



**GUIDANCE – How to submit a draft regulation**  
**(FORM A (PDF VERSION))**

This guidance is to assist departments completing the notification form.

The start of the form is shown below.

European Commission  
Enterprise and Industry v. 1.1

**Directive 98/34/EC**

**Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine -  
Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums -  
Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie -  
Notificação - Hlásenie-Obvestilo - Ilmoitus - Anmälan - Нотификация**

**Country**  
UK - United Kingdom

**Language**  
EN - English

Ensure that the country and language are set to UK and English respectively.

Do not change 3A – that should read as shown below:

**3A. Department Responsible**

Department for Business, Innovation and Skills  
Innovation & Enterprise Group  
1 Victoria Street, London, SW1H 0ET.  
Email: 9834@bis.gsi.gov.uk.

**3B. Originating Department**

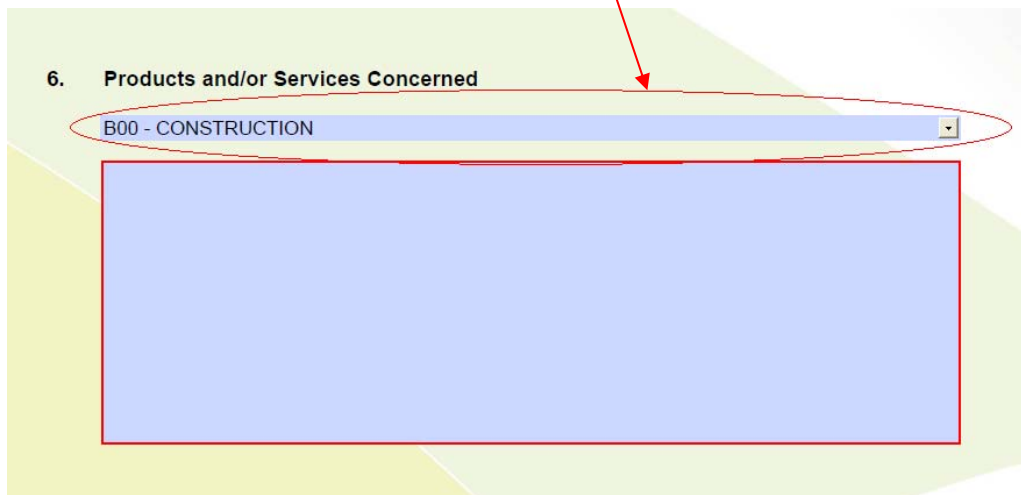
**3B.** Insert name of the Department responsible for drawing up the draft regulation.

**5.** Insert full title of draft regulation.

6. Indicate products and/or services covered by the draft technical regulation. To do this click on the drop down list

6. **Products and/or Services Concerned**

B00 - CONSTRUCTION



....Then highlight the appropriate category.

Detail can be provided in the text box below:

6. **Products and/or Services Concerned**

B00 - CONSTRUCTION

B00 - CONSTRUCTION

B10 - Construction materials

B20 - Safety

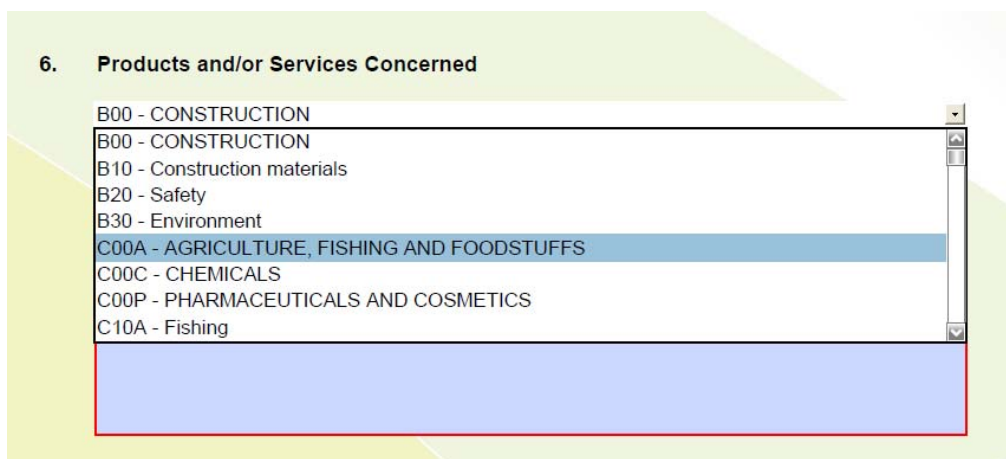
B30 - Environment

C00A - AGRICULTURE, FISHING AND FOODSTUFFS

C00C - CHEMICALS

C00P - PHARMACEUTICALS AND COSMETICS

C10A - Fishing



7. If draft regulation is also notified under another Community Act, indicate the relevant Community legislation. The list of examples is not exhaustive.

