



EUROPEAN PARLIAMENT

2009 - 2014

Committee on the Internal Market and Consumer Protection

2013/0048(COD)

11.9.2013

AMENDMENTS

66 - 392

Draft report
Sirpa Pietikäinen
(PE513.324v01-00)

on the proposal for a regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council

Proposal for a regulation
(COM(2013)0075 – C7 0043/2013 – 2013/0048(COD))

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PE516.934v02-00

Amendment 66

Andreas Schwab, Birgit Collin-Langen, Sabine Verheyen, Jürgen Creutzmann

Proposal for a regulation

Recital 1

Text proposed by the Commission

(1) In order to guarantee the free movement of products within the Union, it is necessary to ensure that they fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment and public security. Robust enforcement of these requirements is essential to the proper protection of these interests and to create the conditions in which fair competition in the Union goods market can thrive. Rules are therefore necessary on market surveillance and on controls of products entering the Union from third countries.

Amendment

(1) In order to guarantee the free movement of products within the Union, it is necessary to ensure that they fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment, ***intellectual property rights*** and public security. Robust enforcement of these requirements is essential to the proper protection of these interests and to create the conditions in which fair competition in the Union goods market can thrive. Rules are therefore necessary on market surveillance and on controls of products entering the Union from third countries.

Or. de

Amendment 67

Constance Le Grip

Proposal for a regulation

Recital 1

Text proposed by the Commission

(1) In order to guarantee the free movement of products within the Union, it is necessary to ensure that they fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment and public security. Robust enforcement of these

Amendment

(1) In order to guarantee the free movement of products within the Union, it is necessary to ensure that they fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, ***fair trading practices***, protection of consumers, protection of the environment, ***protection of intellectual***

requirements is essential to the proper protection of these interests and to create the conditions in which fair competition in the Union goods market can thrive. Rules are therefore necessary on market surveillance and on controls of products entering the Union from third countries.

property rights and public security. Robust enforcement of these requirements is essential to the proper protection of these interests and to create the conditions in which fair competition in the Union goods market, **both offline and online**, can thrive. Rules are therefore necessary on **physical and digital** market surveillance and on controls of products entering the Union from third countries.

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels. Lastly, if a product is authentic, consumers can be sure that it is safe and that it complies with the relevant standards.

Amendment 68

Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation

Recital 8

Text proposed by the Commission

(8) This Regulation should therefore integrate the provisions of Regulation 765/2008, Directive 2001/95/EC and several sector-specific acts of Union harmonisation legislation relating to market surveillance into a single regulation which covers products in both the harmonised and non-harmonised areas of the Union legislation, regardless whether they are intended for use, or are likely to be used, by consumers or professionals.

Amendment

(8) This Regulation should therefore integrate the provisions of Regulation 765/2008, Directive 2001/95/EC and several sector-specific acts of Union harmonisation legislation relating to market surveillance into a single regulation which covers products in both the harmonised and non-harmonised areas of the Union legislation, regardless whether they are intended for use, or are likely to be used, by consumers or professionals **and whether they are sold offline or online.**

Or. en

Justification

There should be no difference in the market surveillance rules in the online and offline

environments, so that the online market doesn't become an entry point for unsafe products on the EU market. Therefore, market surveillance activities should cover the products in the scope of this Regulation irrespective of their distribution channel.

Amendment 69
Constance Le Grip

Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) This Regulation should therefore integrate the provisions of Regulation 765/2008, Directive 2001/95/EC and several sector-specific acts of Union harmonisation legislation relating to market surveillance into a single regulation which covers products in both the harmonised and non-harmonised areas of the Union legislation, regardless whether they are intended for use, or are likely to be used, by consumers or professionals.

Amendment

(8) This Regulation should therefore integrate the provisions of Regulation 765/2008, Directive 2001/95/EC and several sector-specific acts of Union harmonisation legislation relating to market surveillance into a single regulation which covers products in both the harmonised and non-harmonised areas of the Union legislation, regardless whether they are ***traded online or offline and are*** intended for use, or are likely to be used, by consumers or professionals.

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels.

Amendment 70
Constance Le Grip

Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) This Regulation should establish a comprehensive framework for market surveillance in the Union. It should define the scope of the products covered and those excluded, impose an obligation on Member

Amendment

(12) This Regulation should establish a comprehensive framework for market surveillance in the Union. It should define the scope of the products covered and those excluded, impose an obligation on Member

States to organise and carry out market surveillance, require Member States to appoint market surveillance authorities and to specify their powers and duties, and make Member States responsible for setting up general and sector-specific market surveillance programmes.

States to organise and carry out market surveillance, require Member States to appoint market surveillance authorities and to specify their powers and duties, and make Member States responsible for setting up general and sector-specific ***physical and digital*** market surveillance programmes.

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels.

Amendment 71

Lara Comi

Proposal for a regulation

Recital 14

Text proposed by the Commission

(14) In order to make the entire market surveillance process transparent and easy to follow for both market surveillance authorities and economic operators, the Regulation should clearly set out the chronological steps of that process, from the moment when market surveillance authorities identify a product which they believe may present a risk, to the assessment of the risk presented, the corrective action to be taken by the relevant ***economic operator*** within a specified period and the measures to be taken by market surveillance authorities themselves if ***economic operators*** do not comply or in cases of urgency.

