



**2017/0353(COD)**

25.5.2018

# **AMENDMENTS**

## **37 - 177**

**Draft opinion**  
**Miroslav Mikolášik**  
(PE620.896v01-00)

Rules and procedures for compliance with and enforcement of Union  
harmonisation legislation on products

Proposal for a regulation  
(COM(2017)0795 – C8-0004/2018 – 2017/0353(COD))



**Amendment 37**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Title 1**

*Text proposed by the Commission*

Proposal for a  
REGULATION OF THE EUROPEAN  
PARLIAMENT AND OF THE COUNCIL  
laying down rules and procedures for  
compliance with and enforcement of Union  
harmonisation legislation on products and  
amending Regulations (EU) No 305/2011,  
(EU) No 528/2012, (EU) 2016/424, (EU)  
2016/425, (EU) 2016/426 and (EU)  
2017/1369 of the European Parliament and  
of the Council, and Directives 2004/42/EC,  
2009/48/EC, 2010/35/EU, 2013/29/EU,  
2013/53/EU, 2014/28/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  
(Text with EEA relevance)

*Amendment*

Proposal for a  
REGULATION OF THE EUROPEAN  
PARLIAMENT AND OF THE COUNCIL  
laying down rules and procedures for  
compliance with and enforcement of Union  
harmonisation legislation on products **and**  
**Member States' legislation on products,**  
and amending Regulations (EU) No  
305/2011, (EU) No 528/2012, (EU)  
2016/424, (EU) 2016/425, (EU) 2016/426  
and (EU) 2017/1369 of the European  
Parliament and of the Council, and  
Directives 2004/42/EC, 2009/48/EC,  
2010/35/EU, 2013/29/EU, 2013/53/EU,  
2014/28/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  
(Text with EEA relevance)

*(This amendment applies throughout the  
text. Adopting it will necessitate  
corresponding changes.)*

Or. en

*Justification*

*The annual RAPEX statistics show that consumers are often exposed to dangerous products for which no harmonised legislation exists. A consumer can hardly make the difference between harmonised and non-harmonised products and believe that his safety is ensured when it is not the case. Considering this, the scope of this regulation needs to be broadened to ensure a better protection of the health, safety and security of consumers and of the environment.*

**Amendment 38**  
**Luke Ming Flanagan**

## Proposal for a regulation

### Recital 2

*Text proposed by the Commission*

(2) Strengthening the Single Market for goods through further enhancing efforts to keep non-compliant products from being placed on the Union market was identified as a priority in the Communication from the Commission ‘Upgrading the Single Market: more opportunities for people and businesses’<sup>24</sup>. This should be achieved by strengthening market surveillance, providing the right incentives to economic operators, intensifying compliance controls and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities.

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<sup>24</sup> COM(2015) 550 final of 28 October 2015.

*Amendment*

(2) Strengthening the Single Market for goods through further enhancing efforts to keep non-compliant products from being placed on the Union market was identified as a priority in the Communication from the Commission ‘Upgrading the Single Market: more opportunities for people and businesses’<sup>24</sup>. This should be achieved by, ***amongst others***, strengthening market surveillance, providing the right incentives to economic operators, intensifying compliance controls and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities.

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<sup>24</sup> COM(2015) 550 final of 28 October 2015.

Or. en

## Amendment 39

Luke Ming Flanagan

## Proposal for a regulation

### Recital 2 a (new)

*Text proposed by the Commission*

*Amendment*

***(2 a) Union legislation on packaging and packaging waste, as for example Directive 94/62/EC<sup>1a</sup>, as recently amended, should be taken into account as regards the rules and procedures for compliance on products laid down in this Regulation.***

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<sup>1a</sup> ***European Parliament and Council Directive 94/62/EC of 20 December 1994***

**Amendment 40**

**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**

**Recital 5**

*Text proposed by the Commission*

(5) This Regulation should cover products that are subject to the Union harmonisation legislation *listed in the Annex. The legislation listed in the Annex* should cover all Union *harmonisation legislation concerning manufactured products other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level.* Several instruments of Union harmonisation legislation on products need to be amended in consequence, in particular to remove references to certain provisions of Regulation (EC) No 765/2008. *If new Union harmonisation legislation is adopted in the future, it will be for that legislation to provide whether this Regulation is also to apply to that legislation.*

*Amendment*

(5) This Regulation should cover *all* products that are subject to the Union harmonisation legislation *as well as to Member States' legislation on products. Therefore, this Regulation* should cover all *products subject to harmonised and non-harmonised areas of* Union legislation. Several instruments of Union harmonisation legislation on products need to be amended in consequence, in particular to remove references to certain provisions of Regulation (EC) No 765/2008.

*(This amendment applies throughout the text. Adopting it will necessitate corresponding changes.)*

## *Justification*

*The annual RAPEX statistics show that consumers are often exposed to dangerous products for which no harmonised legislation exists. A consumer can hardly make the difference between harmonised and non-harmonised products and believe that his safety is ensured when it is not the case. Considering this, the scope of this regulation needs to be broadened to ensure a better protection of the health, safety and security of consumers and of the environment.*

### **Amendment 41**

**Françoise Grossetête**

### **Proposal for a regulation**

#### **Recital 5**

#### *Text proposed by the Commission*

(5) This Regulation should cover products that are subject to the Union harmonisation legislation listed in the Annex. The legislation listed in the Annex should cover all Union harmonisation legislation concerning manufactured products other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level. Several instruments of Union harmonisation legislation on products need to be amended in consequence, in particular to remove references to certain provisions of Regulation (EC) No 765/2008. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to provide whether this Regulation is also to apply to that legislation.

#### *Amendment*

(5) This Regulation should cover products that are subject to ***Directive 2001/95/EC or*** the Union harmonisation legislation listed in the Annex. The legislation listed in the Annex should cover all Union harmonisation legislation concerning manufactured products other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level. Several instruments of Union harmonisation legislation on products need to be amended in consequence, in particular to remove references to certain provisions of Regulation (EC) No 765/2008. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to provide whether this Regulation is also to apply to that legislation.

Or. fr

**Amendment 42**  
**Julie Girling, Sirpa Pietikäinen**

**Proposal for a regulation**  
**Recital 5**

*Text proposed by the Commission*

(5) This Regulation should cover products that are subject to the Union harmonisation legislation listed in the Annex. The legislation listed in the Annex should cover all Union harmonisation legislation concerning manufactured products other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level. Several instruments of Union harmonisation legislation on products need to be amended in consequence, in particular to remove references to certain provisions of Regulation (EC) No 765/2008. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to provide whether this Regulation is also to apply to that legislation.

*Amendment*

(5) This Regulation should cover products that are subject to *the Directive 2001/95/EC or* the Union harmonisation legislation listed in the Annex. The legislation listed in the Annex should cover all Union harmonisation legislation concerning manufactured products other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level. Several instruments of Union harmonisation legislation on products need to be amended in consequence, in particular to remove references to certain provisions of Regulation (EC) No 765/2008. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to provide whether this Regulation is also to apply to that legislation.

Or. en

*Justification*

*It is essential for effective consumer protection that the Directive is included in the legislation. A number of products under the Directive are particularly important to the general public, such as toys, and should be protected.*

**Amendment 43**  
**Nicola Caputo, Guillaume Balas**

**Proposal for a regulation**  
**Recital 7**

*Text proposed by the Commission*

(7) Safety of consumers largely depends on the active enforcement of Union **harmonisation** legislation on products providing for safety requirements. It is therefore necessary to strengthen enforcement measures. These measures should be continuously improved and increasingly effective with a view to meeting the current challenges of a global market and an increasingly complex supply chain.

*Amendment*

(7) Safety of consumers largely depends on the active enforcement of Union legislation on products providing for safety requirements. It is therefore necessary to strengthen enforcement measures, ***including with regard to the products that are offered for sale online to end-users within the Union.*** These measures should be continuously improved and increasingly effective with a view to meeting the current challenges of a global market and an increasingly complex supply chain.

Or. en

**Amendment 44**

**Guillaume Balas, Christel Schaldemose, Nicola Caputo**

**Proposal for a regulation**

**Recital 7 a (new)**

*Text proposed by the Commission*

*Amendment*

***(7 a) Special attention should be given to Internet of Things (IoT) and the increasing number of Artificial Intelligence (AI) enabled devices, taking into account that consumers are increasingly using connected devices in their daily lives without knowing the security threats these devices can represent and the remote risks that exist. The Union regulatory framework should therefore address these issues to ensure a better protection of consumers.***

Or. en

**Amendment 45**

**Julie Girling, Sirpa Pietikäinen**



## Proposal for a regulation

### Recital 14

#### *Text proposed by the Commission*

(14) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers and the market surveillance authorities is a key element allowing immediate intervention and corrective action in relation to the product. It is important that there should be a contact person established in the Union so that market surveillance authorities have someone to whom questions can be addressed regarding a product's compliance with Union harmonisation legislation. The person responsible for providing such compliance information should be the manufacturer, or the importer, *or* another person designated by the manufacturer for this purpose, for example another economic operator. The role of a person responsible for compliance information established in the Union is essential for providing market surveillance authorities with an interlocutor established in the Union, and for performing specific tasks in a timely manner to ensure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, workers and businesses within the Union. The provisions in this Regulation requiring there to be a person established in the Union responsible for compliance information should not apply where specific requirements set out in certain legal instruments on products achieve the same result in effect, namely Article 4 of Regulation (EC) No 1223/2009, Article 15 of Regulation (EU) 2017/745 and Article

#### *Amendment*

(14) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers, *wholesalers, retailers* and the market surveillance authorities is a key element allowing immediate intervention and corrective action in relation to the product. It is important that there should be a contact person established in the Union so that market surveillance authorities have someone to whom questions can be addressed regarding a product's compliance with Union harmonisation legislation. The person responsible for providing such compliance information should be the manufacturer, or the *authorised representative, an importer when the manufacturer is not established in the Union and there is no other authorised representative, or - in the case there is no manufacturers or importer established in the Union -* another person designated by the manufacturer for this purpose, for example another economic operator. The role of a person responsible for compliance information established in the Union is essential for providing market surveillance authorities with an interlocutor established in the Union, and for performing specific tasks in a timely manner to ensure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, workers and businesses within the Union. The provisions in this Regulation requiring there to be a person established in the Union responsible for compliance information should not apply

15 of Regulation 2017/746.

where specific requirements set out in certain legal instruments on products achieve the same result in effect, namely Article 4 of Regulation (EC) No 1223/2009, Article 15 of Regulation (EU) 2017/745 and Article 15 of Regulation 2017/746.

