



National Standards Authority of Ireland

Guidance for Officials

EU Directive 2015/1535

December 2018

Contents

Contents	1
1 Introduction	2
2 Information about EU Directive 2015/1535	2
2.1 What is the purpose of the Directive?	2
2.2 Role of the Member States	3
2.2.1 What is a technical regulation?	3
2.2.2 What is a 'de facto' technical regulation?	4
2.2.3 What is a 'de jure' technical regulation?	4
2.3 What is the scope of the Directive?	4
2.4 Role of the National Standards Authority of Ireland (NSAI)	6
2.5 Role of the Department/Official.....	6
2.6 What are the consequences when you don't notify?.....	7
2.7 Do you need to make a notification?.....	8
2.8 Do you need to make a comment or detailed opinion?	9
3 Notification Procedure	10
3.1 Overview	10
3.2 Technical Regulations Information System (TRIS)	10
3.3 Notification Documents.....	11
3.3.1 Form A 16pt	11
3.3.2 Confidentiality.....	11
3.3.3 Urgency Procedure	11
3.3.4 Draft Text.....	12
3.3.5 Supporting Documentation	12
3.3.6 Editing Rules Checklist	12
3.4 Standstill Period.....	13
3.4.1 Standstill period variations	14
3.5 Comments	15
3.6 Detailed Opinions.....	15
3.7 End of Standstill Period.....	15
3.8 Submittal of a notification	16
3.9 Submittal of Comment(s) and/or Detailed Opinions.....	17
3.10 Confidential Notifications	19
3.11 Submittal of final text.....	19
4 Additional Information.....	20
4.1 Useful Links	20
4.2 Contact.....	20
4.3 Exception of the message 9 (Closure of a notification)	21
Annex A – Filling out 16pt Form	22
Annex B – Notification Submittal Checklist	26

1 Introduction

This is a guide created by the National Standards Authority of Ireland (NSAI), the National Contact Point for EU Directive 2015/1535. NSAI acts as the intermediary under this Directive.

The guide provides information regarding EU Directive 2015/1535, the notification procedure for the Directive, the procedures in NSAI for submitting and processing a notification, and the procedures in NSAI for processing comments and/or detailed opinions to other Member States. NSAI processes notifications, comments, and detailed opinions through the Technical Regulations Information System (TRIS) portal.

This is a guide for Officials, i.e. The Irish Government and the subsidiaries of the Irish Government. This includes departments, authorities, local government, etc., as institutions that are drafting or reviewing technical regulations and notifications. For the purpose of this guide, they will be referred to as "Department" or for individuals as "Official(s)" throughout the guide.

2 Information about EU Directive 2015/1535

2.1 What is the purpose of the Directive?

The [EU Directive 2015/1535](#) is an update from the [EU Directive 98/48/EC](#) which has been extended to include the application to Information Society services. This Directive applies to those who are within the European Union (EU) Member States, the Agreement on the European Economic Area (EEA) countries, Switzerland, and Turkey.

The basis of this Directive comes from the EU's and Member States' grounded approach in the development and continued growth for the European Internal Market. It aims to ensure that the free movement of goods and services are not restricted or prevented by technical regulations that Member States intend to introduce before they are adopted. These technical regulations apply to:

- Products (industrial, agricultural, and fishery)
- Information Society services

The outlined notification procedure for the relevant technical regulations supports the objective to ensure that the technical regulations are congruent to the EU laws and the Internal Market principles. This also supports the smooth functioning of the Internal Market by adhering to as much transparency as possible.

The notifications are submitted through the portal Technical Regulations Information System (TRIS) which also has a limited public access portal. An enacted standstill period occurs once a notification is submitted, during which the Member State cannot adopt the national measure, and where other Member States and the EU Commission may react (through comments or detailed opinions).

2.2 Role of the Member States

This Directive places an obligation on a Member State to notify the EU Commission and the other Member States of any draft technical regulations that fall within the scope of the Directive before they are adopted into national law. This is applicable to whole or a part of the Member State in such that it includes agencies or other bodies responsible on behalf of government for technical regulations.

The Directive imposes a standstill period, usually three months, where the measure cannot be adopted, and allows other Member States and the EU Commission to:

- Detect actual perceived potential barriers to trade,
- Establish transparency in the EU for new national technical regulations,
- To review the new measures which may affect them,
- Establish dialogues and communication through 'comments' and 'detailed opinions' when assessing technical regulation drafts,
- Adapt activities/regulations within their own national regulations if necessary,
- Identify the harmonisation needs.

Notifications submitted under this Directive may also need to be notified under other Directives.

2.2.1 What is a technical regulation?

The [EU Commission states that technical regulations](#) include the following:

- technical specifications;
- other requirements;
- rules on services; and
- regulations prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider.

A. product is defined as "any industrially manufactured product and any agricultural product, including fish products"

B. Information Society services "is defined as any service provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services".

C. technical specification is defined as a "specification contained in a document which lays down the characteristics of a product such as dimension, labelling, packaging, level of quality, conformity assessment procedures etc. This term also covers production methods and processes".

D. other requirements are defined to "cover requirements imposed on a product for the purpose of protecting for instance consumers or the environment and which affects its life cycle once placed on the market, such as conditions of use, reuse or recycling. These conditions have however to influence significantly the composition or nature of the product or its marketing".

E. rules on services is defined as "a requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point (b), in

particular provisions concerning the service provider, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in that point."

2.2.2 What is a 'de facto' technical regulation?

The EU Directive 2015/1535 states that:

"It is necessary to clarify the concept of a de facto technical regulation. In particular, the provisions by which the public authority refers to technical specifications or other requirements, or encourages the observance thereof, and the provisions referring to products with which the public authority is associated, in the public interest, have the effect of conferring on such requirements or specifications a more binding value than they would otherwise have by virtue of their private origin."

