Directive “tidies up” the previous Directive and most of the differences concern the renumbering of Articles and references to other Regulations and Directives.

The new Directive continues to place an obligation on Member States to:

- notify to the Commission any draft technical regulations that fall within scope of the Directive
- operate a “standstill period” of at least 3 months before adopting the draft regulations

This process gives the Commission and other Member States an opportunity to consider and provide comments on the draft proposals.

1b. What are Member States required to do?

Member States are required to inform the Commission of any new technical regulations and technical standards whilst they are in draft and before they are adopted in national law. Once notified, the measure enters a standstill period that usually lasts for 3 months, during which the measure cannot be laid.

The standstill period enables the Commission and other Member States to raise any concerns about whether the proposed measure is a potential barrier to trade.

2. What is in scope of the Directive?

The Directive applies to:

- 'information society services' (i.e. services normally provided for remuneration supplied at a distance by electronic means and at the individual request of a recipient of services); and to all
- industrially manufactured products and agricultural products.

The scope of the Directive is **very broad** and can include:

- laws, regulations or administrative provisions
- primary legislation (Government Bills, Private Bills, Private Members' Bills and Private Legislation Procedure (Scotland) Act 1936 measures) and any form of secondary legislation
- measures such as administrative circulars, departmental guidelines, advice notes, codes of practice, voluntary agreements etc
- technical specifications or other requirements or rules on services that are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with technical specifications

Proposals are notifiable if they recommend the use of given specifications or standards and the consequences of following/not following them are such that they are effectively obligatory.

3. Where does the Directive apply?

The Directive applies to all EU Member States, the European Economic Area (Norway, Iceland and Liechtenstein), Switzerland¹ and Turkey.

Technical regulations applicable in the whole or a major part of a Member State are caught by the Directive. So, any regulations laid down by Central Government, including agencies or other bodies responsible on behalf of government for technical regulations that apply to the UK or to a major part of England, Wales, Scotland and Northern Ireland, will be in scope of the Directive.

Technical regulations laid down by local authorities are unlikely to be in scope of the Directive.

4. Does your proposed Regulation or standard need to be notified?

The team responsible for Directive 2015/1535/EU notifications within the Department for Business, Innovation & Skills (BIS) can advise you on the process of submitting a notification.

¹ The Directive applies to EFTA, which includes all EEA countries plus Switzerland

In order to help you decide whether a regulation/standard is notifiable, we have drawn up a 'decision tree' but, **ultimately, the decision as to whether to notify is for you and your legal advisors to make.**

The BIS decision tree can be found at: [Decision Tree](#)

5. What are the consequences of not notifying?

Departments must ensure that all those responsible for preparing and drafting national measures are aware of the Directive and its requirements to notify any new draft technical regulations. **This will help avoid the possibility of national courts being unable to apply i.e. enforce, the regulations or of enforcement authorities being prevented from taking action given that non-notified measures cannot be enforced against individuals.**

Rulings on failures to fulfill obligations can be found on the Commission's website: [Notifications Case Law](#)

6. Process Overview

Regulations or standards that need to be notified must be sent to the Commission in draft i.e. at a stage when substantial amendments can still be made. The measure will then face a standstill period, which normally lasts for 3 months, before it can be made or brought into force. The standstill period gives the Commission and Member States time to raise any concerns they might have about potential barriers to trade they believe the measure may introduce.

In certain circumstances, the 3 month standstill period can be extended to 6 months. There is also an exception for urgent notifications and for some fiscal and financial measures.

See paragraphs 11-13 under the "How the notification procedure works" section below for more information on standstill periods.

7. The Technical Regulations Information System (TRIS)

Notifications are made via the Commission's Technical Regulations Information System (TRIS) database. Each Member State has one central contact point for submitting notifications although there is public access to some documents (see: [TRIS](#)).

TRIS helps make the notification process more transparent and allows public access to some of the details that are being notified.

8. The role of the Department for Business, Innovation & Skills (BIS)

The Department for Business, Innovation & Skills (BIS) is the UK's central contact point and is responsible for processing notifications on behalf of all Government Departments and Agencies as well as for Scotland, Wales and Northern Ireland.