Or. en

### *Justification*

*This broadens the scope of the legislation to all economic actors.*

## **Amendment 46**

**Françoise Grossetête**

### **Proposal for a regulation**

#### **Recital 14**

#### *Text proposed by the Commission*

(14) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers and the market surveillance authorities is a key element allowing immediate intervention and corrective action in relation to the product. It is important that there should be a contact person established in the Union so that market surveillance authorities have someone to whom questions can be addressed regarding a product's compliance with Union harmonisation legislation. The person responsible for providing such compliance information should be the manufacturer, *or the* importer, or another person designated by the manufacturer for this purpose, for example another economic operator. The role of a person responsible for compliance

#### *Amendment*

(14) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers, *distributors* and the market surveillance authorities is a key element allowing immediate intervention and corrective action in relation to the product. It is important that there should be a contact person established in the Union so that market surveillance authorities have someone to whom questions can be addressed regarding a product's compliance with Union harmonisation legislation. The person responsible for providing such compliance information should be the manufacturer *or an authorised representative of that manufacturer, an importer when the manufacturer is not established in the EU and does not have another authorised*

information established in the Union is essential for providing market surveillance authorities with an interlocutor established in the Union, and for performing specific tasks in a timely manner to ensure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, workers and businesses within the Union. The provisions in this Regulation requiring there to be a person established in the Union responsible for compliance information should not apply where specific requirements set out in certain legal instruments on products achieve the same result in effect, namely Article 4 of Regulation (EC) No 1223/2009, Article 15 of Regulation (EU) 2017/745 and Article 15 of Regulation 2017/746.

*representative, or if there is no manufacturer or importer established in the EU*, or another person designated by the manufacturer for this purpose, for example another economic operator. The role of a person responsible for compliance information established in the Union is essential for providing market surveillance authorities with an interlocutor established in the Union, and for performing specific tasks in a timely manner to ensure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, workers and businesses within the Union. The provisions in this Regulation requiring there to be a person established in the Union responsible for compliance information should not apply where specific requirements set out in certain legal instruments on products achieve the same result in effect, namely Article 4 of Regulation (EC) No 1223/2009, Article 15 of Regulation (EU) 2017/745 and Article 15 of Regulation 2017/746.

Or. fr

**Amendment 47**  
**Frédérique Ries**

**Proposal for a regulation**  
**Recital 14**

*Text proposed by the Commission*

(14) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers and the market surveillance authorities is a key element allowing immediate intervention and corrective

*Amendment*

(14) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers, *distributors* and the market surveillance authorities is a key element allowing immediate intervention and

action in relation to the product. It is important that there should be a contact person established in the Union so that market surveillance authorities have someone to whom questions can be addressed regarding a product's compliance with Union harmonisation legislation. The person responsible for providing such compliance information should be the manufacturer, or the **importer**, or another person designated by the manufacturer for this purpose, for example another economic operator. The role of a person responsible for compliance information established in the Union is essential for providing market surveillance authorities with an interlocutor established in the Union, and for performing specific tasks in a timely manner to ensure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, workers and businesses within the Union. The provisions in this Regulation requiring there to be a person established in the Union responsible for compliance information should not apply where specific requirements set out in certain legal instruments on products achieve the same result in effect, namely Article 4 of Regulation (EC) No 1223/2009, Article 15 of Regulation (EU) 2017/745 and Article 15 of Regulation 2017/746.

corrective action in relation to the product. It is important that there should be a contact person established in the Union so that market surveillance authorities have someone to whom questions can be addressed regarding a product's compliance with Union harmonisation legislation. The person responsible for providing such compliance information should be the manufacturer, **the importer** or the **distributor**, or another person designated by the manufacturer for this purpose, for example another economic operator. The role of a person responsible for compliance information established in the Union is essential for providing market surveillance authorities with an interlocutor established in the Union, and for performing specific tasks in a timely manner to ensure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, workers and businesses within the Union. The provisions in this Regulation requiring there to be a person established in the Union responsible for compliance information should not apply where specific requirements set out in certain legal instruments on products achieve the same result in effect, namely Article 4 of Regulation (EC) No 1223/2009, Article 15 of Regulation (EU) 2017/745 and Article 15 of Regulation 2017/746.

Or. fr

**Amendment 48**  
**Françoise Grossetête**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(18) Market surveillance activities

*Amendment*

(18) Market surveillance activities

should be thorough and effective, to ensure that Union harmonisation legislation on products is applied correctly. Given that controls may represent a burden for economic operators, market surveillance authorities should organise and conduct inspection activities, taking their interests into account and limiting the said burden to what is necessary for the performance of efficient and effective controls.

Furthermore, market surveillance activities should be performed with the same level of care by the competent authorities of the Member State irrespective of whether non-compliance of the given product is relevant on the territory of that Member State or is likely to have an impact on the market of another Member State.

should be thorough and effective, to ensure that Union harmonisation legislation on products is applied correctly. Given that controls may represent a burden for economic operators, market surveillance authorities should organise and conduct inspection activities, taking their interests into account and limiting the said burden to what is necessary for the performance of efficient and effective controls.

Furthermore, market surveillance activities should be performed with the same level of care by the competent authorities of the Member State irrespective of whether non-compliance of the given product is relevant on the territory of that Member State or is likely to have an impact on the market of another Member State. ***Uniform conditions could be envisaged for inspection activities carried out by the market surveillance authorities when a product presents a known or emerging risk.***

Or. fr

**Amendment 49**  
**Luke Ming Flanagan**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

(18) Market surveillance activities should be thorough and effective, to ensure that Union harmonisation legislation on products is applied correctly. Given that controls may represent a burden for economic operators, market surveillance authorities should organise and conduct inspection activities, taking ***their*** interests into account and limiting the said burden to what is necessary for the performance of efficient and effective controls. Furthermore, market surveillance activities should be performed with the same level of

*Amendment*

(18) Market surveillance activities should be thorough and effective, to ensure that Union harmonisation legislation on products is applied correctly. Given that controls may represent a burden for economic operators, market surveillance authorities should organise and conduct inspection activities taking ***the*** interests ***of those operators*** into account, and limiting the said burden to what is necessary for the performance of efficient and effective controls. Furthermore, market surveillance activities should be performed with the

care by the competent authorities of the Member State irrespective of whether non-compliance of the given product is relevant on the territory of that Member State or is likely to have an impact on the market of another Member State.

same level of care by the competent authorities of the Member State irrespective of whether non-compliance of the given product is relevant on the territory of that Member State or is likely to have an impact on the market of another Member State.

Or. en

**Amendment 50**  
**Luke Ming Flanagan**

**Proposal for a regulation**  
**Recital 23 a (new)**

*Text proposed by the Commission*

*Amendment*

***(23 a) Market surveillance authorities should be able to advise on packaging and order changes in practice where they find situations in conflict with Union legislation.***

Or. en

**Amendment 51**  
**Mireille D'Ornano**

**Proposal for a regulation**  
**Recital 24**

*Text proposed by the Commission*

*Amendment*

(24) Market surveillance authorities should be able to require any representative or ***member of staff*** of the economic operator concerned to give explanations or provide facts, information or documents relating to the subject matter of the on-site inspection, and to record the answers given by that representative or ***staff member***.

(24) Market surveillance authorities should be able to require any representative or ***manager*** of the economic operator concerned to give explanations or provide facts, information or documents relating to the subject matter of the on-site inspection, and to record the answers given by that representative or ***manager***.

Or. fr

**Amendment 52**  
**Mireille D'Ornano**

**Proposal for a regulation**  
**Recital 30**

*Text proposed by the Commission*

(30) This Regulation should be without prejudice to the safeguard clause procedure provided for by sectoral Union harmonisation legislation, pursuant to Article 114(10) of the Treaty. With a view to ensuring an equivalent level of protection throughout the Union, Member States should be authorised to take restrictive measures in relation to products presenting a risk to health and safety, or other aspects of public interest protection. They should also be required to notify those measures to other Member States and the Commission, ***allowing the Commission to take a position on the national measures that restrict the free movement of products with a view to ensuring the functioning of the internal market.***

*Amendment*

(30) This Regulation should be without prejudice to the safeguard clause procedure provided for by sectoral Union harmonisation legislation, pursuant to Article 114(10) of the Treaty. With a view to ensuring an equivalent level of protection throughout the Union, Member States should be authorised to take restrictive measures in relation to products presenting a risk to health and safety, or other aspects of public interest protection. They should also be required to notify those measures to other Member States and the Commission.

Or. fr

**Amendment 53**  
**Mireille D'Ornano**

**Proposal for a regulation**  
**Recital 31**

*Text proposed by the Commission*

(31) Information exchanged between market surveillance authorities, and the use of evidence and investigation findings should be subject to the strictest guarantees of confidentiality and of professional and commercial secrecy. Information should be handled according to applicable national

*Amendment*

(31) Information exchanged between market surveillance authorities, and the use of evidence and investigation findings should be subject to the strictest guarantees of confidentiality and of professional and commercial secrecy. Information should be handled according to applicable national

law, *in order to ensure that investigations are not compromised and that the reputation of the economic operator is not prejudiced.*

law.

Or. fr

**Amendment 54**  
**Margrete Auken**

**Proposal for a regulation**  
**Recital 33**

*Text proposed by the Commission*

(33) To ensure the reliability and consistency of testing across the Union in the market surveillance framework, the Commission should designate Union testing facilities. Furthermore, a more comprehensive information system should be developed for sharing test results within the Union in order to avoid unnecessary duplication and to ensure greater consistency at Union level.