2.2.3 What is a 'de jure' technical regulation?

The EU Directive 2015/1535 states that:

"The technical regulation is compulsory 'de jure' when compliance with it is made mandatory by a measure emanating directly from the relevant public authorities or attributable to the latter. Compliance with the technical specifications or other requirements or rules on services which it contains is compulsory for the marketing or use of the products or services in question."

2.3 What is the scope of the Directive?

The Directive is applicable to whole or a part of the Member State in such that it includes agencies or other bodies responsible on behalf of the government.

With a view to facilitating the adoption of measures by the European Parliament and the Council, Member States should refrain from adopting technical regulations once the Council has adopted a position at first reading on a Commission proposal concerning that sector.

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

Within the power of the EU Commission, they may decide to block a notification.

This Directive can include the following:

- Laws, regulations, or administrative provisions
- Primary legislation
 - Government Bills
 - Private Bills
 - Private Members' Bills
 - Private Legislation Procedure
 - Acts
- Secondary legislation
- Administrative circulars, department 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

The Directive applies to the following:

- Products (industrial, agricultural, and fishery)
- Information Society services

If there are requirements, other than technical specifications, referring to the life cycle of a product after it has been placed on the market are liable to affect the free movement of that product or to create obstacles to the proper functioning of the internal market.

Examples of applications include:

- Levels of quality performance, safety
- Dimensions
- Terminology, symbols, labelling
- Testing, test methods
- Conformity assessment procedures

Under this Directive, notifications must also account take for the Mutual Recognition Regulation (MRR) 764/2008 which relates to the free movement of goods within the EU. Therefore, where appropriate, the draft should include aspects that relate to this.

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 764/2008.

Similar considerations will also apply if the proposed measure stipulates particular test methods or forms of certification.

A. If there is an **amendment to adopted technical regulations** that requires notification under the Directive, it should be ensured that any original technical regulations made after 28 March 1984 were notified, if required.

- If the original technical regulation was not notified, but should have been, it is recommended that the regulations be consolidated including the amendments and notified as a whole

B. If there is **deregulation/relaxing/consolidating of technical regulations**, see the following:

- A measure that relaxes or deregulations 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 ***will not require notification***.
- When consolidating technical regulations, it is essential to identify any sections of a regulation that have already been notified otherwise they will be deemed notified again and subject to comments and detailed opinions.
- 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*

to require notification, being akin to a repeal for these products where the measure is no longer applied. 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***.

C. If there is an **amendment to the draft text after notification** or there is an amendment to the adopted regulation which has the effect of one of the following:

- Significantly altering its scope
- Shortening the timeline for implementation
- Adds specifications or requirements
- Makes specifications or requirements more restrictive

The amended draft text must be notified again as a new notification, and go through the notification procedure.

For draft measures that simply transpose the full text of an international or European standard, the notification should provide information regarding the relevant standard, along with the statement of grounds. This should indicate the grounds by which the enactment is necessary, and where it is not clearly identified in the draft.

Although measures may go through the notification process without any challenges, this does not mean that the measure cannot be challenged on subsequent grounds that it is incompatible with EU legislation.

2.4 Role of the National Standards Authority of Ireland (NSAI)

The National Standards Authority of Ireland (NSAI) is the Republic of Ireland's National Contact Point for this Directive. As the contact point, NSAI processes:

- notifications by the Republic of Ireland through the TRIS portal,
- comments/detailed opinions from the EU Member States and EU Commission to the Republic of Ireland's submitted notifications,
- comments/detailed opinions from the Republic of Ireland to the EU Member States and EU Commission for Member State's submitted notifications
- confidential notifications submitted from Member States

See **Section 3** on submitting a notification under the Directive. See **Section 3.6** on sending comments/detailed opinions to notifications from other Member States.

It is not the responsibility of NSAI to review TRIS notifications from other Member States. For confidential notifications, NSAI will review the product/service area and determine which Department that may be best suited to direct the notification to.

2.5 Role of the Department/Official

It is the responsibility of the Officials, as part of the Department, policy teams, authorities, local governments, etc. to review any notifications from Member States. To receive e-mails about relevant notifications, register with a mailing list for selected

sectors, countries, etc., through the [TRIS public website](#), the NSAI TRIS Mailing List Guide provides information and guideline on how to do this. If it is deemed that a comment and/or detailed opinion is required for a particular notification contact the NSAI notifications officer eudirective2015.1535@nsai.ie

It is the responsibility of the Departments to review any national measures to determine if it is necessary to submit a notification under this Directive. It should be stressed that the technical regulation should be notified at draft stage. See the procedure in **Section 3** for further details of submitting a notification.

Departments should ensure that all responsible parties and individuals who are preparing and drafting national measures are aware of this Directive and the particular requirements of the notification procedure.

Consideration regarding confidentiality should be kept in mind during this process, as even consulting outside of the Government may be a breach of confidentiality. Any detailed opinions or comments that are sent or received in the TRIS portal are to be treated as "in confidence". In additional notifications identified as confidential are "strictly" confidential and therefore need to be treated as such.

2.6 What are the consequences when you don't notify?

Examples of failures to fulfil obligations regarding this Directive can be found on the [EU Commissions website](#). The consequences of non-notification of the technical regulation, the inapplicability of the non-notified technical regulations can be invoked by individuals before national Courts, referring to [CIA Security \(C-194/94\)](#) and [Unilever \(C-443/98\)](#) CJEU cases.

Failures to notify a relevant regulation, may render the regulation unenforceable and result in legislative issues.