Please e-mail enquiries to: technicalregulations@bis.gsi.gov.uk

How the notification procedure works

9. Introduction

Notification is a systematic and formal process.

A mandatory form (see here: [Form A](#))

- a. is completed by the notifying body. Form A is a standardised form that contains basic information about the notification.
- b. The notifying body will also need to submit the following supporting documentation along with the completed Form A:
 - A copy of the draft measure (in Word format only)
 - supporting documentation (where appropriate), including:
 - impact assessment (Word format only)
 - details of any previous notifications on the subject
 - documents necessary or helpful for understanding the measure (e.g. legislation that is being amended)

Note: these can be attached as documents, weblinks or included as references to the previous notification, whatever is most appropriate.

- c. The completed Form A plus any supporting documentation should be sent to the BIS contact point.
- d. The BIS contact point will upload these documents on to the Commission's TRIS database, which will then disseminate that information to other Member States.
- e. The notification is then reviewed by the Commission and other Member States during the standstill period, when they may ask questions or raise 'detailed opinions' on the draft measure.
- f. Only once the notification has successfully completed this process will the notifying Member State be allowed to enact the measure.
- g. The notification process is completed when the notifying Member State has loaded the final text of the enacted measure onto TRIS.

A simplified flow chart of the process can be found at [Annex A](#)

10. How to submit a notification

When a new technical regulation is to be notified, the notification form (Form A) should be completed by the Government Department or Agency proposing the measure, specifying the content and reasons why it is being introduced.

The completed Form A, together with any attachments, should then be sent to the BIS contact point for processing and forwarding to the Commission.

Form A can be downloaded here: [Form A](#)

11. Standstill periods

The Commission sends the information received from the notifying Member State to all other Member States via TRIS and allocates a standstill period (usually 3 months). The standstill period starts on the day the Commission receives the draft national technical regulation plus all of the supporting documentation.

The notifying Member State should not adopt the draft notified regulation during the standstill period.

During the standstill period, the Commission and/or other Member States can submit 'comments' or a 'detailed opinion'.

12. Standstill period variations

The initial standstill period usually lasts for 3 months (see paragraph 13 below for exemptions to this general rule). However, the initial standstill period is extended when a detailed opinion is made, as follows:

- for product notifications, the initial standstill period is extended by a further 3 months to a total of 6 months;
- for information society services notifications, the initial standstill period is extended by a further 1 month to a total of 4 months; and
- for voluntary agreement notifications, the initial standstill period is extended by a further 1 month to a total of 4 months.

With the exception of notifications relating to information society services and voluntary agreements, please note that:

- (i) if the Commission announces its intention to propose or adopt a Directive, Regulation or Decision on the subject, within the 3 month standstill period, the notifying Member State may not make the regulation for 12 months from the date of receipt by the Commission of its notification
- (ii) If the Commission announces that a proposal for a Directive, Regulation or Decision on the subject has already been submitted to the Council of Ministers within the 3 month standstill period, the notifying Member State may not make the regulation for 12 months from the beginning of the initial 3 month standstill

- (iii) If the Council of Ministers adopts a Common Position during the 12 month standstill mentioned in (i) and (ii) above, the standstill period would be extended to 18 months.

The standstill periods in (i) and (ii) above will lapse:

- when the Commission informs the Member States that it no longer intends to propose or adopt a Community measure
- when the Commission informs Member States of the withdrawal of the Commission's draft or proposal
- when the Commission or the Council has adopted a Community measure

Summary of standstill provisions

| | Products | Information Society Services | Voluntary agreements |
|--|--|----------------------------------|----------------------|
| Notification: initial standstill ⁽¹⁾ | 3 months (from date of receipt of all relevant papers by the Commission) | | |
| Comments | No further standstill | | |
| Detailed Opinion | 6 months [3 + 3] | 4 months [3 + 1] | 4 months [3 + 1] |
| Intention to propose a Directive etc. | 12 months [3 + 9] ⁽²⁾ | Not applicable | Not applicable |
| Existing proposal for a Directive | 12 months [3 + 9] ⁽²⁾ | 12 months [3 + 9] ⁽²⁾ | Not applicable |

Table Notes

⁽¹⁾ Please refer to paragraphs 11-13 or Article 6 of Directive 2015/1535/EU (see: [Directive 2015/1535/EU](#)), for more information on standstill periods.