*Amendment*

(33) To ensure the reliability and consistency of testing across the Union in the market surveillance framework, the Commission should designate Union testing facilities. Furthermore, a more comprehensive information system should be developed for sharing test results within the Union in order to avoid unnecessary duplication and to ensure greater consistency at Union level. *Union testing facilities competence centres should act as knowledge centres in respect of known and emerging risks and also assist the Union and Member States to develop joint state of the art testing methodologies related to chemicals in consumer products.*

Or. en

**Amendment 55**  
**Frédérique Ries**

**Proposal for a regulation**  
**Recital 33**

*Text proposed by the Commission*

(33) To ensure the reliability and

*Amendment*

(33) To ensure the reliability and



consistency of testing across the Union in the market surveillance framework, the Commission should designate Union testing facilities. Furthermore, a more comprehensive information system should be developed for sharing test results within the Union in order to avoid unnecessary duplication and to ensure greater consistency at Union level.

consistency of testing across the Union in the market surveillance framework, the Commission should designate Union testing facilities. ***The market surveillance authorities should take full account of the results of tests carried out by these Union testing facilities.*** Furthermore, a more comprehensive information system should be developed for sharing test results within the Union in order to avoid unnecessary duplication and to ensure greater consistency at Union level.

Or. fr

#### **Amendment 56**

**Guillaume Balas, Christel Schaldemose, Nicola Caputo**

#### **Proposal for a regulation**

#### **Recital 36 a (new)**

*Text proposed by the Commission*

*Amendment*

***(36 a) The level of penalties applicable to infringements of the provisions of this Regulation that impose obligations on economic operators and to infringements of provisions of any Union and Member States' legislation on products that impose obligations on economic operators should be stepped up in order to efficiently deter the placement of non-compliant products on the market.***

Or. en

#### **Amendment 57**

**Guillaume Balas, Nicola Caputo**

#### **Proposal for a regulation**

#### **Article 1 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

This Regulation *lays down rules and procedures for the provision of compliance information about certain products that are the subject of Union acts harmonising the conditions for the marketing of those products.* It establishes a framework for cooperation with economic operators in relation to such products.

This Regulation *aims to protect the health, safety and security of European consumers as well as the environment, and provides procedures to ensure that only safe and compliant products shall be made available to European consumers. This Regulation applies to all products that are subject to the Union harmonisation legislation and to all products subject to Member States' legislation which are made available on the Union market;* It establishes a framework for cooperation with economic operators in relation to such products.

*(This amendment applies throughout the text. Adopting it will necessitate corresponding changes.)*

Or. en

#### *Justification*

*The annual RAPEX statistics show that consumers are often exposed to dangerous products for which no harmonised legislation exists. A consumer can hardly make the difference between harmonised and non-harmonised products and believe that his safety is ensured when it is not the case. Considering this, the scope of this regulation needs to be broadened to ensure a better protection of the health, safety and security of consumers and of the environment.*

#### **Amendment 58**

**Guillaume Balas, Nicola Caputo**

#### **Proposal for a regulation**

#### **Article 1 – paragraph 2**

*Text proposed by the Commission*

*It also provides* a framework for the market surveillance of *such* products to ensure that those products fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, the protection of consumers, protection of the environment

*Amendment*

*Therefore, this Regulation lays down* a framework for the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, the protection of consumers, *the* protection of the

and security.

environment and security.

Or. en

**Amendment 59**  
**Merja Kyllönen**

**Proposal for a regulation**  
**Article 2 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation applies to all products *that are subject to the Union harmonisation legislation set out in the Annex to this Regulation ('Union harmonisation legislation')*.

*Amendment*

1. This Regulation applies to all products.

Or. en

**Amendment 60**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 2 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation applies to all products that are subject to the Union harmonisation legislation *set out in the Annex to this Regulation ('Union harmonisation legislation')*.

*Amendment*

1. This Regulation applies to all products that are subject to the Union harmonisation legislation *and to all products subject to Member States' legislation which are made available on the Union market.*

*(This amendment applies throughout the text. Adopting it will necessitate corresponding changes.)*

Or. en

*Justification*

*The annual RAPEX statistics show that consumers are often exposed to dangerous products for which no harmonised legislation exists. A consumer can hardly make the difference*

*between harmonised and non-harmonised products and believe that his safety is ensured when it is not the case. Considering this, the scope of this regulation needs to be broadened to ensure a better protection of the health, safety and security of consumers and of the environment.*

**Amendment 61**  
**Margrete Auken**

**Proposal for a regulation**  
**Article 2 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation applies to all products **that are** subject to the Union harmonisation legislation set out in the Annex to this Regulation (‘Union harmonisation legislation’).

*Amendment*

1. This Regulation applies to all products **placed on the market, whether they are products** subject to the Union harmonisation legislation set out in the Annex to this Regulation (‘Union harmonisation legislation’) **or non-harmonised products**.

Or. en

*Justification*

*Whilst the Commission proposal covers only products subject to Union harmonisation legislation, there are many categories of products which are not covered by union harmonisation legislation, but which potentially pose health, security and environmental risks to consumers. Examples being furniture, shoes and textiles, ladders and child care articles. Covering all products placed on the market will also provide clarity and simplicity for authorities, traders, producers and consumers. the changes to the scope should be made throughout the text.*

**Amendment 62**  
**Gesine Meissner**

**Proposal for a regulation**  
**Article 2 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation applies **to all** products **that are** subject to **the** Union harmonisation legislation set out in **the Annex** to this Regulation (‘**Union**

*Amendment*

1. This Regulation applies:  
**(a) from 1 January 2021 to 31 December 2024, to** products subject to **legislation requiring a declaration of conformity and**

*harmonisation legislation’).*

*which have been aligned with Decision 768/2008;  
(b) from 1 January 2025, to other products covered by Union harmonisation legislation as set out in **delegated acts** pursuant to this Regulation.  
No later than 1 January 2023, the Commission shall review the scope of this Regulation and shall present a report thereon to the European Parliament and to the Council. That report shall be accompanied by a legislative proposal pursuant to point (b), if appropriate.*

Or. en

**Amendment 63**  
**Françoise Grossetête**

**Proposal for a regulation**  
**Article 2 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation applies to all products that are subject to the Union harmonisation legislation set out in the Annex to this Regulation (‘Union harmonisation legislation’).

*Amendment*

1. This Regulation applies to all products that are subject to **Directive 2001/95/EC or** the Union harmonisation legislation set out in the Annex to this Regulation (‘Union harmonisation legislation’).

Or. fr

**Amendment 64**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 2 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation **applies** to all products that are subject to the Union harmonisation legislation set out in the

*Amendment*

1. This Regulation **shall apply** to all products that are subject to **Directive 2001/95/EC or** the Union

Annex to this Regulation ('Union harmonisation legislation').

harmonisation legislation set out in the Annex to this Regulation ('Union harmonisation legislation').

Or. en

**Amendment 65**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 2 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation applies to all products that are subject to the Union harmonisation legislation set out in the Annex to this Regulation ('Union harmonisation legislation').

*Amendment*

1. This Regulation applies to all products that are subject to **Directive 2001/95/EC or** the Union harmonisation legislation set out in the Annex to this Regulation ('Union harmonisation legislation').

Or. en

**Amendment 66**  
**Julie Girling, Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 2 – paragraph 1**

*Text proposed by the Commission*

1. This Regulation applies to all products that are subject to the Union harmonisation legislation set out in the Annex to this Regulation ('Union harmonisation legislation').

*Amendment*

1. This Regulation applies to all products that are subject to **Directive 2001/95/EC or** the Union harmonisation legislation set out in the Annex to this Regulation ('Union harmonisation legislation').

Or. en

### *Justification*

*It is essential for effective consumer protection that the Directive is included in the legislation. A number of products under the Directive are particularly important to the general public, such as toys, and should be protected.*

#### **Amendment 67** **Margrete Auken**

#### **Proposal for a regulation** **Article 2 – paragraph 3**

##### *Text proposed by the Commission*

3. The application of this Regulation shall not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC.

##### *Amendment*

3. The application of this Regulation shall not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC. ***Those authorities are to always act on the basis of the precautionary principle, in particular when it comes to health and the environment.***

Or. en

#### **Amendment 68** **Nicola Caputo, Guillaume Balas**

#### **Proposal for a regulation** **Article 3 – paragraph 1 – point 3**

##### *Text proposed by the Commission*

(3) ‘market surveillance’ means the activities carried out and measures taken by market surveillance authorities to ensure that products comply with the requirements under Union ***harmonisation*** legislation and do not endanger health, safety or any other aspect of public interest protection;

##### *Amendment*

(3) ‘market surveillance’ means the activities carried out and measures taken by market surveillance authorities to ensure that products comply with the requirements under Union legislation and do not endanger health ***and safety in general, health and safety in the workplace, the protection of consumers, public*** safety or any other aspect of public interest protection;

**Amendment 69**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 7**

*Text proposed by the Commission*

(7) ‘non-compliance’ means any failure to comply with any of the requirements under the Union harmonisation legislation applicable to the product in question;

*Amendment*

(7) ‘non-compliance’ means any failure to comply with any of the requirements under the Union harmonisation legislation ***or to Member States ‘legislation*** applicable to the product in question;

*(This amendments applies throughout the text. Adopting it will necessitate corresponding changes.)*

Or. en

*Justification*

*The annual RAPEX statistics show that consumers are often exposed to dangerous products for which no harmonised legislation exists. A consumer can hardly make the difference between harmonised and non-harmonised products and believe that his safety is ensured when it is not the case. Considering this, the scope of this regulation needs to be broadened to ensure a better protection of the health, safety and security of consumers and of the environment.*

**Amendment 70**  
**Gesine Meissner**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 7 a (new)**

*Text proposed by the Commission*

*Amendment*

***(7 a) ‘formal non-compliance’ means any administrative non-compliance that does not lead to a breach of the essential requirements, including but not limited to the non-compliances as defined in Article R34 of the reference provisions in***



*Decision No 768/2008/EC the European Parliament and of the Council<sup>1a</sup>;*

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*<sup>1a</sup> Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).*

Or. en

**Amendment 71**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 15**

*Text proposed by the Commission*

(15) ‘serious risk’ means any *serious risk, including a serious risk where the effects are not immediate*, requiring rapid intervention by the *market surveillance authorities*;