Additional recent court cases are listed below:

- [C-144/16 Municipio de Palmela](#)
- [C-303/15 Naczelnik Urzędu Celnego I w Łodzi](#)
- [C-98/14 Berlington](#)
- [C-336/14 Sebat Ince](#)
- [C-613/14 James Elliott Construction](#)
- [Joined cases C-213/11, C-214/11, C-217/11 Fortuna Grand Forta](#)

2.7 Do you need to make a notification?

It should be determined by legal advisors if it is necessary to submit a notification.

It should be noted that relevant technical regulations **must** be notified at an early draft stage, where amendments and comments can be made.

There are certain situations that require notifications but have exemptions to the standstill period of the procedure, which are outlined below:

A. Fiscal and financial agreements (Article 1.1 (f) of the Directive)

- Subject to notification
- No standstill periods required

Where "technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services. Three cumulative conditions have to be fulfilled:

- The draft measures have to contain technical specifications or other requirements or rules on services
- These technical specifications or other requirements or rules on services have to be linked to fiscal or financial measures, and
- The fiscal or financial measures have to affect the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services."

B. Urgency period (Article 6.7 of the Directive)

- Subject to notification
- No standstill periods required
- Requires supporting information, see Section 3.3 for further information
- Regulations that need to be created and enacted and introduced immediately without any consultation being possible

Article 7 of the Directive, sets out exemptions to submitting a notification for draft technical regulations. They include:

- Regulations that fulfil obligations arising out of Community measures
- Regulations that fulfil obligations arising out of international agreements that result in the adoption of uniform technical specifications within the EU.
 - The Commission's view is that this exception only applies when all Member States are a party to the international agreement
 - If one or more of the Member States are not a party of the agreement, the draft technical regulations should be notified.

If a draft technical regulation seeks to limit the marketing or use of a hazardous chemical substance, preparation or product on grounds of public health, protection of consumers or the environment, a risk assessment must be provided with the notification. The risk assessment must be carried out in accordance with the Annex of [Regulation EC 1907/2006](#). The risk assessment should be able to provide the EU Commission and other Member States the information to determine the proportionality

of the measures with regard to its anticipated effects on public health and protection of the consumer and of the environment.

See Section 3 about the notification procedure.

2.8 Do you need to make a comment or detailed opinion?

It is the responsibility of the Department, etc. to review any notifications received through TRIS, to determine whether a comment and/or a detailed opinion should be sent to the notifying Member State. It is at the discretion of the Department to determine how a review may occur. Confidential notifications should be treated as 'strictly confidential'.

Some ways of doing this can be through:

- Consulting with key stakeholders; e.g. other Government Departments, business organisations, authorities, etc.;
- Reviewing upcoming legislation in the pool,
- Conducting research,
- Conduct feasibility studies, etc.

It should be noted that comments need to be submitted within the standstill period. Submitting detailed comments can be submitted beyond the standstill period.

See Section 3.5 for further information regarding comments and Section 3.6 for further information regarding detailed opinions.

3 Notification Procedure

3.1 Overview

The notification procedure follows a formal process within the Directive. An overview of the procedure is shown below in Figure 1.

Any notifications that require submittal need to go through NSAI as the intermediary. The formal procedure is outlined on page 14, Figure 2 for the process within NSAI.

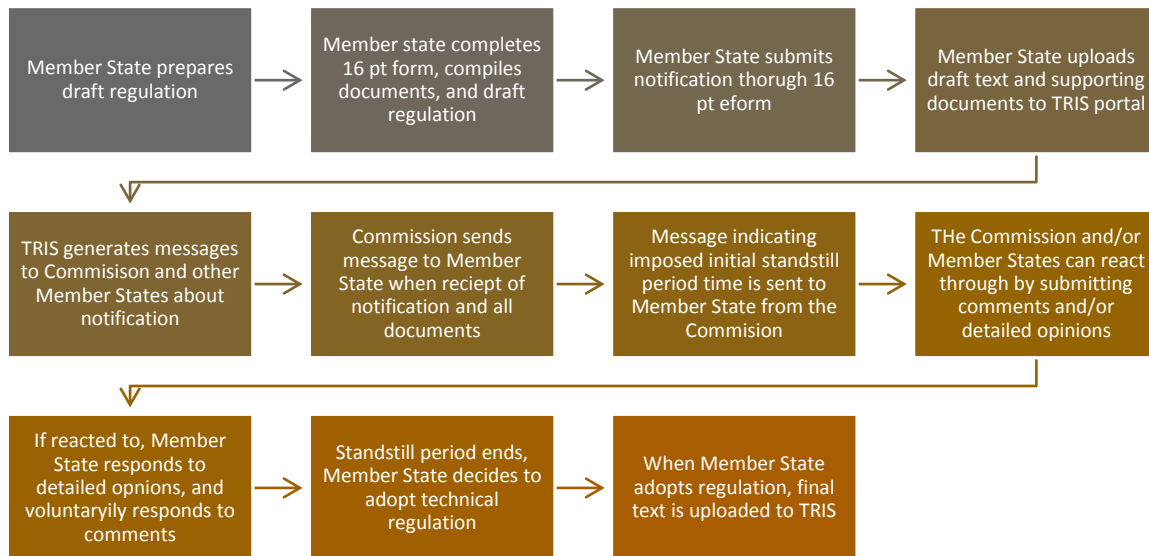


Figure 1 - Overview of 2015/1535 Notification Procedure

3.2 Technical Regulations Information System (TRIS)

The TRIS is the portal through which notifications are submitted for this Directive. Each Member State has a central point for which they will submit their notifications from within the portal.

The mailing list allows for Member States to be e-mailed relevant notifications from particular areas, countries, etc.

The recent addition of a "Contribution" section in the TRIS portal also allows the public to respond to the notifications. This either can be made confidential, to the EU Commission only, or to the public, and would be visible on the public website. These comments can be visible to the public.

