

中国 WTO/TBT 国家通报咨询中心

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From: China WTO/TBT National Notification & Enquiry Center.	Tel: 86-10-57954638 Fax: 86-10-57954689 E-mail: tbt@customs.gov.cn
Subject: Comments from P. R. China on Notification G/TBT/N/EU/1145 Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications	

Comments from P. R. China on Notification

G/TBT/N/EU/1145

Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

Dear Sir or Madam,

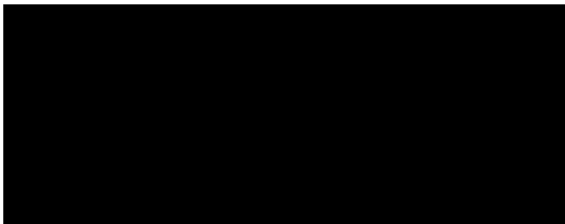
We appreciate the opportunity to submit comments on the notified draft proposed by EU.

Enclosed please find comments in English and Chinese.

Please acknowledge receipt of the comments by e-mail to tbt@customs.gov.cn.

Thank you very much in advance for EU taking into account comments from P.R. China. Your formal reply will be appreciated.

Best regards,



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Comments from P. R. China on Notification

G/TBT/N/EU/1145

Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

The People's Republic of China appreciates EU for fulfilling the transparency obligation under WTO, as well as for the opportunities for other WTO Members to make comments on the notification G/TBT/N/EU/1145. According to Article 2.9.4 of the WTO/TBT Agreement "without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account", China would like to put forward the following comments on the notified regulations and hope EU take these comments into consideration. The detail comments as follows:

1. It is recommended to further clarify the specific communication method of "digital contact" in Article 11 (1) (a), the reasons are as follows:

The explanatory memorandum in Chapter V of this notice states that the main purpose of establishing "digital contact" is to facilitate effective communication between economic practitioners and regulators. It recommends providing clear guidance to economic practitioners on compliance through examples (such as email addresses, online contact windows, etc.).

2. It is recommended to change the requirement for marking the postal address in Article 11 (2) (c) of the nameplate to an optional requirement for the following reasons:

The inclusion of more effective digital contact details can meet the communication needs between economic operators and national authorities. Considering the limited space on product labels, making the postal address non-mandatory can minimize resource waste caused by design changes resulting from the need to accommodate new digital contact details within the limited physical space. The relevant wording could be revised to: "Manufacturers shall indicate their name, registered trade name or trademark, and digital contact details on the radio equipment, and may include their postal address. If the size or nature of the radio equipment..."

3. It is recommended to delete the statement in Article 11(2)(d) that the paper version of safety information is mandatory for the following reasons:

The lack of clear criteria for defining the phrase "even if the intended target is not a consumer" in the draft circular may result in manufacturers being forced to adopt paper carriers as the only form of safety information to avoid legal risks. This is contrary to the first paragraph of this article that manufacturers can choose specific delivery methods based on the expected scenario. ("instructions and safety

information may be provided in electronic form ..." and "when deciding on the format of instructions and safety information, manufacturers shall take into account the intended use of the radio equipment and its foreseeable end-users").

Moreover, the product body has necessary warning signs to remind end users, and safety information is usually used as a specific supplement to the relevant warning signs. Forced paper carriers will lead to additional paper waste and carbon emissions every year, which is contrary to the goals of product information sustainability, low carbon, and digitalization pursued by the European Commission.

In conclusion, it is proposed to delete "For radio equipment intended for consumer use or likely to be used by consumers under reasonably foreseeable conditions, even if it is not designed for consumer use, the manufacturer shall provide safety information in paper format." The safety information must be readily perceptible and legible to the consumer"

4. It is recommended to amend the relevant instructions for use and safety information in Article 11(2)(d) for the following reasons:

Article 11 (2) (d) contains several requirements requiring manufacturers to comprehensively consider the product's intended use scenarios and foreseeable misuse when compiling instructions and safety information. It is recommended that the relevant provisions be consolidated and simplified to improve the conciseness of the regulatory language and the efficiency of implementation.

It is recommended that the statement "When compiling safety information, manufacturers should consider the end-user's intended use scenarios and foreseeable misuse scenarios, and at the same time evaluate the role of instructions in ensuring safety" be deleted and replaced directly with "When determining the specific format and content of instructions and safety information, manufacturers should comprehensively consider the intended use and foreseeable end-users of the radio equipment."