*Amendment*

(15) ‘serious risk’ means any *risk* requiring rapid intervention *and follow-up, including cases where the effects may not be immediate; any product that does not meet an essential requirement defined in the harmonisation legislation, as well as any product that does not meet the general safety requirement as defined in the mandate given by the Commission to the standardisation organisation shall be considered as presenting a serious risk; any product subject to an emergency decision based on Article 13 of Directive 2001/95/CE shall be considered as a product posing a serious risk;*

Or. en

**Amendment 72**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 15**

*Text proposed by the Commission*

(15) ‘serious risk’ means any *serious risk, including a serious risk where the effects are not immediate*, requiring rapid intervention by the *market surveillance authorities*;

*Amendment*

(15) ‘serious risk’ means any *risk* requiring rapid intervention *and follow-up, including cases where the effects may not be immediate; any product that does not meet an essential requirement defined in the harmonisation legislation, as well as any product that does not meet the general safety requirement as defined in the mandate given by the Commission to the standardisation organisation shall be considered as presenting a serious risk; any product subject to an emergency decision based on Article 13 of Directive 2001/95/CE shall be considered as a product posing a serious risk;*

Or. en

**Amendment 73**

**Françoise Grossetête**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 15**

*Text proposed by the Commission*

(15) ‘*serious* risk’ means any serious risk, including a serious risk where the effects are not immediate, requiring rapid intervention by the market surveillance authorities;

*Amendment*

(15) ‘***Serious*** risk’ means any serious risk, including a serious risk where the effects are not immediate, requiring rapid intervention by the market surveillance authorities; ***any product that does not meet an essential condition set out in the harmonisation legislation, or any product that does not meet the general product safety criteria based on Directive 2001/95/EC;***

Or. fr

**Amendment 74**

**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 15**

*Text proposed by the Commission*

(15) ‘serious risk’ means any serious risk, including a serious risk where the effects are not immediate, requiring rapid intervention by the market surveillance authorities;

*Amendment*

(15) ‘serious risk’ means any serious risk, including a serious risk where the effects are not immediate, requiring rapid intervention by the market surveillance authorities, ***in accordance with the precautionary principle***;

Or. en

**Amendment 75**  
**Julie Girling, Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 22 a (new)**

*Text proposed by the Commission*

*Amendment*

***(22 a) ‘distinct models’ means models of products that are considered to be distinct due to different essential characteristics that may have an impact on their safety.***

Or. en

*Justification*

*This amendment will minimise the deliberate breach of safety standards; currently, a common way to circumnavigate safety rules and market surveillance authorities’ decision is to multiply the names/brands of one given model with only very minor differences in appearance, if any.*

**Amendment 76**  
**Françoise Grossetête**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 22 a (new)**

*Text proposed by the Commission*

*Amendment*

*(22a) ‘distinct models’ means all products with different characteristics, even when those differences are minor or even non-existent.*

Or. fr

**Amendment 77**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point a – introductory part**

*Text proposed by the Commission*

(a) the manufacturer is established in the Union *or there is at least one of the following in place with respect to the product:*

*Amendment*

(a) the manufacturer, *or its authorised representative*, is established in the Union;

Or. en

**Amendment 78**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point a – introductory part**

*Text proposed by the Commission*

(a) the manufacturer is established in the Union *or there is at least one of the following in place with respect to the product:*

*Amendment*

(a) the manufacturer, *or its authorised representative*, is established in the Union;

Or. en

**Amendment 79**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point a – point i**

*Text proposed by the Commission*

*Amendment*

(i) an importer;

(i) an importer, *when the manufacturer is not established in the Union and there is no authorised representative*;

Or. en

**Amendment 80**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point a – point i**

*Text proposed by the Commission*

*Amendment*

(i) an importer;

(i) *(b)* an importer, *when the manufacturer is not established in the Union and there is no authorised representative*;

Or. en

**Amendment 81**  
**Frédérique Ries**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point a – point i a (new)**

*Text proposed by the Commission*

*Amendment*

*(ia) a distributor;*

Or. fr

**Amendment 82**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point a – point ii**

*Text proposed by the Commission*

(ii) a natural or legal person established in the Union who has a written mandate from the manufacturer designating him as a person responsible for performing the tasks listed in paragraph 3 **and requiring him to perform those tasks** on the manufacturer's behalf;

*Amendment*

(ii) **(c) in case there is no manufacturers or importer established in the Union**, a natural or legal person established in the Union who has a written mandate from the manufacturer designating him as a person responsible for **compliance and** performing the tasks listed in paragraph 3 on the manufacturer's behalf;

Or. en

**Amendment 83**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point a – point ii**

*Text proposed by the Commission*

(ii) a natural or legal person established in the Union who has a written mandate from the manufacturer designating him as a person responsible for performing the tasks listed in paragraph 3 and requiring him to perform those tasks on the manufacturer's behalf;

*Amendment*

(ii) **in case there is no manufacturers or importer established in the Union**, a natural or legal person established in the Union who has a written mandate from the manufacturer designating him as a person responsible for performing the tasks listed in paragraph 3 and requiring him to perform those tasks on the manufacturer's behalf;

Or. en

**Amendment 84**  
**Frédérique Ries**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point b**

*Text proposed by the Commission*

(b) the identity and contact details of the manufacturer, importer or other person

*Amendment*

(b) the identity and contact details of the manufacturer, importer, **distributor** or

meeting the requirements of point (a) are publicly available in accordance with paragraph 4 and are indicated or identifiable in accordance with paragraph 5.

other person meeting the requirements of point (a) are publicly available in accordance with paragraph 4 and are indicated or identifiable in accordance with paragraph 5.

Or. fr

**Amendment 85**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 4 – paragraph 1 – point b**

*Text proposed by the Commission*

(b) the identity and contact details of the manufacturer, importer or other person meeting the requirements of *point (a)* are publicly available in accordance with paragraph 4 and are indicated or identifiable in accordance with paragraph 5.

*Amendment*

(b) *(d)* the identity and contact details of the manufacturer, importer or other person meeting the requirements of *points (a to c)* are publicly available in accordance with paragraph 4 and are indicated or identifiable in accordance with paragraph 5.

Or. en

**Amendment 86**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point b**

*Text proposed by the Commission*

(b) further to a reasoned request from a market surveillance authority, providing that authority with all the information and documentation necessary to demonstrate the conformity of the product in an official Union language determined by the Member State concerned;

*Amendment*

(b) further to a reasoned request from a market surveillance authority, providing that authority with all the information and documentation necessary to demonstrate the conformity of the product in an official Union language determined by the Member State concerned *and to demonstrate the existence of different essential characteristics between its distinct models as defined in point 22a of Article 3;*

**Amendment 87**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point b**

*Text proposed by the Commission*

(b) further to a reasoned request from a market surveillance authority, providing that authority with all the information and documentation necessary to demonstrate the conformity of the product in an official Union language determined by the Member State concerned;

*Amendment*

(b) further to a reasoned request from a market surveillance authority, providing that authority with all the information and documentation necessary to demonstrate the conformity of the product in an official Union language determined by the Member State concerned; ***and to demonstrate the existence of different essential characteristics between its between its distinct models as defined in point 22a of Article 3;***

**Amendment 88**  
**Françoise Grossetête**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point b**

*Text proposed by the Commission*

(b) further to a reasoned request from a market surveillance authority, providing that authority with all the information and documentation necessary to demonstrate the conformity of the product in an official Union language determined by the Member State concerned;

*Amendment*

(b) further to a reasoned request from a market surveillance authority, providing that authority with all the information and documentation necessary to demonstrate the conformity of the product in an official Union language determined by the Member State concerned, ***and to show significant differences in the characteristics of its distinct models as defined in Article 3(22)(a);***



**Amendment 89**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point c**

*Text proposed by the Commission*

(c) cooperating with the market surveillance authorities, *at their request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by the product.*

*Amendment*

(c) cooperating with the market surveillance authorities, *and take immediate action to remedy the case of a product presenting a risk or the case of a product being non-compliant with the requirements set out in Union harmonisation legislation or harmonised standards applicable to the product in question, at their own initiative or when required to do so by the market surveillance authorities;*

Or. en

**Amendment 90**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point c**

*Text proposed by the Commission*

(c) cooperating with the market surveillance authorities, *at their request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by the product.*

*Amendment*

(c) cooperating with the market surveillance authorities *and take immediate action to remedy the case of a product presenting a risk or the case of a product being non-compliant with the requirements set out in Union harmonisation legislation or harmonised standards applicable to the product in question, at their own initiative or when required to do so by the market surveillance authorities;*

Or. en

**Amendment 91**  
**Frédérique Ries**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point c**

*Text proposed by the Commission*

(c) cooperating with the market surveillance authorities, **at** their request, **on any action taken** to eliminate or, if that is not possible, mitigate the risks posed by the product.

*Amendment*

(c) cooperating with the market surveillance authorities, **on their own initiative or at the request of those authorities, to take all the necessary immediate action** to eliminate or, if that is not possible, mitigate the risks posed by the product.

Or. fr

**Amendment 92**  
**Julie Girling, Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point c**

*Text proposed by the Commission*

(c) cooperating with the market surveillance authorities, **at their request, on any action taken** to eliminate or, if that is not possible, mitigate the risks posed by the product.

*Amendment*

(c) cooperating with the market surveillance authorities, **to take** action to eliminate or, if that is not possible, mitigate the risks posed by the product.