3.3 Notification Documents

3.3.1 Form A 16pt

This is a standardised electronic form that is completed by the originating department, the department drafting the technical regulation.

Some notes regarding the form:

- It needs to be filled out electronically,
- It should be labelled appropriately, e.g. Dept Ag_Microchipping Dogs_16pt_09.03.2017.pdf,
- It should be filled out with the correct cases of words,
- Make sure the title is as short as possible, with the necessary information,
- Make sure that all relevant regulations/directives/etc. are indicated as required,
- If you tick the Yes for "11. Invocation of the Urgency Procedure", you may be challenged, and it may be rejected,
- TBT means Technical Barriers to Trade,
- SPS means Sanitary and Phytosanitary measures,
- References to regulations, Statutory Instruments, etc. that are mentioned in the draft text or as supporting documents should be either provided or up to date web links included,

3.3.2 Confidentiality

Upon the selection of "confidentiality" in the 16pt form, will automatically make it only visible to Member States and the EU Commission. Therefore, this needs to be selected in order for it to be labelled as such when it is being submitted.

If this is selected there must be supported reasons provided with this, which are required under Article 5.4 of the Directive.

3.3.3 Urgency Procedure

The urgency of the notification is determined by the originating department, and therefore it is the responsibility of the department to determine if it is urgent and must provide the relevant supporting information/documentation for it. It can only be used for serious and unforeseeable circumstances which relate 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.

Provide as much supporting information and documentation as possible when selecting this procedure for the notification. The EU Commission will accept or decline the urgency procedure within 10 days of submitting the notification. If it is accepted, the Member State may adopt the regulation without a standstill period. If it is rejected, the normal 3-month standstill period will be put in place, unless other needs of the notification require it to be made longer.

3.3.4 Draft Text

The draft text is the draft technical regulation that the Member State wants to submit for notification. It should be as complete as possible.

If at any point during the standstill period where there are significant amendments made to the draft, a new notification will have to be created, and the procedure will start again from the beginning.

3.3.5 Supporting Documentation

This is to be provided if appropriate for the notification of the measure. Which may include (all documents shall be in MS word .doc format):

1. Supporting documentation for urgency procedure,
2. Supporting documentation for impact assessment,
3. Details of any previous notifications on the subject,
4. Risk Assessment, if relevant,
5. Documents necessary or helpful in understanding the measure.

3.3.6 Editing Rules Checklist

- File should not be corrupted
- File format should be *.doc (no *.rtf)
- All changes in the document should be accepted and track changes option deactivated
- In order to avoid the creation of useless tags in the CAT tool, the colour of the fonts should be changed to Black
- Graphs and tables should be editable
- Tables of contents and numbering (chapters, paragraphs etc.) should be automatic
- No hard returns in the middle of paragraphs
- No optional hyphens,
- No indent build with spaces,
- Rows of hard returns should be replaced by a page break,
- At least one hard return should be left before a section or page breaks.
- Tables:
 - remove tabs or soft returns in column headers,
 - do not use tab to separate columns text, but use real table column option
 - do not use soft return to create extra rows, use real table row option
 - remove hard returns in the middle of cell texts
- Text boxes: as few text boxes as possible (some converters are generating a lot of text boxes to build the word document; it's better to have the text not in boxes) (Also, text in textboxes are not included in the automatic page counting.)
- As few column breaks as possible. Column breaks are not convenient to be worked with Translation tools. Tables build with column breaks need to be re-created with the standard table option of word (with enough rows and

columns to separate the text). Paragraphs build with column breaks should be either re-created in standard tables or changed into one-column text.

- Tabs should be used instead of a lot of blanks
- Generate automatic endnote and footnote
- Formatting paragraphs with appropriate Word formats. e.g.:
 - body text as "Standard"
 - titles as Heading 1, Heading 2 (needed to build an automatic table of content)
- Specific characters used for – subscript and superscript fonts should be used instead of regular fonts (e.g. m₂ instead of m2): applicable for figures, measurements, units, currencies, codes, special characters (e.g.: chemical codes), names, etc.

3.4 Standstill Period

During the standstill period, a Member State may make comments and/or detailed opinions to notifications by other Member States, this gives the opportunity to indicate potential adverse effects to Ireland or the Single Market. It also provides the opportunity to clarify any inconsistencies, uncertainties, or ask questions.

It is the responsibility of the lead Department/policy team to review any notifications and determine whether there should be a comment or detailed opinion submitted.

See paragraphs 11 – 13 of Article 6 of the Directive for further information regarding standstill periods, variations, and exemptions. See standstill period variations in Section 3.4.1.

Once a non-urgent notification is submitted through TRIS with the draft and all supporting documents, an automatic set three-month standstill period is enacted.

The draft notified regulation should not be adopted during the standstill period.

The duration of the standstill period may vary, however regardless of the length of the standstill, the EU Commission and Member States can submit 'comments' and/or 'detailed opinions' during this time. The public may also submit 'comments' through the public accessible area of TRIS, with the option of it being submitted to the EU commission confidentially or made publicly available on the TRIS website.

- i. If the EU Commission's is proposing or adopting a Directive, Regulation or Decision on the subject of the submitted notification within the 3-month standstill period, the notifying Member State may not adopt 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

3.4.1 Standstill period variations

Although the set standstill period is three months, it may vary depending on the following:

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

	Products	Information Society Services	Voluntary agreements
Initial Standstill	3 months (from date of receipt of all relevant information by the Commission through TRIS)		
Comments	No additional standstill enacted		
Detailed Opinions	Additional 3 months Total – 6 months	Additional 1 month Total – 4 months	Additional 1 month Total – 4 months
Proposal of Directive	Additional 9 months Total – 12 months ¹	Not Applicable	Not Applicable
Existing proposal for a Directive	Additional 9 months Total – 12 months ¹	Additional 9 months Total – 12 months ¹	Not Applicable

¹ The standstill period is extended additional 6 months for a total of 18 months if a common position is reached within the 12 months period

3.5 Comments

When the notifying Member State is sent comments, either by the EU Commission or other Member states, it is general practice, where possible, for them to take these comments into account for the preparation of the regulation.