⁽²⁾ The standstill is extended to 18 months if a common position is reached within the 12 months period.

13. Standstill Exemptions

The following are the only exemptions from the standstill periods:

- Fiscal and financial agreements** (see Article 1.1(f) of the Directive) are subject to the notification procedure only with no standstill periods
- The urgency procedure** (see Article 6.7 of the Directive) can only be used for serious and unforeseeable circumstances relating to the following:
 - protection of public health or safety, protection of animals and preservation of plants

- rules on services
- public policy, in particular, the protection of minors
- the security and integrity of the financial system, notably protection of depositors, investors and insured persons
- The urgency procedure is used when a Member State is obliged to prepare regulations in a very short space of time in order to enact and introduce them immediately without any consultation being possible
- When using the urgency procedure, the Member State is required to set out the reasons why for the Commission to consider. If the Commission accepts that the urgency procedure is valid, the Member State is free to adopt the regulation without a standstill period.
- Departments considering using the urgency procedure must give the BIS contact point as much notice as possible of their intention to do so. The urgency procedure is not to be used by Government Departments that have forgotten or overlooked their legal obligations under Directive 2015/1535/EU. The urgency procedure can only be used in the circumstances set out above.
- The Commission will review any notifications made under the urgency procedure within 10 working days. The Commission will then confirm to the notifying Member State whether the notification falls under the urgency procedure. The Commission will open the 3 month standstill period if the urgency procedure is refused.

Note: Urgent proposed technical regulations must still be notified, in draft, under the urgency procedure, before being made.

14. Comments and Detailed Opinions

The notification of draft technical regulations provides an opportunity to challenge proposals that may adversely affect UK interests and/or the effectiveness of the Single Market. It is the responsibility of the lead Department/policy team to review any notifications received to check whether they introduce a potential barrier to trade or require clarification. In order to do this, they should:

- consult with key stakeholders e.g. other Government Departments, business organisations, trade associations etc as appropriate²
- decide whether to make 'comments' or deliver a 'detailed opinion' in the case of a notification by another Member State³
- decide whether to make 'comments' in the case of a notification by an EEA/EFTA country

² Please take care when consulting outside Government if the notifying Member State has requested confidentiality under Article 5(4)

³ if you are going to make comments or submit a detailed opinion, please specify whether your response is under Article 5.2 (comment) or Article 6.2 (detailed opinion)

- clear and confirm the status of any comments received from industry i.e. whether to be treated as comments or a detailed opinion, with the BIS contact point
- send any comments/detailed opinion to the BIS contact point in good time for them to notify the Commission before the deadline

14a. When to send comments

Comments are usually sent by the Commission or other Member States when the notified draft regulation raises issues of interpretation or they want more information about how it is going to be implemented.

The notifying Member State is required to take any comments received into account, where possible, in the subsequent preparation of the regulation but is otherwise free to make the draft regulation at the end of the standstill period.

Comments do not extend the standstill period.

14b. Responding to comments

The notifying Member State has no legal obligation to reply to any comments it receives. However, in practice and on a voluntary basis, Member States usually do reply and take account of the comments received.

UK responses to any comments should be emailed to the BIS contact point for forwarding on to the Commission. Government Departments may consult industry, business representative organisations, trade associations etc as appropriate when considering whether to comment on a particular notification received from another Member State.

14c. When to send a detailed opinion

Detailed opinions are sent by the Commission or other Member States when they consider that the draft measure would create obstacles to:

- the free movement of goods
- the freedom to provide services
- the freedom of establishment of service operators within the internal market.

Detailed opinions seek to obtain an amendment to the proposed measure in order to remove any resulting barriers to these freedoms before they are implemented. A detailed opinion will extend the initial 3 month standstill period as set out in paragraph 12 above.