Or. en

*Justification*

*Typographical consistency/clarity.*

**Amendment 93**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

*(c a) when considering or having reason to believe that a product in question present a risk or is not in conformity with the applicable Union harmonisation legislation or harmonised standard, immediately inform the manufacturer and, where applicable, other economic operators;*

Or. en

**Amendment 94**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

*(c a) when considering or having reason to believe that a product in question present a risk or is not in conformity with the applicable Union harmonisation legislation or harmonised standard, immediately inform the manufacturer and, where applicable, other economic operators;*

Or. en

**Amendment 95**  
**Frédérique Ries**

**Proposal for a regulation**  
**Article 4 – paragraph 3 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

*(ca) immediately inform the manufacturer and all other economic operators concerned when there is enough evidence to believe that a product*

*could present a serious risk or does not comply with the applicable EU harmonisation laws.*

Or. fr

**Amendment 96**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 4 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

**4. Manufacturers shall make the identity and contacts details of the person responsible for compliance information with respect to the product publicly available either on their website or, in the absence of a website, by any other means that allows the information to be readily accessed by the general public in the Union free of charge.**

**deleted**

Or. en

**Amendment 97**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 4 – paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

**5 a. The manufacturer, importer and any other person meeting the requirements of point (a) of paragraph 1 of this Article, shall make available to the public and to other economic operators by any appropriate means, lists of their product models, accompanied by a picture, in particular for products that are or have been the subject of a decision by the Commission under Article 13 of**

*Directive 2001/95/CE and for products that are the subject of widespread distribution.*

Or. en

**Amendment 98**  
**Julie Girling, Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 4 a (new)**

*Text proposed by the Commission*

*Amendment*

*Article 4 a*

*Obligations of distributors*

*1. Before making a product available on the market, distributors shall take all reasonable steps to ensure that the manufacturer and the importer have complied with the requirements set out in the applicable harmonisation legislation, harmonised standards or the Directive 2001/95/EC.*

*2. Further to a reasoned request from a market surveillance authority, the person responsible for compliance information shall provide that authority with all the information and documentation necessary to demonstrate the conformity of the product in an official Union language determined by the Member State concerned, and to demonstrate the existence of different essential characteristics between its distinct models as defined in point 22a of Article 3.*

Or. en

*Justification*

*Retailers are consistently allowing the sale and consumption of illegal or non-compliant goods. This amendment will oblige distributors to take a more proactive role in interdicting illegal goods.*

**Amendment 99**  
**Gesine Meissner**

**Proposal for a regulation**  
**Article 5 – paragraph 1**

*Text proposed by the Commission*

Where Union harmonisation legislation provides for the drawing up of an EU declaration of conformity, manufacturers shall make the declaration **publicly available on their website or, in the absence of a website, by any other means that allows the declaration to be readily accessed by the general public in the Union** free of charge.

*Amendment*

Where Union harmonisation legislation provides for the drawing up of an EU declaration of conformity, manufacturers shall make the declaration available free of charge.

Or. en

**Amendment 100**  
**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**  
**Article 5 – paragraph 1**

*Text proposed by the Commission*

Where Union harmonisation legislation provides for the drawing up of an EU declaration of conformity, manufacturers shall make the declaration publicly available on their website or, in the absence of a website, by any other means that allows the declaration to be readily accessed by the general public in the Union free of charge.

*Amendment*

Where Union harmonisation legislation provides for the drawing up of an EU declaration of conformity, manufacturers **including those from third countries, or importers**, shall make the declaration publicly available on their website or, in the absence of a website, by any other means that allows the declaration to be readily accessed by the general public in the Union free of charge.

Or. en

**Amendment 101**

**Margrete Auken**

**Proposal for a regulation**

**Article 7**

*Text proposed by the Commission*

*Amendment*

*Article 7*

*deleted*

*Compliance partnership arrangements*

**1.**

***A market surveillance authority may enter into a partnership arrangement with an economic operator established in its territory under which the authority agrees to provide the economic operator with advice and guidance in relation to the Union harmonisation legislation applicable to the products for which the economic operator is responsible.***

***The arrangement shall not cover the provision of conformity assessment activities that are entrusted to notified bodies under the Union harmonisation legislation.***

***2. If a market surveillance authority enters into a partnership arrangement under paragraph 1, it shall enter that fact in the system referred to in Article 34, along with details of the scope of the arrangement and the names and addresses of itself and of the economic operator.***

***3. If a market surveillance authority enters into a partnership arrangement under paragraph 1, other market surveillance authorities shall inform that authority of any temporary measure taken by them against the economic operator, and any corrective action taken by the economic operator, in relation to compliance with the applicable Union harmonisation legislation.***

***4. A market surveillance authority that enters into a partnership arrangement under paragraph 1 may charge the***

*economic operator fees representing the costs reasonably incurred by the authority in the exercise of its functions under paragraphs 1 and 2.*

Or. en

**Amendment 102**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 7**

*Text proposed by the Commission*

*Amendment*

*Article 7*

*deleted*

*Compliance partnership arrangements*

*1.*

*A market surveillance authority may enter into a partnership arrangement with an economic operator established in its territory under which the authority agrees to provide the economic operator with advice and guidance in relation to the Union harmonisation legislation applicable to the products for which the economic operator is responsible.*

*The arrangement shall not cover the provision of conformity assessment activities that are entrusted to notified bodies under the Union harmonisation legislation.*

*2. If a market surveillance authority enters into a partnership arrangement under paragraph 1, it shall enter that fact in the system referred to in Article 34, along with details of the scope of the arrangement and the names and addresses of itself and of the economic operator.*

*3. If a market surveillance authority enters into a partnership arrangement under paragraph 1, other market*



*surveillance authorities shall inform that authority of any temporary measure taken by them against the economic operator, and any corrective action taken by the economic operator, in relation to compliance with the applicable Union harmonisation legislation.*

*4. A market surveillance authority that enters into a partnership arrangement under paragraph 1 may charge the economic operator fees representing the costs reasonably incurred by the authority in the exercise of its functions under paragraphs 1 and 2.*

Or. en

**Amendment 103**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

Market surveillance authorities may enter into memoranda of understanding with businesses or organisations representing businesses or end-users for the carrying out, or financing, of joint activities aimed at identifying non-compliance or promoting compliance in specific geographical areas or with respect to specific categories of **product**.

*Amendment*

Market surveillance authorities may enter into memoranda of understanding with **custom authorities, port and airport authorities**, businesses or organisations representing businesses or end-users for the carrying out, or financing, of joint activities aimed at identifying non-compliance or promoting compliance in specific geographical areas or with respect to specific categories of **products**. **The market surveillance authority shall provide a draft memorandum to the Commission at least 2 months before its adoption and a report on its implementation every year from the date of its adoption. The Commission shall provide an opinion to the market surveillance authorities on the draft memorandum and the implementation report.**

**Amendment 104**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

Market surveillance authorities may enter into memoranda of understanding with businesses or organisations representing businesses or end-users for the carrying out, or financing, of joint activities aimed at identifying non-compliance or promoting compliance in specific geographical areas or with respect to specific categories of **product**.

*Amendment*

Market surveillance authorities may enter into memoranda of understanding with **custom authorities, port and airport authorities**, businesses or organisations representing businesses or end-users for the carrying out, or financing, of joint activities aimed at identifying non-compliance or promoting compliance in specific geographical areas or with respect to specific categories of **products**.

**Amendment 105**  
**Frédérique Ries**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

Market surveillance authorities may enter into memoranda of understanding with businesses or organisations representing businesses or end-users for the carrying out, or financing, of joint activities aimed at identifying non-compliance or promoting compliance in specific geographical areas or with respect to specific categories of product.

*Amendment*

Market surveillance authorities may enter into memoranda of understanding with **the customs, port and airport authorities**, businesses or organisations representing businesses or end-users for the carrying out, or financing, of joint activities aimed at identifying non-compliance or promoting compliance in specific geographical areas or with respect to specific categories of product.

**Amendment 106**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 8 – paragraph 1 – subparagraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***The market surveillance authority shall provide a draft memorandum to the Commission at least 2 months before its adoption and a report on its implementation every year from the date of its adoption. The Commission shall provide an opinion to the market surveillance authorities on the draft memorandum and the implementation report.***

Or. en

**Amendment 107**  
**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**  
**Article 8 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. A market surveillance authority may use any information resulting from activities carried out or financed by other parties to a memorandum of understanding entered into by it under paragraph 1 as part of any investigation undertaken by it into non-compliance, but only if the activity in question was carried out independently, impartially and without bias.

2. A market surveillance authority may use any information resulting from activities carried out or financed by other parties to a memorandum of understanding entered into by it under paragraph 1 as part of any investigation undertaken by it into non-compliance, but only if the activity in question was carried out independently, impartially and without bias. ***Information on how products have been tested and the results of such tests shall be made publicly available.***

Or. en

**Amendment 108**  
**Gesine Meissner**

**Proposal for a regulation**  
**Article 8 – paragraph 3**

*Text proposed by the Commission*

3. Any exchange of information between market surveillance authorities and businesses or organisations referred to in paragraph 1 for the purposes of preparing or implementing a memorandum of understanding entered into by them under that paragraph shall be ***deemed not to infringe*** the requirements of professional secrecy.

*Amendment*

3. Any exchange of information between market surveillance authorities, ***the Commission, or the EU Product Compliance Board*** and businesses or organisations referred to in paragraph 1 for the purposes of preparing or implementing a memorandum of understanding entered into by them under that paragraph shall be ***treated in accordance with*** the requirements of professional secrecy. ***Any further use of that information shall be subject to the strictest guarantees of confidentiality and of professional and commercial secrecy.***

Or. en

**Amendment 109**  
**Merja Kyllönen**

**Proposal for a regulation**  
**Article 10 – paragraph 1**

*Text proposed by the Commission*

1. Market surveillance authorities shall establish appropriate communication and coordination mechanisms with other market surveillance authorities.

*Amendment*

1. ***Based on common Union-wide rules***, market surveillance authorities shall establish appropriate communication and coordination mechanisms with other market surveillance authorities.