The Member State has no legal obligation to reply to any comments that it receives and is free to adopt the draft regulation at the end of the standstill period without making any editions.

3.6 Detailed Opinions

The Commission and other EU countries may submit a detailed opinion or comments to the draft if they deem that the notified text may create barriers to:

- the [free movement of goods](#);
- the free provision of Information Society services;
- EU secondary legislation.

Submitting a detailed opinion is done with the intention that there should be an amendment to the proposed measure being put into place.

When a detailed opinion is submitted to a notifying Member State, they must inform the Commission of what action it proposes to take. It should be made within the extended standstill period of 6 months for goods or 4 months for Information Society services.

When there are draft texts that relate to fiscal or financial measures made by Member States, only aspects that might hinder trade, free movement of services, or the freedom of establishment of service operations should be considered. The fiscal or financial aspects should not be considered

3.7 End of Standstill Period

Once the standstill period is over, the Member State, must decide whether they are to adopt the national measure.

Dialogue between the EU Commission and Member States may continue until the draft technical regulation has been adopted.

NSAI Process for Notification Procedure

All communication for the submittal of notification, submittal of comments and/or detailed opinions shall be sent to:

Republic of Ireland EU Directive 2015/1535 National Contact Point

E-mail: EUDirective2015.1535@nsai.ie

Telephone: +353 01 807 3824

The national contact point is identified as the "Information Officer" in the description of the procedures

3.8 Submittal of a notification

See Figure 2 for the NSAI process for notification procedure for the Department to submit a notification. See the Checklist in Annex B for submitting a notification.

Ensure that all the documents and forms are filled out completely, labelled correctly, and submitted all together as outlined in the Checklist in Annex B.