Note: Detailed Opinions must be sent to the BIS contact point within the 3 month standstill period for them to notify the Commission. If the deadline is missed then the standstill period will not be extended.

14d. How to respond to a detailed opinion

The notifying Member State must report to the Commission what action it proposes to take concerning the detailed opinion received. A response to a detailed opinion should be made

within the extended standstill period of 6 months for goods or 4 months for information society services.

Responses to detailed opinions received by the UK should be emailed to the BIS contact point for forwarding on to the Commission.

Please allow sufficient time for the BIS contact point to submit your comments or detailed opinion before the deadline.

14e. Treatment of comments and detailed opinions

The BIS contact point will circulate any ‘comments’ or ‘detailed opinion’ received. **Any detailed opinions or comments from the Commission or other Member States are to be treated as “in confidence” and should not be released to any person or organisation outside of government.**

Please be aware that the UK has informed the Commission and other Member States that, unless we have specifically requested confidentiality, any detailed opinions or comments from the UK can be made available to interested parties outside of government.

Where a Member State or the Commission’s detailed opinion or comment is to be treated “in confidence”, this may restrict the ability of the UK to release any response it makes in full.

15. What happens once the standstill period has ended

Once a standstill period for any particular notification has ended and provided that no comments or opinions have been received and/or there are no issues still outstanding as result of a detailed opinion, the notifying body is free to make the regulation. However, before doing so, it is advisable to check with the BIS contact point just after the standstill period has ended, in case any last minute comments or opinions have been submitted.

Note: the technical standards notification process is procedural in nature. The fact that a measure passes without challenge does not prevent the measure being challenged subsequently on grounds that it is incompatible with EU law.

16. Publication of the Final Text

Article 9 of the Directive states that:

“When Member States adopt a technical regulation, it shall contain a reference to this Directive [i.e. Directive 2015/1535/EU] or shall be accompanied by such reference on the occasion of its official publication. The methods of making such reference shall be laid down by Member States.”

Where the technical regulation is contained in a Statutory Instrument (SI), Departments must ensure that a reference to the Directive is included in the explanatory note to the SI and, wherever possible, in the notified draft.

Departments should email an electronic copy of the definitive text to the BIS contact point to forward on to the Commission. Please note that a hyperlink will not be accepted.

17. Additional Information

17a. Notification

Technical regulations: must be notified in draft. However, if there is an amendment to the draft text after notification or an amendment to the adopted regulation, which has the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive, the amended draft text must be notified again and the usual three-month standstill will apply.

Amendments to adopted Technical Regulations: when introducing amendments to technical regulations that require notification under the Directive, Departments should ensure that any original technical regulations made after 28 March 1984 were notified, if notification was required. If the original was not notified but should have been, we recommend that the regulations are consolidated, with amendments, and notified as a whole in order to avoid the problems that would otherwise arise over non-notification of a technical regulation.

Deregulating/Relaxing/Consolidating Technical Regulations:

- a measure that relaxes or deregulates a technical regulation by replacing it with another comes within the scope of the Directive and will require notification.
- Measures that consolidate existing technical regulations and merely replicate them in new legislation are not notifiable.
- Where an amendment removes some products from the scope covered by a technical regulation, in so far as this was all that it achieved, it is unlikely that the measure would be notifiable, being akin to a repeal for these products where the measure is disappplied. However, if the measure also has the effect of revising a technical specification for other products that remain within its scope, the measure will require notification, even if the new technical specification is considered to be less onerous.
- There may be instances where it is difficult to establish whether a new specification is being established and notification in these cases is recommended.

17b. Risk assessment

The draft measure must be accompanied by a risk assessment if it seeks to limit the marketing or use of a chemical (hazardous) substance, preparation or product on grounds of public health, protection of consumers or the environment. This should enable the Commission and other Member States to determine the proportionality of the measure with regard to its anticipated effects on public health and protection of the consumer and of the environment.

The risk assessment must be carried out in accordance with the principles provided for in the relevant part of Section II.3 of Annex XV to Regulation (EC) No 1907/2006.

