Council of the European Union
General Secretariat

Interinstitutional files:
2022/0279 (COD)

Brussels, 08 May 2023

WK 6139/2023 INIT

LIMITE

MI
COMPET
IND
CODEC

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

NOTE

From:	LU Delegation
To:	Working Party on Technical Harmonisation (SMEI Omnibus)
N° prev. doc.:	WK 4856 2023
Subject:	SMEI Omnibus Directive and Regulation - Comments on template provisions by LU

Template provisions for SMEI Omnibus Directive and SMEI Omnibus Regulation

LU COMMENTS

Amendments to Directive/Regulation […]

In Directive/Regulation […], the following Chapter […] is inserted:

"CHAPTER […]
EMERGENCY PROCEDURES

Article 1a
Application of emergency procedures

1. *Directives:* Member States shall ensure that measures taken to transpose Articles 1b to 1g of this [Directive] only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this [Directive].

   Regulations: Articles 1b to 1g of this [Regulation] shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this [Regulation].

2. [*Only for amendments to Directives*: Member States shall ensure that measures taken to transpose] Articles 1b to 1g apply exclusively to [name of the goods covered by the Directive/Regulation], which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. [*Only for amendments to Directives*: Member States shall ensure that measures taken to transpose] Articles 1b to 1g [*only for amendments to Regulations:*, except as regards provisions concerning the powers of the Commission,] apply during the Single Market emergency mode.

   However, Article 1c(2), second subparagraph, and Article 1c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to [name of the goods covered by the Directive/Regulation] placed on the market in accordance with Articles 1c to 1f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article [reference to the corresponding Article on the committee procedures in the Directive/Regulation].

Article 1b

Prioritisation of the conformity assessment of crisis-relevant [name of the goods covered by the Directive/Regulation]

1. This Article shall apply to all [name of the goods covered by the Directive/Regulation] designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article [reference to the corresponding Article on the conformity assessment procedures in the Directive/Regulation] requiring mandatory involvement of a notified body.

2. The notified bodies shall process all applications for conformity assessment of [name of the goods covered by the Directive/Regulation] designated as crisis-relevant goods as a matter of priority.

3. All pending applications for conformity assessment of such [name of the goods covered by the Directive/Regulation] shall be processed as a matter of priority, ahead of any other applications for conformity assessment of [name of the goods covered by the Directive/Regulation], which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of [name of the goods covered by the Directive/Regulation] designated as crisis-relevantgood, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 1a.

4. The prioritisation of applications for conformity assessment of [name of the goods covered by the Directive/Regulation] pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for [name of the goods covered by the Directive/Regulation] designated as crisis-relevant goods in respect to which they have been notified.

Article 1c

Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body

1. By way of derogation from Article [reference to the corresponding Article on the conformity assessment procedures in the Directive/Regulation], any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of specific [name of the goods covered by the Directive/Regulation] which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring mandatory involvement of a notified body, referred to in that Article have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated.

2. The manufacturer of [name of the goods covered by the Directive/Regulation] subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the [name of the goods covered by the Directive/Regulation] concerned complies with all the applicable essential requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.

~~**The manufacturer, [*in some cases:* the importer and the distributor] shall also deploy all reasonable measures to ensure that the [name of the goods covered by the Directive/Regulation], which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.**~~

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the [name of the goods covered by the Directive/Regulation] may be placed on the market, including:

   (a) a description of the procedures, by means of which the compliance with the applicable essential requirements of this [Directive/Regulation] was successfully demonstrated;

   (b) specific requirements regarding the traceability of the [name of the goods covered by the Directive/Regulation] concerned;

   (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated;

   (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the [name of the goods covered by the Directive/Regulation] concerned;

   (e) measures to be taken with respect to the [name of the goods covered by the Directive/Regulation] concerned upon expiry of the authorisation in order to ensure that the [name of the goods covered by the Directive/Regulation] concerned is ~~**brought back in**~~ complian**t**~~**tee**~~ with all the requirements of this [Directive/Regulation].