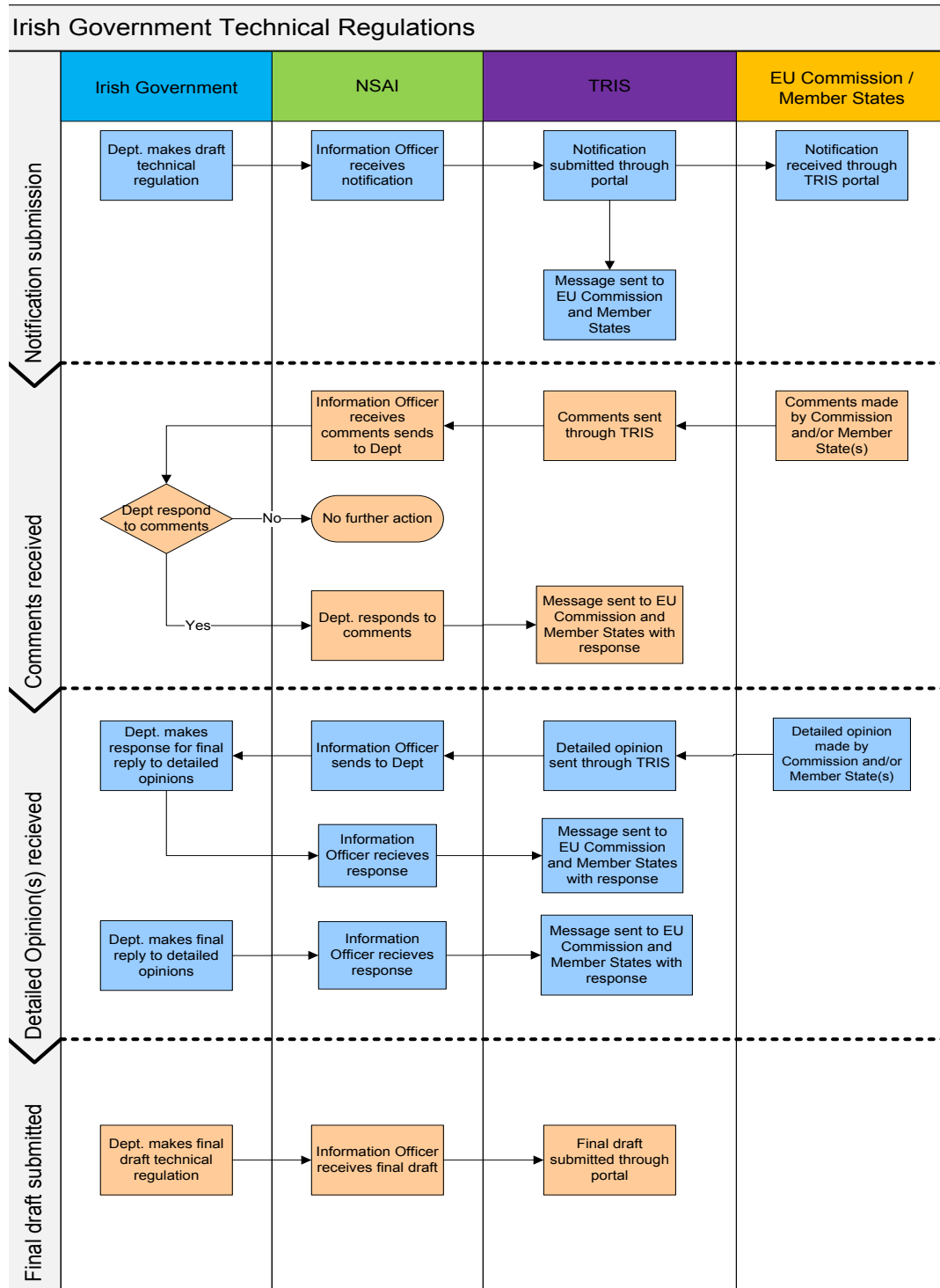


Figure 2 - Department submittal of notification

3.9 Submittal of Comment(s) and/or Detailed Opinions

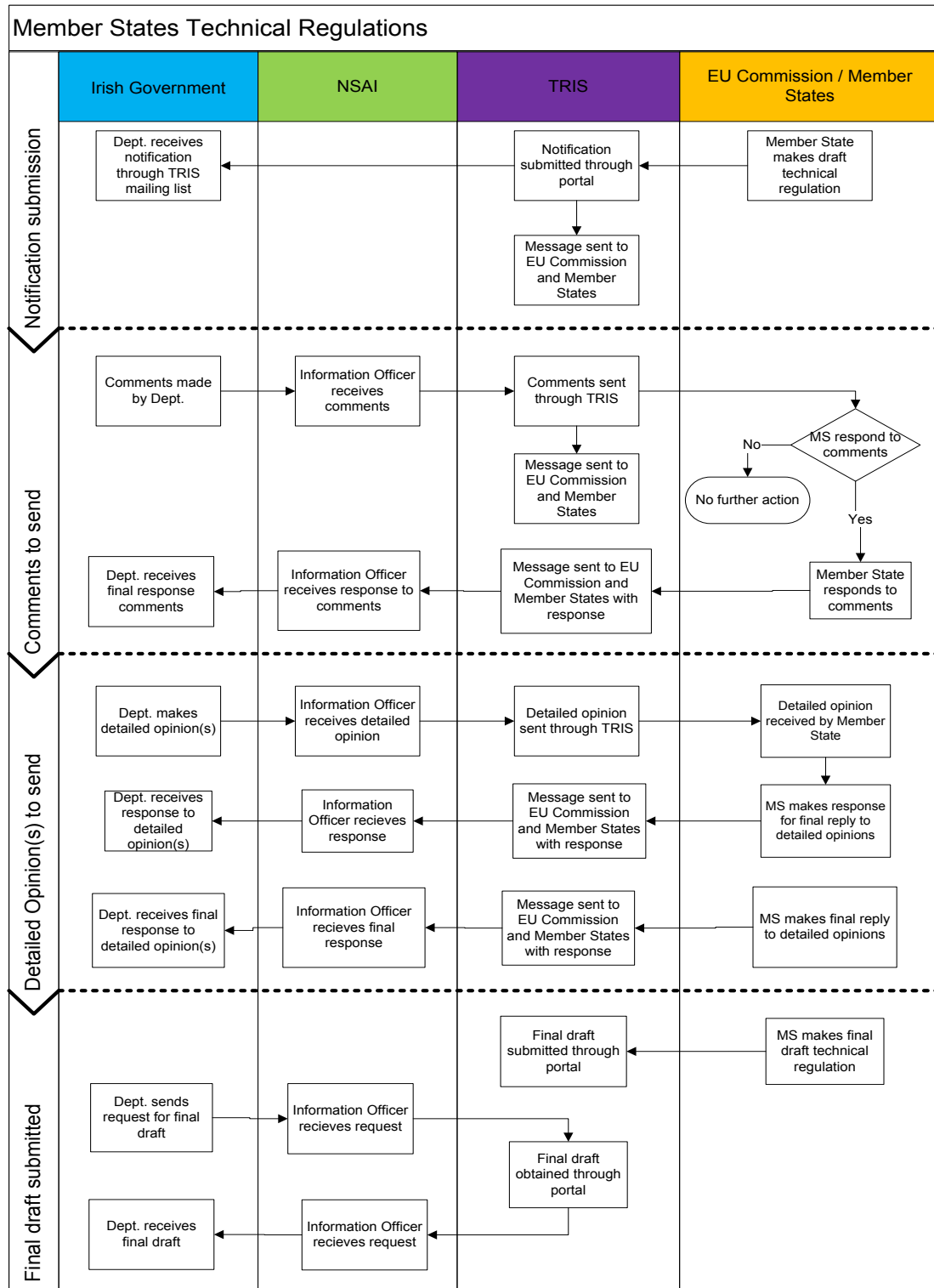


Figure 3 - Department submit comments and/or detailed opinions

The 6pt eform should be completed for submitting comments and/or detailed opinions and general communication to the Member States and the EU Commission.

The relevant sections of the form should be completed as indicated below:

A. Country

This will always be Ireland.

B. Language

The language in which the message is written. The labels will appear in the language selected.

There will be a language check when the form is submitted through TRIS, so ensure that it is selected correctly.

C. Message

The relevant message number should be selected as indicated below:

Message Type	Description	Used to react to a message type	Will be replied by a message type
7	General communication		77
77	Pursuit of Dialogue between COM and MS	7, 77, 191	77
101	Request for supplementary information		201
103	Comments from a MS		201
111	Detailed Opinion – Fiscal Measures		201
113	Detailed Opinion – Voluntary Agreement		201
115	Classical Detailed Opinion		201
117	Detailed Opinion – Information Society		201
191	Reply from reacting MS to message 201	201	77
201	Reply from the notifying MS	101, 103, 111 – 117, 301, 303, 311-317, 517-569	191
807	General communication		877
877	Dialogue between CAND, EC, and MS	807	
881	MS comments		
907	General Communication		977
977	Dialogue between EFTA, EC and MS	907	
981	Draft MS comments on EFTA notification		

You may NSAI information officer to seek guidance on the message type.