Regulatory Impact Assessment (RIA): an RIA whether draft, interim, partial, full or final as long as it is publicly available, should also be included as part of the supporting documentation submitted along with Form A.

17c. Fiscal or financial measures

If the draft text relates to fiscal or financial measures, only the aspects that might hinder trade or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators should be considered (i.e. not the fiscal or financial aspects) for the purposes of comments or detailed opinions by the Commission or Member States.

17d. Other issues, including exceptions to the requirement to notify

Draft technical specifications or a standard for specific products drawn up by standards institutions e.g. BSI at the request of public authorities for the purposes of enacting a technical regulation for such products, are notifiable as draft technical regulations.

For draft technical regulations that simply transpose the full text of an international or European standard, it is sufficient to let the Commission have information regarding the relevant standard when notifying through the BIS contact point.

Exceptions: Article 7 sets out the only exceptions to the requirement to notify draft technical regulations. These include regulations that fulfill obligations arising out of Community measures, and regulations that fulfill obligations arising out of international agreements that result in the adoption of uniform technical specifications within the EU. The Commission's view is that the exception relating to international agreements only applies when all Member States are a party to the international agreement.

The draft technical regulation should be notified, if one or more Member States are not a party to the agreement.

The Directive states that, where appropriate, Member States shall simultaneously communicate to the Commission both the draft technical regulation and the text of the basic legislative or regulatory provisions if they are needed in order to assess the implications of the draft technical regulation.

17e. Confidentiality under Article 5.4

Information supplied under the Directive, for example, the completed notification form or the draft measure, is not confidential except at the express request of the notifying Member State.

All requests for confidential notifications **must** be supported by valid reasons, as required under Article 5.4.

17f. Mutual Recognition Clause

Technical regulations notified under the Directive will also need to take account of the requirements set out in The Mutual Recognition Regulation (MRR) (see: [\(EC\) No 764/2008](#)), which aims to improve the free movement of goods within the EU.

A requirement in a draft technical regulation to comply with a national standard will be objected to on the basis that it constitutes a barrier to trade that is not justifiable unless it also allows for recognition of standards within the EEA that provide equivalent levels of performance, safety, health, consumer protection etc as required under the MRR. Similar considerations will also apply if the proposed measure stipulates particular test methods or forms of certification.

General Mutual Recognition Clause: in order to comply with the MRR, the following paragraph should therefore be included in any draft proposal:

“Any requirement for goods or materials to comply with a specified standard shall be satisfied by compliance with:

- 1) a relevant standard or code of practice of a national standards body or equivalent body of any EEA State; or*

- 2) any relevant international standard recognised for use in any EEA State; or
- 3) any relevant technical regulation with mandatory or de facto mandatory application for marketing or use in any EEA State

in so far as the standard, code of practice, technical regulation or process in question enables the [objectives pursued by the present regulation] to be met in an equivalent manner.”*

* - specify as appropriate: protection of health, safety etc.

Note: the above wording is for guidance only and should be adapted as necessary.