5. It is suggested that in Article 11(2)(d), the priority of the applicable scenario of the method for obtaining the specification should not be set. The reasons are as follows:

(a) Access to instructions typically carries a lot of information (text descriptions, website addresses, specific implementation steps, etc.), and should not be mandatory for priority inclusion on the product itself. This is especially true for large equipment, where including such information on the product itself is less efficient and direct compared to providing it in accompanying documentation. It is recommended that the EU grant manufacturers the flexibility to decide, based on different practical business scenarios, what would be most beneficial for the end user's experience. A specific amendment suggestion would be: "When the user manual referred to in the first item is provided in electronic form, the manufacturer shall: (a) provide it on the radio equipment itself, or, if not feasible, indicate it on its packaging or in the accompanying documentation..."

6. It is proposed to change the requirement to indicate a mailing address on the nameplate in Article 11 (4) (a) to an optional requirement for the following reasons:

Adding more effective digital contact information can already meet the needs of economic operators and national authorities for efficient communication. Furthermore, considering the limited space on product labels, making the mailing address optional can minimize the waste of resources caused by design changes due to the physical space occupied by the added digital contact information, which restricts the label layout. The relevant wording could be revised to read, "Importers should indicate on radio equipment their name, registered trade name or registered trademark, and digital contact information. They may also indicate their postal address, if this is not feasible..."

7. It is recommended to further optimize the relevant provisions concerning the general specifications in Article 11(6) 1(a)(b).

The current clause fails to clearly define the relationship between general specifications and harmonized standards, and lacks procedural provisions regarding the development, use, and withdrawal of general technical specifications. This can lead to confusion when enterprises choose standards and may conflict with EU standardization regulations (especially in clause (b)), hindering the free movement of goods within the single market.

It is recommended to clarify that general specifications should only serve as a supplementary tool when harmonized standards do not cover or inadequately cover specific requirements, and to reference the language used in the medical industry. The applicability should be specifically limited to the following two situations: (a) when the requirements of Article 3 are not covered by harmonized standards; (b) when the requirements of Article 3 are not fully covered by harmonized standards published in the Official Journal of the European Union or their parts. Additionally, a transparent, stakeholder-inclusive, professional, and inclusive development process should be established to ensure the scientific rigor and international credibility of general specifications.

8. It is recommended to delete the provision in Article 11(8)(b).

In the previous amendments to the RED, there was no mention of the DPP (Digital Product Passport). Therefore, the applicability of the conformity declaration with regard to DPP requirements should be governed by the relevant regulations on DPP, rather than being stipulated in the RED. Additionally, Article 18 of the RED primarily concerns the requirements for the Declaration of Conformity (DoC) and should not address information related to user manuals. Deleting this provision would avoid confusion of roles and ensure the provisions of the RED are clearer, improving the operability and consistency of the regulation.

Comments in Chinese are in below:

中国对 G/TBT/N/EU/1145 通报的评议意见

中国政府赞赏欧盟履行 WTO 透明度义务，给予其他 WTO 成员评议 G/TBT/N/EU/1145 通报的机会，根据 WTO/TBT 协定 2.9.4 条“无歧视地给予其他成员合理的时间以提出书面意见，并对这些书面意见和讨论的结果予以考虑

的规定”，请欧盟对中方的评议意见予以考虑并做出答复。中方具体意见如下：

1.建议进一步明确 Article 11 (1) (a) 中“digital contact”的具体通信方式，理由如下：

此次通报解释性备忘录第五章中指出设立“数字联系”的主要目的是便于经济从业者和监管机构之间进行有效沟通，建议通过实例（email 地址、在线联系窗口等）清晰指导经济从业者合规。

2.建议将 Article 11 (2) (c) 铭牌中标注邮寄地址的要求改为可选性要求，理由如下：

增加更有效的数字联系方式已可满足经济经营者和国家当局的有效沟通需求，同时考虑到产品标签空间有限，将邮寄地址变为非强制项，可最大限度避免因新增数字联系方式占用物理空间导致标签布局受限而引发的设计变更所产生的资源浪费。可将相关表述改为“制造商应在无线电设备上标明其名称、注册号或注册商标以及数字联系方式，并可标注其邮政地址。若无线电设备的尺寸或性质……”