D. Department Responsible

This will always be NSAI, the relevant information to input, if it not already done is:

National Standards Authority of Ireland
1 Swift Square
Northwood
Santry, Dublin 9
D09 A0E4
Ireland
Tel: 00 353 (0)1 807 3854
Email: EUDirective2015.1535@nsai.ie

E. Originating Department

Include the following information about the Department:

- Name
- Address
- Contact Person
- Telephone number
- E-mail Address

This process may occur multiple times depending upon the Department's needs.

It should be noted that Member States are not required to respond to comments.

If the Department determines that they would like to submit a "contribution" they can do so through the TRIS public website.

3.10 Confidential Notifications

NSAI will routinely check the TRIS portal for confidential notifications. If any are found, the Information Officer will assess the notification based upon the product/service identified relevant area in the Republic of Ireland. The Information Officer will forward the notification to the relevant Department providing opportunity to react. If there is no response

3.11 Submittal of final text

Once the decision to finalise the draft text is made the Department shall e-mail the finalised draft to NSAI.

NSAI will then upload the final draft to TRIS.

The final text should be in Microsoft Word format.

4 Additional Information

4.1 Useful Links

Reference	Link
EU Directive 2015/1535	http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32015L1535&from=EN
EU Commission information about EU Directive 2015/1535	http://ec.europa.eu/growth/tools-databases/tris/en/about-the-20151535/
Access to public TRIS portal	http://ec.europa.eu/growth/tools-databases/tris/en/
The aim of the 2015/1535 Procedure	http://ec.europa.eu/growth/tools-databases/tris/en/about-the-20151535/the-aim-of-the-20151535-procedure/
NSAI Guide for Mailing List	
16pt Form A	
EU Commission guide to fill out 16pt Notification Form	
6pt Form – For comments or detailed opinions	

4.2 Contact

As the national point of contact for this Directive, NSAI will be happy to answer any questions and give you further information if you require anything whilst processing your notification. You may contact NSAI at:

Republic of Ireland EU Directive 2015/1535 National Contact Point

National Standards Authority of Ireland
1 Swift Square, Northwood
Santry, Dublin 9
D09 A0E4
Ireland

E-mail: EUDirective2015.1535@nsai.ie

Telephone: +353 01 807 3824

4.3 Exception of the message 9 (Closure of a notification)

At the moment it lays in the hands of the Commission. Just send a regular email to CENTRAL mailbox, as usual, specifying one of the following closure types:

- 1 Withdrawal by the Member State
- 2a Draft already adopted during the initial standstill period
(Case C-194/94 - CIA Security Intl)
- 2b Draft already adopted during the prolonged standstill period
(Case C-443/98 - Unilever)
- 3-1 Exception - Community acts
- 3-2 Exception - International agreements
- 3-3 Exception - Safeguard clauses
- 3-4 Exception - 92/59/EEC
- 3-5 Exception - Court of Justice
- 3-6 Exception - Commission request
- 4 Irregular procedure
- 5 Not a technical regulation
- 6 Already notified
- 7-1 Examine in the framework of 2000/13/EC
- 7-2 Examine in the framework of 93/43/EEC
- 7-3 Examine in the framework of 315/93
- 7-4 Examine in the framework of Article 88

Other message numbers:

Message type	Description	Used to react to a message type	Will be replied by a message type
1	Notification of a draft text from a MS.		
3	Receipt of draft text. <i>(auto generated)</i>		
7	General communication.		77
19	Standstill for a MS notification. <i>(auto generated)</i>		
29	Long text translated in only 3 languages <i>(auto generated)</i>		
49	Receipt of the adopted text. <i>(auto generated)</i>		

Annex A – Filling out 16pt Form

The following sections are in the 16pt eform and provide assistance in filling out the form. See Annex B for the checklist for submitting a notification.

A. Country

This will always be Ireland.

B. Language

The language in which the message is written. The labels will appear in the language selected.

There will be a language check when the form is submitted through TRIS, so ensure that it is selected correctly.

C. Department Responsible

This will always be NSAI, the relevant information to input, if it not already done is:

National Standards Authority of Ireland
1 Swift Square, Northwood
Santry, Dublin 9
D09 A0E4
E-mail: EUDirective2015.1535@nsai.ie
Telephone: +353 (01) 807 3854

D. Originating Department

The Department that is responsible for drawing up the draft.

Include the following information about the Department:

- Name
- Address
- Contact Person
- Telephone number
- E-mail Address

E. Title

The official title of the draft in full.

F. Products and/or Services Concerned

This must clearly indicate the products and/or services for the draft text.

Select the appropriate category in the boxes. i.e. B00 Construction

G. Notification under another Community Act

If the Department or another government body is notifying the draft under another EU Act, the relevant EU legislation must be selected. If it is not listed, it must be specified under "Other/Additional Information"

If there is a notification being made under Directive 2006/123/EC on services in the internal market, one of the options must be done:

- 1) Tick the "Information society services only" box
- 2) Specify the provisions of its notified draft which contain requirements referred to in Article 15§2 of Directive 2006/123/EC and select the requirements referred to the draft amongst those listed

If you need to make a notification under any of these see the relevant parties to contact:

EU Legislation	Department Responsible
Regulation (EC) no 315/93 contaminants in food	Food Safety Authority of Ireland (FSAI)
Regulation (EC) no 852/853/854/2004 relation to the hygiene of foodstuffs	Food Safety Authority of Ireland (FSAI)
Regulation EC no 1924/2006 concerning nutrition and health claims made on foods	Food Safety Authority of Ireland (FSAI)
Regulation (EC) no 1925/2006 concerning the addition of vitamins and minerals and certain other substances to foods	Food Safety Authority of Ireland (FSAI)
Directive 94/62/EC on packaging and packaging waste	Department of Housing, Planning, Community and Local Government
Regulation (EU) no 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers	Food Safety Authority of Ireland (FSAI)
Directive 2006/123/EC on services in the internal market	Department of Jobs, Enterprise and Innovation imi@djei.ie

H. Main Content

A summary of the draft with a maximum of 20 lines.