18. Useful links

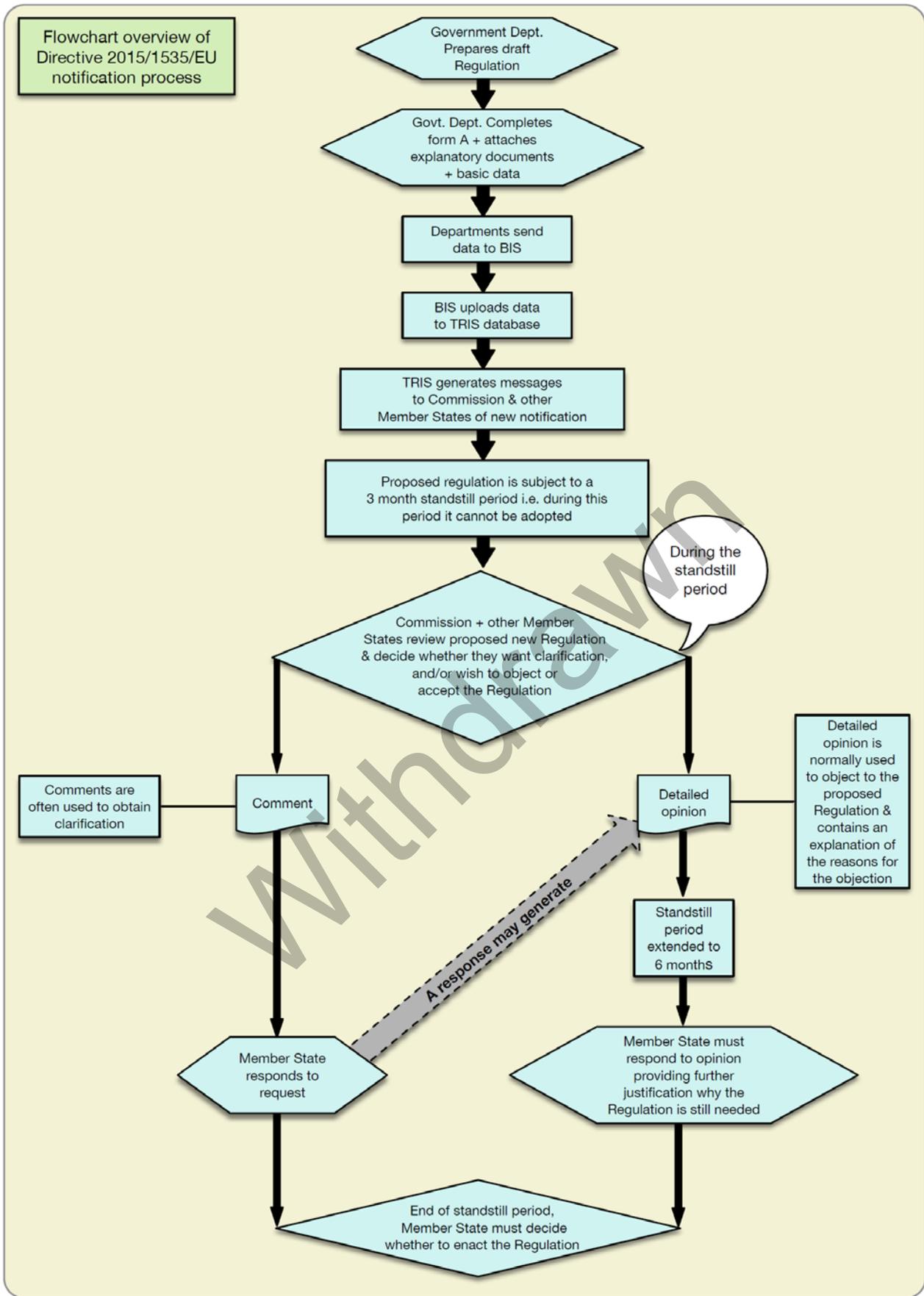
| Reference | Link |
|---|--|
| Form A | Form A |
| Link to: a “Tool to see if a measure requires notification to the Commission and if a standstill period applies – The Technical Standards Directive (Directive 2015/1535/EU)” | Diagnostic Tool |
| Link to: access to the public TRIS portal | TRIS |
| Link to: EU Commission webpage: “What is the Directive 2015/1535/EU procedure?” | Directive 2015/1535/EU Procedure |
| Link to: Directive 2015/1535/EU | Directive 2015/1535/EU |

19. Contact:

The central contact point in BIS will be happy to give you further information or answer your queries on processing your notification and can be contacted at:

technicalregulations@bis.gsi.gov.uk

Annex A: Process Flowchart



© Crown copyright 2016

You may re-use this information (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. Visit www.nationalarchives.gov.uk/doc/open-government-licence, write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email: psi@nationalarchives.gsi.gov.uk.

This publication is available from www.gov.uk/bis

Any enquiries regarding this publication should be sent to:

Department for Business, Innovation and Skills
1 Victoria Street
London SW1H 0ET
Tel: 020 7215 5000

If you require this publication in an alternative format, email enquiries@bis.gsi.gov.uk, or call 020 7215 5000.

BIS/16/15