Or. en

**Amendment 110**

**Merja Kyllönen**

**Proposal for a regulation**

**Article 10 – paragraph 2 – introductory part**

*Text proposed by the Commission*

2. Market surveillance authorities shall establish the following procedures in connection with products subject to the Union harmonisation legislation set out in the Annex:

*Amendment*

2. **Based on common Union-wide rules**, market surveillance authorities shall establish the following procedures in connection with products subject to the Union harmonisation legislation set out in the Annex:

Or. en

**Amendment 111**

**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**

**Article 10 – paragraph 2 – introductory part**

*Text proposed by the Commission*

2. Market surveillance authorities shall establish the following procedures in connection with products subject to **the Union harmonisation legislation set out in the Annex**:

*Amendment*

2. Market surveillance authorities shall establish the following procedures in connection with products subject to **this Regulation**:

Or. en

**Amendment 112**

**Merja Kyllönen**

**Proposal for a regulation**

**Article 10 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) procedures for monitoring any accidents or any harm to the health or safety of end-users which are suspected of having been caused by such products;

*Amendment*

(b) procedures for monitoring any accidents or any harm to the health or safety of end-users which are suspected of having been caused by such products; **to ensure consistency, the Commission shall**

*set up a Pan-European harmonised database for the collection of accident and injury data.*

Or. en

**Amendment 113**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 10 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) procedures for monitoring any accidents or any harm to the health *or* safety of end-users which are suspected of having been caused by such products;

*Amendment*

(b) procedures for monitoring any accidents or any harm to the health safety *or security* of end-users which are suspected of having been caused by such products;

Or. en

**Amendment 114**  
**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**  
**Article 10 – paragraph 2 – point d a (new)**

*Text proposed by the Commission*

*Amendment*

*(d a) procedures for collecting and exploring scientific and technical knowledge concerning safety issues, impacting in particular health and environmental protection.*

Or. en

**Amendment 115**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**

## Article 11 – paragraph 4

*Text proposed by the Commission*

4. Member States shall ensure that their market surveillance authorities and single liaison office have the necessary resources, ***including sufficient budgetary and other resources, expertise, procedures and other arrangements*** for the proper performance of their duties.

*Amendment*

4. ***The Commission shall adopt in cooperation with the Member states, operational rules, including regarding human and financial resources, expertise and procedures, for the Member States to set up effective liaison offices.*** Member States shall ensure ***accordingly*** that their market surveillance authorities and single liaison office have the necessary resources, for the proper performance of their duties.

Or. en

## Amendment 116

Margrete Auken

### Proposal for a regulation

#### Article 12 – paragraph 1 – point a

*Text proposed by the Commission*

(a) the effective surveillance of the market within their territory with respect to ***any products that are subject to the Union harmonisation legislation set out in the Annex;***

*Amendment*

(a) the effective surveillance of the market within their territory with respect to ***all products; this surveillance entails that at least 20% of products placed on the market in each category is checked;***

Or. en

## Amendment 117

Merja Kyllönen

### Proposal for a regulation

#### Article 12 – paragraph 1 – point a

*Text proposed by the Commission*

(a) the effective surveillance of the market within their territory with respect to any products ***that are subject to the Union harmonisation legislation set out in the***

*Amendment*

(a) the effective surveillance of the market within their territory with respect to any products; ***this surveillance entails that at least 20% of products placed on the***

*Annex;*

*market in each category is checked;*

Or. en

**Amendment 118**

**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**

**Article 12 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) the effective surveillance of the market within their territory with respect to ***any products that are subject to the Union harmonisation*** legislation ***set out in the Annex***;

*Amendment*

(a) the effective surveillance of the market within their territory with respect to Union legislation ***on products***;

Or. en

**Amendment 119**

**Merja Kyllönen**

**Proposal for a regulation**

**Article 12 – paragraph 1 – point b**

*Text proposed by the Commission*

(b) the taking by them of appropriate and proportionate temporary measures and the taking by economic operators of appropriate and proportionate corrective action in relation to compliance with that legislation and this Regulation.

*Amendment*

(b) the taking by them of appropriate and proportionate temporary measures and the taking by economic operators of appropriate and proportionate corrective action in relation to compliance with that legislation and this Regulation ***and based on common Union rules***.

Or. en

**Amendment 120**

**Margrete Auken**

**Proposal for a regulation**



## Article 12 – paragraph 2 – introductory part

*Text proposed by the Commission*

2. Market surveillance authorities shall perform controls as part of their activities set out in paragraph 1, on a risk-based approach, taking into account, as a minimum, the following factors:

*Amendment*

2. Market surveillance authorities shall perform controls as part of their activities set out in paragraph 1, on a risk-based approach ***and in accordance with the precautionary principle***, taking into account, as a minimum, the following factors:

Or. en

## Amendment 121 Merja Kyllönen

### Proposal for a regulation

## Article 12 – paragraph 2 – introductory part

*Text proposed by the Commission*

2. Market surveillance authorities shall perform controls as part of their activities set out in paragraph 1, on a risk-based approach, taking into account, as a minimum, the following factors:

*Amendment*

2. Market surveillance authorities shall perform controls as part of their activities set out in paragraph 1, on a risk-based approach, taking into account ***the precautionary principle and***, as a minimum, the following factors:

Or. en

## Amendment 122 Guillaume Balas, Nicola Caputo, Christel Schaldemose

### Proposal for a regulation

## Article 12 – paragraph 2 – introductory part

*Text proposed by the Commission*

2. Market surveillance authorities shall perform controls as part of their activities set out in paragraph 1, on a risk-based approach, taking into account, as a minimum, the following factors:

*Amendment*

2. Market surveillance authorities shall perform controls as part of their activities set out in paragraph 1, on a risk-based approach, taking into account ***the precautionary principle and***, as a

minimum, the following factors:

Or. en

**Amendment 123**  
**Margrete Auken**

**Proposal for a regulation**  
**Article 12 – paragraph 2 – point a – introductory part**

*Text proposed by the Commission*

*Amendment*

(a) the identified risks associated with:

(a) the identified ***and potential*** risks associated with:

Or. en

**Amendment 124**  
**Margrete Auken**

**Proposal for a regulation**  
**Article 12 – paragraph 3 – subparagraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

(a) the product is liable to compromise the health or safety of end-users;

(a) the product is liable, ***or is suspected of being able***, to compromise the health, ***security*** or safety of end-users;

Or. en

**Amendment 125**  
**Merja Kyllönen**

**Proposal for a regulation**  
**Article 12 – paragraph 3 – subparagraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

(a) the product is liable to compromise the health or safety of end-users;

(a) the product is liable to compromise the health or safety ***or security*** of end-users;

**Amendment 126**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 12 – paragraph 3 – subparagraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

(a) the product is liable to compromise the health *or* safety of end-users;

(a) the product is liable to compromise the health, safety *or security* of end-users;

Or. en

**Amendment 127**  
**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**  
**Article 12 – paragraph 3 – subparagraph 1 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

*(a a) the product is liable to pollute or endanger the environment;*

Or. en

**Amendment 128**  
**Julie Girling, Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 12 – paragraph 3 – subparagraph 1 – point b**

*Text proposed by the Commission*

*Amendment*

(b) the product does not conform to applicable requirements under Union harmonisation legislation.

(b) the product does not conform to applicable requirements under Union harmonisation legislation *or under Directive 2001/95/EC.*

Or. en

*Justification*

*Consistency through the legislation.*

**Amendment 129**  
**Margrete Auken**

**Proposal for a regulation**  
**Article 12 – paragraph 3 – subparagraph 2**

*Text proposed by the Commission*

Where the products are withdrawn, recalled, prohibited or restricted, the market surveillance authority shall ensure that the Commission through the Network established under Article 31, the other Member States and end-users are informed accordingly.

*Amendment*

Where the products are withdrawn, recalled, prohibited or restricted, the market surveillance authority shall ensure that the Commission through the Network established under Article 31, the ***Union testing facilities***, other Member States and end-users are informed accordingly.

Or. en

**Amendment 130**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 12 – paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

***5 a. To settle any disputes arising out of a divergent risk assessment among the authorities of the Member States, the economic operators and the conformity assessment bodies the Commission may, of its own initiative or at the request of a surveillance authority, have a risk assessment carried out by a reference laboratory of the European Union referred to in Article 28, which shall be binding on all of the stakeholders.***

Or. en

**Amendment 131**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 12 – paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

***5 a. To settle any disputes arising out of a divergent risk assessment among the authorities of the Member States, the economic operators and the conformity assessment bodies the Commission may, of its own initiative or at the request of a surveillance authority, have a risk assessment carried out by a reference laboratory of the European Union referred to in Article 28, which shall be binding on all of the stakeholders.***

Or. en

**Amendment 132**  
**Julie Girling, Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 13 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. Each Member State shall draw up a national market surveillance strategy, as a minimum, every 3 years. The strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and enforcement of Union harmonisation legislation within the territory of the Member State and shall include all sectors and stages of the product supply chain, including imports and digital supply chains.

1. Each Member State shall draw up a national market surveillance strategy, as a minimum, every 3 years. The strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and enforcement of Union harmonisation legislation within the territory of the Member State and shall include all sectors and stages of the product supply chain, including imports and digital supply chains. ***In establishing their national market surveillance strategies, the Member States shall consult stakeholders and make their comments available to the general public.***

*Justification*

*Stakeholder involvement should be encouraged in the formation of national market surveillance strategies and these comments be made available to the general public to ensure transparency.*

**Amendment 133****Guillaume Balas, Nicola Caputo****Proposal for a regulation****Article 13 – paragraph 1***Text proposed by the Commission*

1. Each Member State shall draw up a national market surveillance strategy, as a minimum, every 3 years. The strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and enforcement of Union **harmonisation** legislation within the territory of the Member State and shall include all sectors and stages of the product supply chain, including imports and digital supply chains.

*Amendment*

1. Each Member State shall draw up a national market surveillance strategy, as a minimum, every 3 years, ***in view of the rapid market evolutions and new emerging risks***. The strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and enforcement of Union legislation within the territory of the Member State and shall include all sectors and stages of the product supply chain, including imports and digital supply chains.

Or. en

**Amendment 134****Margrete Auken****Proposal for a regulation****Article 13 – paragraph 1***Text proposed by the Commission*

1. Each Member State shall draw up a national market surveillance strategy, as a minimum, every 3 years. The strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and enforcement of Union harmonisation

*Amendment*

1. Each Member State shall draw up a national market surveillance strategy, as a minimum, every 3 years ***to follow the fast development of markets***. The strategy shall promote a consistent, comprehensive and integrated approach to market surveillance

legislation within the territory of the Member State and shall include all sectors and stages of the product supply chain, including imports and digital supply chains.

and enforcement of Union harmonisation legislation within the territory of the Member State and shall include all sectors and stages of the product supply chain, including imports and digital supply chains.