4. By way of derogation from Articles [reference to the corresponding Article on the free movement in the Directive/Regulation] and [reference to the corresponding Article on the rules and conditions for affixing the CE marking and the identification number of the notified body in the Directive/Regulation], [name of the goods covered by the Directive/Regulation], for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not ~~**leave the territory of the Member State which has issued the authorisation and shall not**~~ bear the CE marking. **The mutual recognition principle shall be applied with regard to the validity of authorisation issued by the competent national authorities of another Member State.**

5. The market surveillance authorities of ~~**the**~~ Member State**s**~~**, whose competent authority has granted an authorisation pursuant to paragraph 1,**~~ shall be entitled to take all corrective and restrictive measures at national level provided for under **Regulation (EU) 2019/1020 and** this [Directive/Regulation] with respect to such [name of the goods covered by the Directive/Regulation].

6. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of [name of the goods covered by the Directive/Regulation] in accordance with paragraph 1.

7. The application of Articles 1a to 1g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article [reference to the corresponding Article on

the conformity assessment procedures in the Directive/Regulation] on the territory of the Member State concerned.

8. By way of derogation from Article 1a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 also after the deactivation or expiry of the Single Market Emergency mode.

Article 1d

Presumption of conformity based on national and international standards

Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that the [name of the goods covered by the Directive/Regulation] which complies with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential requirements set out in Article [reference to the corresponding Article on the essential safety requirements in the Directive/Regulation], complies with those essential requirements in either of the following cases:

(a) where no reference to harmonised standards covering the relevant essential requirements set out in Article [reference to the corresponding Article on the essential safety requirements in the Directive/Regulation] is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;

(b) severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Article [reference to the corresponding Article on the essential safety requirements in the Directive/Regulation] of this [Directive/Regulation] and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

Article 1e

Adoption of common specifications conferring a presumption of conformity

1. Where [name of the goods covered by the Directive/Regulation], has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such [name of the goods covered by the Directive/Regulation] to cover the essential requirements set out in Article [reference to the corresponding Article on the essential safety requirements in the Directive/Regulation] in either of the following cases:

(a) where no reference to harmonised standards covering the relevant essential requirements set out in Article [reference to the corresponding Article on the essential safety requirements in the Directive/Regulation] has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;

(b) where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Article [reference to the corresponding Article on the essential safety requirements in the Directive/Regulation] and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article [reference to the corresponding Article on the committee procedures in the Directive/Regulation]. They shall apply to [name of the goods covered by the Directive/Regulation] placed on the market until the last day of the period for which the Single Market emergency remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article [reference to the presumption of conformity in the Directive/Regulation], [name of the goods covered by the Directive/Regulation] which is in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Article [reference to the corresponding Article on the essential safety requirements in the Directive/Regulation] covered by those common specifications or parts thereof.

4. By way of derogation from Article 1a(3), first subparagraph, unless there is sufficient reason to believe that the [name of the goods covered by the Directive/Regulation] covered by the common specifications referred to in paragraph 1 of this Article presents a risk to the health or safety of persons, the [name of the goods covered by the Directive/Regulation] in compliance with those common specifications which has been placed on the market shall be deemed compliant with this [Directive/Regulation] after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Article [reference to the corresponding Article on the essential safety requirements in the Directive/Regulation], it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question.

~~***Article 1f***~~

~~**Adoption of mandatory common specifications**~~

~~**1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the**~~

~~essential requirements set out in Article [reference to the corresponding Article on the essential safety requirements in the Directive/Regulation] for [name of the goods covered by the Directive/Regulation], which has been designated as crisis-relevant goods.~~

~~2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article [reference to the corresponding Article on the committee procedures in the Directive/Regulation] and they shall apply to [name of the goods covered by the Directive/Regulation] placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~

~~3. By way of derogation from Article 1a(3), first subparagraph, unless there is sufficient reason to believe that the [name of the goods covered by the Directive/Regulation] covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the [name of the goods covered by the Directive/Regulation] in compliance with those common specifications which has been placed on the market shall be deemed compliant with this [Directive/Regulation] after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~

Article 1g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for [name of the goods covered by the Directive/Regulation] designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for [name of the goods covered by the Directive/Regulation] designated as crisis-relevant goods.'