**7. Notification under another Community Act**

☐ Regulation (EC) n° 315/93 on contaminants in food

☐ Regulations (EC) n° 852/853/854/2004 relating to the hygiene of foodstuffs

☐ Regulation (EC) n° 1924/2006 concerning nutrition and health claims made on foods

☐ Regulation (EC) n° 1925/2006 concerning the addition of vitamins and minerals and certain other substances to foods

☐ Directive 94/62/EC on packaging and packaging waste

☐ Directive 2000/13/EC on the labelling and presentation and advertising of foodstuffs

☐ Directive 2006/123/EC on services in the internal market

☐ 98/48/EC information society services only

or specify provisions

<input type="checkbox"/> quantitative or territorial restrictions	<input type="checkbox"/> obligation to take a specific legal form
<input type="checkbox"/> requirements which relate to the shareholding of a company	<input type="checkbox"/> requirements which reserve access to particular providers
<input type="checkbox"/> a ban on having more than one establishment in the territory of the same State	<input type="checkbox"/> requirements fixing a minimum number of employees
<input type="checkbox"/> fixed tariffs with which the provider must comply	<input type="checkbox"/> obligation to supply other specific services

8. Describe the main content of draft regulations - summarise the content of the draft technical regulation. The length of the summary should be in keeping with the importance of the draft. It is important to include at least a few keywords to summarise the text in order to facilitate computer retrieval.
9. Indicate the reasons and necessity (i.e. the grounds) for making the regulation. Do not repeat information already under other points in the notification message.

10. The draft measure must be forwarded with the notification, this part relates to other documents necessary for an understanding of the measure (basic texts). Note that consultation documents are not accepted as draft text.

10. Reference Documents, Basic Texts

☐ No Basic Text exists

☐ Limit the marketing or use of a chemical substance, preparation or product

☐ References of the Basic Texts

☐ Basic Texts have been forwarded within the framework of a previous notification

Reference of previous notification(s)

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>
<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>

If the draft aims in particular to limit 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, Member States must also forward, under Article 8.1(4) of Directive 98/34/EC, 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 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.

12. If the emergency procedure is used then a precise and detailed justification of the grounds in support of the emergency of the measures in question, pursuant to Article 9.7 of the Directive, **must** be provided.
13. Notifications are normally not confidential but if required pursuant to Article 8.4 of the Directive, the reasons in support of your request **must** be stipulated.
14. If the measure is considered as a fiscal measure ie a solely fiscal measure in accordance with Article 1.11 of the Directive.
15. If no Impact Assessment is available, state "Impact Assessment not available", note that internet links are not accepted.

16. TBT aspect: Indicate whether the draft will be notified within the framework of the TBT Agreement (Agreement on Technical Barriers to Trade - [http://www.wto.org/english/docs\\_e/legal\\_e/17-tbt\\_e.htm](http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm)). If you indicate yes, you must separately send an appropriate notification under the TBT Agreement via the UK TBT contact point - currently [marilyn.swain@bis.gsi.gov.uk](mailto:marilyn.swain@bis.gsi.gov.uk).

**16. TBT and SPS aspects**

**TBT aspect**

☐ Yes

☐ No - The draft is not a technical regulation nor a conformity assessment

☐ No - The draft is in conformity with an international standard

☐ No - The draft has no significant impact on international trade

**SPS aspect**

☐ Yes

☐ No - The draft is not a sanitary or phytosanitary measure

☐ No - Content is the same as that of an international standard, directive or recommendation

☐ No - The draft has no significant impact on international trade

SPS aspect: Indicate whether the draft will be notified within the framework of the Agreement on SPS (Agreement on Sanitary and Phytosanitary Measures - [http://www.wto.org/english/tratop\\_e/sps\\_e/sps\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/sps_e.htm)). If you indicate yes, you must separately send an appropriate notification under the SPS Agreement via the SPS contact point, currently [Katherine.quinteros@defra.gsi.gov.uk](mailto:Katherine.quinteros@defra.gsi.gov.uk).

**Points to note:**

- **Some notified draft regulations will require a provision for the recognition of equivalent standards and testing in other Member States.**
- **Departments should make their own arrangements to comply with this requirement of the Directive:**

Article 12 of the Directive states: “When Member States adopt a technical regulation, it shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of its official publication. The method of making such reference should be laid down by Member States”.

**Departments are advised that it would be preferable to include a**

reference to the Directive in the instrument itself (such as the Explanatory Note to the Regulations). The following is an example of a form of words used:

*“These regulations were notified in draft to the European Commission in accordance with Directive 98/34/EC, as amended by Directive 98/48/EC.*

If this is not possible, Departments should include the following words at point 8 of this notification form:

*“The UK will fulfil its obligation under Article 12 of Directive 98/34/EC when these regulations are officially published”*

Send by email attaching the draft measure and any necessary background documents to:

Email: <a href="mailto:9834@bis.gsi.gov.uk">9834@bis.gsi.gov.uk</a>
Tel: 020 7215 5440

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**PLEASE make sure you send us the final text when the measure is adopted, or tell us if you have decided not to proceed to make the measure.**

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