Or. en

**Amendment 135**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 13 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) the areas identified as a priority for the enforcement of Union harmonisation legislation;

*Amendment*

(b) the areas identified as a priority for the enforcement of Union harmonisation legislation. ***Member States shall consider products that are or have been subject to an emergency decision based on Article 13 of Directive 2001/95/EC as priority areas.***

Or. en

**Amendment 136**  
**Sirpa Pietikäinen**

**Proposal for a regulation**  
**Article 13 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) the areas identified as a priority for the enforcement of Union harmonisation legislation;

*Amendment*

(b) the areas identified as a priority for the enforcement of Union harmonisation legislation; ***Member States shall consider products that are or have been subject to an emergency decision based on Article 13 of Directive 2001/95/EC as priority areas;***

Or. en

**Amendment 137**

**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**

**Article 13 – paragraph 2 – point f a (new)**

*Text proposed by the Commission*

*Amendment*

*(f a) an assessment of new risks for consumers related to products which can connect to the internet and endanger consumers security;*

Or. en

**Amendment 138**

**Julie Girling, Sirpa Pietikäinen**

**Proposal for a regulation**

**Article 13 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

3. Member States shall communicate their national market surveillance strategy through the system referred to under Article 34.

3. Member States shall communicate their national market surveillance strategy through the system referred to under Article 34, *and shall make it available to the general public.*

Or. en

*Justification*

*Increased transparency.*

**Amendment 139**

**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**

**Article 14 – paragraph 3 – point h**

*Text proposed by the Commission*

*Amendment*



(h) the power to take temporary measures, where there are no other effective means available to prevent a serious risk, including in particular **temporary** measures requiring hosting service providers to remove, disable or restrict access to content or to suspend or restrict access to a website, service or account or requiring domain registries or registrars to put a fully qualified domain name on hold for a specific period of time;

(h) the power to take temporary **and/or final** measures **regarding unsafe or non-compliant products**, where there are no other effective means available to prevent a serious risk, including in particular measures requiring hosting service providers to remove, disable or restrict access to content or to suspend or restrict access to a website, service or account or requiring domain registries or registrars to put a fully qualified domain name on hold for a specific period of time;

Or. en

**Amendment 140**  
**Margrete Auken**

**Proposal for a regulation**  
**Article 14 – paragraph 3 – point h**

*Text proposed by the Commission*

(h) the power to take temporary measures, where there are no other effective means available to prevent a serious risk, including in particular temporary measures requiring hosting service providers to remove, disable or restrict access to content or to suspend or restrict access to a website, service or account or requiring domain registries or registrars to put a fully qualified domain name on hold for a specific period of time;

*Amendment*

(h) the power to take temporary **and final** measures, where there are no other effective means available to prevent a serious risk, including in particular temporary measures requiring hosting service providers to remove, disable or restrict access to content or to suspend or restrict access to a website, service or account or requiring domain registries or registrars to put a fully qualified domain name on hold for a specific period of time;

Or. en

**Amendment 141**  
**Merja Kyllönen**

**Proposal for a regulation**  
**Article 14 – paragraph 3 – point h**

*Text proposed by the Commission*

(h) the power to take temporary measures, where there are no other effective means available to prevent a serious risk, including in particular temporary measures requiring hosting service providers to remove, disable or restrict access to content or to suspend or restrict access to a website, service or account or requiring domain registries or registrars to put a fully qualified domain name on hold for a specific period of time;

*Amendment*

(h) the power to take temporary ***and final*** measures, where there are no other effective means available to prevent a serious risk, including in particular temporary measures requiring hosting service providers to remove, disable or restrict access to content or to suspend or restrict access to a website, service or account or requiring domain registries or registrars to put a fully qualified domain name on hold for a specific period of time;

Or. en

**Amendment 142**

**Gesine Meissner**

**Proposal for a regulation**

**Article 14 – paragraph 3 – point i**

*Text proposed by the Commission*

(i) the power to start investigations or proceedings on their own initiative in order to bring an instance of non-compliance within the territory of the Member State concerned to an end and, where appropriate, to publish information about the investigation through the system referred to in Article 34;

*Amendment*

(i) the power to start investigations or proceedings on their own initiative in order to bring an instance of non-compliance within the territory of the Member State concerned to an end and, where appropriate, to publish information about the investigation through the system referred to in Article 34, ***subject to the strictest guarantees of confidentiality and of professional and commercial secrecy;***

Or. en

**Amendment 143**

**Christofer Fjellner**

**Proposal for a regulation**

**Article 14 – paragraph 3 – point m**

*Text proposed by the Commission*

*Amendment*

**(m) the power to order the restitution of profits obtained as a result of an instance of non-compliance;**

**deleted**

Or. en

**Amendment 144**  
**Margrete Auken**

**Proposal for a regulation**  
**Article 14 – paragraph 3 – point m**

*Text proposed by the Commission*

*Amendment*

(m) the power to order the restitution of profits obtained as a result of an instance of non-compliance;

(m) the power to order the restitution of profits obtained as a result of an instance of non-compliance **and demand companies to refund affected consumers;**

Or. en

**Amendment 145**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 14 – paragraph 3 – point n**

*Text proposed by the Commission*

*Amendment*

(n) the power to publish any final decisions, final measures, commitments given by the economic operator or decisions taken or made pursuant to this Regulation, including the publication of the identity of the economic operator who was responsible for the non-compliance.

(n) the power to publish any final decisions, final measures, commitments given by the economic operator or decisions taken or made pursuant to this Regulation, including the publication of the identity of the economic operator who was responsible for the non-compliance **and the terms stating how the economic operator will have to compensate the loss or damage endured by consumers.**

Or. en

**Amendment 146**  
**Gesine Meissner**

**Proposal for a regulation**  
**Article 14 – paragraph 3 – point n**

*Text proposed by the Commission*

(n) the power to publish any final decisions, final measures, commitments given by the economic operator or decisions taken or made pursuant to this Regulation, including the publication of the identity of the economic operator who was responsible for the non-compliance.

*Amendment*

(n) the power to publish any final decisions, final measures, commitments given by the economic operator or decisions taken or made pursuant to this Regulation, including the publication of the identity of the economic operator who was responsible for the non-compliance, ***subject to the strictest guarantees of confidentiality and of professional and commercial secrecy.***

Or. en

**Amendment 147**  
**Gesine Meissner**

**Proposal for a regulation**  
**Article 14 – paragraph 4**

*Text proposed by the Commission*

4. Market surveillance authorities shall publish any commitments given to them by economic operators, details of any corrective action taken by economic operators in their territory, and details of any temporary measures taken by the relevant market surveillance authority pursuant to this Regulation.

*Amendment*

4. Market surveillance authorities shall publish any commitments given to them by economic operators, details of any corrective action taken by economic operators in their territory, and details of any temporary measures taken by the relevant market surveillance authority pursuant to this Regulation, ***subject to the strictest guarantees of confidentiality and of professional and commercial secrecy.***

Or. en

**Amendment 148**  
**Margrete Auken**

**Proposal for a regulation**  
**Article 14 – paragraph 5**

*Text proposed by the Commission*

5. Market surveillance authorities shall exercise their powers in accordance with the principle *of proportionality*.

*Amendment*

5. Market surveillance authorities shall exercise their powers in accordance with the *precautionary* principle.

Or. en

**Amendment 149**  
**Merja Kyllönen**

**Proposal for a regulation**  
**Article 14 – paragraph 5**

*Text proposed by the Commission*

5. Market surveillance authorities shall exercise their powers in accordance with the principle of proportionality.

*Amendment*

5. Market surveillance authorities shall exercise their powers in accordance with the *precautionary principle and the* principle of proportionality.

Or. en

**Amendment 150**  
**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**  
**Article 14 – paragraph 5**

*Text proposed by the Commission*

5. Market surveillance authorities shall exercise their powers in accordance with the principle of proportionality.

*Amendment*

5. Market surveillance authorities shall exercise their powers in accordance with the *precautionary principle and the* principle of proportionality.

Or. en

**Amendment 151**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 15 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory controls on the basis of a representative sample.

*Amendment*

Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, ***with a minimum of 20% checks performed on products placed on the market, in accordance with the priorities determined by the compliance network and the common methodology defined by the Commission***, by means of documentary checks and, where appropriate, physical and laboratory controls on the basis of a representative sample.

Or. en

**Amendment 152**  
**Gesine Meissner**

**Proposal for a regulation**  
**Article 16 – paragraph 1**

*Text proposed by the Commission*

Market surveillance authorities shall ***observe the principle*** of confidentiality ***where necessary in order to protect*** professional and commercial ***secrets or to*** preserve personal data pursuant to national legislation, subject to the requirement that information be made public to the fullest extent possible in order to protect the interests of end-users in the Union.

*Amendment*

Market surveillance authorities shall ***ensure the strictest guarantees*** of confidentiality ***and of*** professional and commercial ***secrecy and shall*** preserve personal data pursuant to national legislation, subject to the requirement that information be made public to the fullest extent possible in order to protect the interests of end-users in the Union.

Or. en

## Amendment 153

Guillaume Balas, Nicola Caputo, Christel Schaldemose

### Proposal for a regulation

#### Article 18 – paragraph 2

*Text proposed by the Commission*

2. The decision whether or not a product presents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard **and** the likelihood of its occurrence. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

*Amendment*

2. The decision whether or not a product presents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard, the likelihood of its occurrence **and the precautionary principle**. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

Or. en

## Amendment 154

Margrete Auken

### Proposal for a regulation

#### Article 20 – paragraph 3

*Text proposed by the Commission*

3. A notified body or any other conformity assessment body designated pursuant to Union harmonisation legislation may not be designated as a Union testing facility.

*Amendment*

3. **To prevent conflicts of interest**, a notified body or any other conformity assessment body designated pursuant to Union harmonisation legislation may not be designated as a Union testing facility.