I. Brief Statement of Grounds

The grounds justifying the drawing up of this draft with a maximum of 10 lines.

Points in other parts of the form should not be repeated.

J. Reference Documents, Basic Texts

One of the following must be indicated:

1. If no Basic Text exists
2. If the draft aims in particular at limiting the marketing or use of a chemical substance, preparation or product for reasons relating to public health, protection of the consumer or of the environment, under Article 5 (1), either

a summary or the references of pertinent data relating to the substance, preparation or product referred to and those relating to known and available substitute products, to the extent that such information is sent as supporting documentation and made available, as well as the expected effects of the measure with regard to public health or protection of the consumer and the environment, with an analysis of the risks incurred, in appropriate cases, pursuant to the general principles of evaluating the risks of chemical products as referred to in Article 10.4 of Regulation (EEC) 793/93 if it concerns an existing substance or to Article 3.2 of Directive 67/548/EEC (as amended by Directive 92/32/EEC) if it concerns a new substance.

3. The references of the Basic Texts required to understand and assess the draft. Mention of this reference implies that the Basic Texts is communicated to the Commission at the same time as the draft.
4. If the Basic Texts have been forwarded in the framework of a previous notification, then the number must be specified

K. Invocation of the Urgency Procedure

If this is selected, provide a precise and detailed justification of the grounds in support of the urgency request for of the measures in question, pursuant to Article 9.7 of the Directive. If you tick the Yes for "11. Invocation of the Urgency Procedure" you need to complete "12. Grounds for the Urgency" and provide relevant supporting information and documentation for it.

See Section 3.3.3. for additional information.

L. Confidentiality

Indicate whether the information communicated under is to be treated as confidential, pursuant to Article 5(4) of the Directive, if it is not applicable, leave blank.

If the Yes box is ticked, stipulate the reasons in support of its request in the box below the Yes.

See Section 3.3.2. for additional information.

M. Fiscal Measures

Indicate if the draft is a fiscal measure or if it is not applicable, leave blank.

If yes, the Commission will send out a message 005.

N. Impact Assessment

If an impact assessment is not applicable, leave blank. If it is applicable, do one of the following:

Indicate if the impact assessment is sent in a separate file, indicate the name of the document, which will be sent when submitting the notification

Write the information in the box provided.

O. TBT and SPS aspects

Select one of the following TBT Aspects:

1. Select "Yes" if the draft will be notified in the framework of the TBT Agreement on TBTs (Agreement on Technical Barriers to Trade).
2. Select "No – The draft is not a technical regulation nor a conformity assessment" if the draft is neither a technical regulation nor a conformity assessment within the meaning of Appendix 1 of the TBT Agreement.
3. Select "No – The draft is in conformity with an international standard" if the draft is in conformity with an international standard
4. Select "No – The draft has no significant impact on international trade" if the draft has no significant impact on international trade

Select one of the following SPS Aspects

1. Select "Yes" if the draft will be notified in the framework of the SPS Agreement (Agreement on Sanitary and Phytosanitary Measures).
2. Select "No – The draft is not a sanitary or phytosanitary measure" if the draft is not a sanitary or phytosanitary measure within the meaning of Appendix A to the SPS agreement.
3. Select "No – Content is the same as that of an international standard, directive or recommendation" if the tenor of the draft is substantially the same as that of a standard, directive or international recommendation.
4. Select "No – The draft has no significant impact on international trade" if the draft has no significant impact on international trade

Annex B – Notification Submittal Checklist

16pt Form

	Filled out electronically
	Correct case of words
	Document File labelled i.e.

Select or input the relevant information as indicated on the checklist

Section of Form	Checklist
Country	Ireland
Language	EN – English
Department Responsible	NSAI information details
Originating Department	Includes Department name, address, contact person, e-mail address and telephone number
Title	Concise, includes all necessary information
Products and/or Services Concerned	Selected correct option i.e. B00 Construction, with description in text box
Notification under another Community Act	All relevant ones selected, additional information provided if required for selection
Fiscal Measures	Check if selected; additional information provided if selected
Impact Assessment	Check if selected; additional information provided if selected
TBT aspect	Selected one of the options
SPS aspect	Selected one of the options
"Other/Additional Information"	Check if selected; additional information provided if selected
Main content	Summary, maximum 20 lines
Brief Statement of Grounds	Grounds, maximum 10 lines
Reference Documents, Basic Texts	One of multiple selections of the 4 options
Invocation of the Urgency Procedure	Select option, additional information provide if required for selection
Confidentiality	Check if selected; additional information provided if selected

Draft Text

	Filled out electronically
	Correct case of words
	Document File labelled i.e.
	In Microsoft Word .doc format type
	Tracked changes are accepted/rejected and track changes is turned off
	Comments are deleted

Draft text and Impact Assessment should not contain track changes, nor comments, nor OLE references to external software parts, like drawings or excel tables.

If such elements are necessary, they must be included as images like windows bitmap in the document itself.

A language check is performed, and the loading can be refused if the language is not correctly selected in the drop down.

Additional Documents

Impact Assessment	If relevant, provide document as indicated above
Reference Documents, Basic Texts	If relevant, provide document as indicated above
Invocation of the Urgency Procedure	If relevant, provide document as indicated above

Notification procedure reminder:

	Filled out electronically
	Correct case of words
	Document File labelled i.e.
	In Microsoft Word .doc format type
	Tracked changes are accepted/rejected and track changes is turned off
	Comments are deleted