3.建议删除 Article 11 (2) (d) 中强制要求提供纸质版本安全信息的表述，理由如下：

通报草案中“即使预期对象不是消费者”的表述缺乏明确的界定标准，可能导致制造商不得不为规避法律风险而被迫采取纸质载体作为安全信息的唯一形式，而这与本条首段中提出的制造商可以结合预期场景选择具体提供方式相矛盾。（“使用说明与安全信息可根据……以电子形式提供”以及“制造商在决定使用说明与安全信息的具体格式时，应综合考虑无线电设备的预期用途及可预见的最终用户”）。

此外产品本体已具备必要的警告标识予以提醒最终用户，安全信息通常是作为相关警告标识的具体补充。强制纸质载体将导致每年额外产生纸质废弃物并会带来碳排放，与欧盟委员会所追求的产品信息可持续性、低碳、数字化等目标相悖。

综上，建议删除“对于供消费者使用或在合理可预见条件下可能被消费者使用的无线电设备（即使非专为消费者设计），制造商应提供纸质格式的安全信息。该安全信息须保证消费者易于察觉且清晰可辨”。

4.建议对 Article 11 (2) (d) 中编制使用说明和安全信息的相关表述做修订，理由如下：

Article 11 (2) (d) 中包含多项关于制造商编制使用说明及安全信息时需综合考虑产品预期使用场景及可预见误用情形的要求，建议对相关条款内容予以合并简化处理，以提升法规表述的精炼性和执行效率。建议删除“制造商编制安全信息时，应考量最终用户的预期使用场景及可预见的误用情景，同时评估使用说明对保障安全所起的作用”相关表述，直接在“制造商在确定使用说明与安全信息的具体格式及编制内容时，应综合考虑无线电设备的预期用途及可预见的最终用户”，予以体现。

5.建议 Article 11 (2) (d) 中不设定说明书获取方式适用场景的优先级，理由

如下：

(a) 获取说明书途径通常承载的信息内容较多（文字描述、网址、具体实施步骤等），不应强制优先在产品本体上体现。特别是对于大型设备而言，在本体上体现并不如在随附文件中来得更为高效直接，建议欧盟给予制造商选择权，结合不同实际业务场景做出最有利于最终用户使用的决定。具体修改建议为：“当第一项所述使用说明以电子形式提供时，制造商应：（a）在无线电设备本体上提供，如不可行，则在其包装或随附文件中注明……”

6.建议将 Article 11 (4) (a) 铭牌中标注邮寄地址的要求改为可选性要求，理由如下：

增加更有效的数字联系方式已可满足经济经营者和国家当局的有效沟通需求，同时考虑到产品标签空间有限，将邮寄地址变为非强制项，可最大限度避免因新增数字联系方式占用物理空间导致标签布局受限而引发的设计变更所产生的资源浪费。可将相关表述改为“进口商应在无线电设备上标明其名称、注册号或注册商标以及数字联系方式，并可标注其邮政地址，如不可行……”

7.建议进一步优化 Article 11 (6) 1 (a) (b) 中有关通用规范的相关表述。

当前条款未清晰界定通用规范与协调标准的关系，且缺乏关于通用技术规范制定、使用和撤销的程序性表述，易导致企业选用标准时产生混淆，并与欧盟标准化法规特别是 (b) 条款相冲突，不利于单一市场货物自由流通。

建议明确通用规范仅作为协调标准未覆盖或覆盖不充分时的补充工具，并参考医疗行业表述，将适用情形具体限定为以下两种：（a）第 3 条要求未被协调标准涵盖；（b）第 3 条要求未被已公布于《欧盟官方公报》的协调标准或其部分充分涵盖。同时，应建立透明、利益相关方参与、专业且包容的制定程序，确保通用规范的科学性与国际公信力。

8.建议删除 Article 11 (8) (b) 的表述。

在前文关于 RED 的修订中，并未提及 DPP 的相关描述，因此，符合性声明如何适用 DPP 的要求，应由 DPP 的相关法规进行约束，而非在 RED 中规定。此外，RED Article 18 主要是针对符合性声明（DOC）的要求，不应涉及使用说明的信息。删除该条款表述，可避免条款职能混淆，确保 RED 的条款更加清晰，提高法规的可操作性和一致性。