Or. en

## Amendment 155

Margrete Auken

### Proposal for a regulation

## Article 20 – paragraph 4 – point e a (new)

*Text proposed by the Commission*

*Amendment*

*(e a) act as a knowledge centre in respect of risks and emerging risks, for example in relation to chemicals that are classified as carcinogenic, mutagenic and toxic for reproduction or other substances of concern in consumer products such as endocrine disruptors and sensitizers. Union testing facilities shall also assist the Commission and Member States to develop joint state of the art testing methodologies related to chemicals in consumer products. Close relationships shall be established between the European Chemicals Agency and the knowledge centre of the Union testing facilities to avoid overlaps and ensure optimal support for the Member States market surveillance and enforcement activities.*

Or. en

### *Justification*

*Art 57f of REACH recognises, for example, endocrine disruptors and sensitizers as substances of concern, but more action is needed to protect consumers and embryos from such chemicals. There is new research available related to endocrine disruptors which shows that the old rule that the higher the exposure, the higher the damage is not true for many chemicals. You can have for example a very tiny exposure at a bad moment (e.g. embryo under development) and the impact is much worse than having a higher impact at a later stage in life (e.g. adult of 30 years). However, while this is discussed in research, this is not sufficiently being taken into account in risk assessment and risk management decisions.*

## **Amendment 156**

**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

### **Proposal for a regulation**

## **Article 20 – paragraph 4 – point e a (new)**

*Text proposed by the Commission*

*Amendment*

*(e a) act as a knowledge hub on risks and emerging risks for consumers and the environment stemming from harmful*



*chemicals;*

Or. en

**Amendment 157**

**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**

**Article 20 – paragraph 4 – point e b (new)**

*Text proposed by the Commission*

*Amendment*

*(e b) act as a knowledge hub on new risks for consumers related to products which can connect to the internet;*

Or. en

**Amendment 158**

**Merja Kyllönen**

**Proposal for a regulation**

**Article 20 – paragraph 4 – point e a (new)**

*Text proposed by the Commission*

*Amendment*

*(e a) act as a knowledge hub on risks for consumers stemming from harmful chemicals.*

Or. en

**Amendment 159**

**Merja Kyllönen**

**Proposal for a regulation**

**Article 20 – paragraph 4 – point e b (new)**

*Text proposed by the Commission*

*Amendment*

*(e b) act as a knowledge hub on new risks for consumers related to products*

*which can connect to the internet.*

Or. en

**Amendment 160**

**Frédérique Ries**

**Proposal for a regulation**

**Article 20 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4a. The market surveillance authorities shall take due account of the results of tests carried out by Union testing facilities when adopting appropriate market surveillance measures.***

Or. fr

**Amendment 161**

**Julie Girling, Sirpa Pietikäinen**

**Proposal for a regulation**

**Article 20 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4 a. Market surveillance authorities shall take due account of the test, results, analysis and conclusions of the Union testing facilities to adopt appropriate market surveillance measures.***

Or. en

*Justification*

*The regulation should make it clear that market surveillance authorities are obliged to recognize the test results from these facilities.*

## Amendment 162

Guillaume Balas, Nicola Caputo, Christel Schaldemose

### Proposal for a regulation

#### Article 21 – paragraph 2

*Text proposed by the Commission*

2. Market surveillance authorities *may* charge economic operators administrative fees in relation to instances of non-compliance by that economic operator in order to enable the authorities to recover the costs of their activities with respect to these instances of non-compliance. Those costs may include the costs of carrying out testing for the purposes of a risk assessment, the costs of taking measures in accordance with Article 30(1) and (2) and the costs of their activities relating to products that are found to be non-compliant and subject to corrective action prior to their release for free circulation.

*Amendment*

2. Market surveillance authorities *shall* charge economic operators administrative fees in relation to instances of non-compliance by that economic operator in order to enable the authorities to recover the costs of their activities with respect to these instances of non-compliance. Those costs may include the costs of carrying out testing for the purposes of a risk assessment, the costs of taking measures in accordance with Article 30(1) and (2) and the costs of their activities relating to products that are found to be non-compliant and subject to corrective action prior to their release for free circulation.

Or. en

## Amendment 163

Cristian-Silviu Buşoi

### Proposal for a regulation

#### Article 23 – paragraph 1

*Text proposed by the Commission*

1. At the request of an applicant authority, the requested authority shall without delay take all necessary enforcement measures using the powers conferred on it under this Regulation in order to bring an instance of non-compliance to an end.

*Amendment*

1. At the request of an applicant authority *or the Commission or any other stakeholders bringing due evidence of non-compliance*, the requested authority shall without delay take all necessary enforcement measures using the powers conferred on it under this Regulation in order to bring an instance of non-compliance to an end. *In case the requested authority would not take action, the Commission could itself take all*

*necessary enforcement measures.*

Or. en

#### **Amendment 164**

**Julie Girling, Sirpa Pietikäinen**

#### **Proposal for a regulation**

#### **Article 25 – paragraph 3**

*Text proposed by the Commission*

3. Products deemed *to be non-compliant* on the basis of a decision of a market surveillance authority in one Member State, shall be presumed to be *non-compliant* by market surveillance authorities in another Member State, unless economic operators can provide evidence to the contrary.

*Amendment*

3. Products deemed *unsafe* on the basis of a decision of a market surveillance authority in one Member State, shall be presumed to be *illegal* by market surveillance authorities in another Member State, unless economic operators can provide evidence to the contrary.

Or. en

#### **Amendment 165**

**Françoise Grossetête**

#### **Proposal for a regulation**

#### **Article 25 – paragraph 3**

*Text proposed by the Commission*

3. Products deemed to be *non-compliant* on the basis of a decision of a market surveillance authority in one Member State, shall be presumed to be *non-compliant* by market surveillance authorities in another Member State, unless economic operators can provide evidence to the contrary.

*Amendment*

3. Products deemed to be *unsafe* on the basis of a decision of a market surveillance authority in one Member State, shall be presumed to be *unsafe* by market surveillance authorities in another Member State, unless economic operators can provide evidence to the contrary.

Or. fr

**Amendment 166**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 29 – paragraph 1**

*Text proposed by the Commission*

1. Market surveillance authorities shall treat *as a matter of priority products declared free for circulation by an authorised economic operator as set out in Article 38(2) of Regulation (EU) No 952/2013*, the release of which is suspended in accordance with Article 28(1) of this Regulation.

*Amendment*

1. Market surveillance authorities shall treat the release of *products* which *are* suspended in accordance with Article 28(1) of this Regulation *equally for all economic operators*.

Or. en

**Amendment 167**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 33 – paragraph 1 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

*(a a) to monitor the activities of market surveillance and customs authorities in order to ensure that there is an equal and stringent level of controls of harmonised and non-harmonised products in the different Member States;*

Or. en

**Amendment 168**  
**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**  
**Article 33 – paragraph 1 – point a b (new)**

*Text proposed by the Commission*

*Amendment*

*(a b) to define a common testing methodology in order to ensure there is uniformity in the controls carried out by Member States;*

Or. en

## **Amendment 169**

**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

### **Proposal for a regulation**

#### **Article 33 – paragraph 1 – point f**

*Text proposed by the Commission*

(f) to organise cooperation and the effective exchange of information and best practices between market surveillance authorities;

*Amendment*

(f) to organise cooperation and *facilitate* the effective *and regular* exchange of information and best practices between *Member States as well as between* market surveillance authorities, *and between Member States and relevant stakeholders*;

Or. en

## **Amendment 170**

**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

### **Proposal for a regulation**

#### **Article 33 – paragraph 1 – point m a (new)**

*Text proposed by the Commission*

*Amendment*

*(m a) to set up procedures for the provision of a pan-European database for the collection of data regarding accidents, harm or damages caused to the health, safety and/or security of end-users or to the environment, and to make the information provided in that database readily accessible to all relevant stakeholders;*

Or. en

**Amendment 171**  
**Cristian-Silviu Buşoi**

**Proposal for a regulation**  
**Article 35**

*Text proposed by the Commission*

*Amendment*

[...]

*deleted*

Or. en

**Amendment 172**  
**Gesine Meissner**

**Proposal for a regulation**  
**Article 35 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. The Commission may exchange confidential market surveillance related information with regulatory authorities of third countries or international organisations *where it has concluded confidentiality arrangements based on reciprocity with those authorities or organisations.*

1. The Commission may exchange confidential market surveillance related information with regulatory authorities of third countries or international organisations, *subject to the strictest guarantees of confidentiality and of professional and commercial secrecy.*

Or. en

**Amendment 173**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 61 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation that impose obligations on

The *Commission, together with* Member States, shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation that impose

economic operators and to infringements of provisions of any Union *harmonisation* legislation on products *covered by this Regulation* that impose obligations on economic operators where that legislation does not provide for penalties, and shall take all measures necessary to ensure that they are implemented. The penalties *provided for* shall be effective, proportionate and dissuasive.

obligations on economic operators and to infringements of provisions of any Union legislation on products that impose obligations on economic operators where that legislation does not provide for penalties, and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. *The Commission shall also lay down the operational rules for Member States to take temporary measures and corrective actions regarding non-compliant products and/or non compliant economic operators in order to speedily protect consumers when facing a risk.*

Or. en

**Amendment 174**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 61 – paragraph 2 – point a**

*Text proposed by the Commission*

*Amendment*

(a) *the financial situation of small and medium-sized enterprises;* *deleted*

Or. en

*Justification*

*This criteria is not related to the proportionality of harm caused to end-users or to the environment and therefore should not come first in the process of the penalty decision.*

**Amendment 175**  
**Guillaume Balas, Nicola Caputo, Christel Schaldemose**

**Proposal for a regulation**  
**Article 61 – paragraph 2 – point b**

*Text proposed by the Commission*

*Amendment*



(b) the nature, gravity and duration of the non-compliance taking into account the harm caused to end-users;

(b) the nature, gravity and duration of the non-compliance taking into account the harm caused to end-users, *to the environment, to social and economic interests*;

Or. en

**Amendment 176**  
**Guillaume Balas, Nicola Caputo**

**Proposal for a regulation**  
**Article 61 – paragraph 2 – point e a (new)**

*Text proposed by the Commission*

*Amendment*

*(e a) the financial situation of small and medium-sized enterprises;*

Or. en

**Amendment 177**  
**Guillaume Balas**

**Proposal for a regulation**  
**Annex I**

*Text proposed by the Commission*

*Amendment*

*[...]*

*deleted*

Or. en

*Justification*

*The annual RAPEX statistics show that consumers are often exposed to dangerous products for which no harmonised legislation exists. A consumer can hardly make the difference between harmonised and non-harmonised products and believe that his safety is ensured when it is not the case. Considering this, the scope of this regulation needs to be broadened to ensure a better protection of the health, safety and security of consumers and of the environment.*