Amendment

(14) In order to make the entire market surveillance process transparent and easy to follow for both market surveillance authorities and economic operators, the Regulation should clearly set out the chronological steps of that process, from the moment when market surveillance authorities identify a product which they believe may present a risk, to the assessment of the risk presented, the corrective action to be taken by the relevant ***party responsible for placing the product on the market*** within a specified period and the measures to be taken by market surveillance authorities themselves if ***those responsible for placing on the market*** do not comply or in cases of urgency.

Or. it

Amendment 72
Constance Le Grip

Proposal for a regulation
Recital 14

Text proposed by the Commission

(14) In order to make the entire market surveillance process transparent and easy to follow for both market surveillance authorities and economic operators, the Regulation should clearly set out the chronological steps of that process, from the moment when market surveillance authorities identify a product which they believe may present a risk, to the assessment of the risk presented, the corrective action to be taken by the relevant economic operator within a specified period and the measures to be taken by market surveillance authorities themselves if economic operators do not comply or in cases of urgency.

Amendment

(14) In order to make the entire market surveillance process transparent and easy to follow for both market surveillance authorities and economic operators, the Regulation should clearly set out the chronological steps of that process, from the moment when market surveillance authorities identify a product which they believe may present a risk, to the assessment of the risk presented, the corrective action to be taken by the relevant economic operator ***in the physical and digital markets*** within a specified period and the measures to be taken by market surveillance authorities themselves if economic operators do not comply or in cases of urgency.

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels.

Amendment 73
Matteo Salvini

Proposal for a regulation
Recital 14

Text proposed by the Commission

(14) In order to make the entire market surveillance process transparent and easy to follow for both market surveillance authorities and economic operators, the Regulation should clearly set out the

Amendment

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chronological steps of that process, from the moment when market surveillance authorities identify a product which they believe may present a risk, to the assessment of the risk presented, the corrective action to be taken by the relevant ***party responsible for placing the product on the market*** within a specified period and the measures to be taken by market surveillance authorities themselves if ***those responsible for placing on the market*** do not comply or in cases of urgency.

Or. it

Amendment 74
Norica Nicolai

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission

Amendment

(14a) In order to facilitate the work of market surveillance authorities, economic operators should make available all the documentation and information necessary to such authorities for the purpose of carrying out their activities. Market surveillance authorities should only require documentation and information that the relevant economic operator can be expected to possess according to their role in the supply chain.

Or. en

Justification

Clarification of the obligations of economic operators laid down in Article 8.

Amendment 75
Preslav Borissov

Proposal for a regulation
Recital 15

Text proposed by the Commission

(15) Market surveillance should be based on the assessment of the risk presented by a product taking all relevant data into account. A product that is subject to Union harmonisation legislation which lays down essential requirements relating to protection of certain public interests should be presumed not to present a risk to those public interests if it complies with those essential requirements.

Amendment

(15) Market surveillance should be based on the assessment of the risk presented by a product taking all relevant data into account. ***The methodology and criteria of assessing risks should be homogeneous in all Member States in order to ensure level playing field for all economic operators.*** A product that is subject to Union harmonisation legislation which lays down essential requirements relating to protection of certain public interests should be presumed not to present a risk to those public interests if it complies with those essential requirements.

Or. en

Amendment 76
Constance Le Grip

Proposal for a regulation
Recital 15

Text proposed by the Commission

(15) Market surveillance should be based on the assessment of the risk presented by a product taking all relevant data into account. A product that is subject to Union harmonisation legislation which lays down essential requirements relating to protection of certain public interests should be presumed not to present a risk to those public interests if it complies with those essential requirements.

Amendment

(15) Market surveillance should be based on the assessment of the risk presented by a product taking all relevant data into account, ***and on a duty of care for all relevant economic operators, regardless of whether the products are traded online or offline.*** A product that is subject to Union harmonisation legislation which lays down essential requirements relating to protection of certain public interests should be presumed not to present a risk to those public interests if it complies with those essential requirements.

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels.

Amendment 77
Sirpa Pietikäinen

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission

Amendment

(15a) Consumers can play an active and important role in contributing to market surveillance, as they are usually in direct contact with products presenting a risk, including products that are not compliant with applicable Union legislation. In that context Member States should raise awareness of the consumers with regard to their rights to submit complaints on issues relating to product safety and market surveillance activities and ensure that the reporting procedure is easily accessible, relatively simple and efficient. The Commission should further explore the opportunities of making the submission of such complaints harmonized throughout the Union, for example through creation of a central database where the complaints filed by the consumers could be stored as well as examine possibilities of making those complaints public, subject to the right of review and reply by the economic operators involved.

Or. en

Amendment 78
Christel Schaldemose

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) For the purposes of this Regulation risk assessment should be carried out to identify products which have the potential to affect adversely the public interests protected by [Regulation (EU) No xxxx (on consumer product safety)], sector-specific Union harmonisation legislation and other Union legislation on products that are subject to this Regulation. It should include, where available, data on risks that have materialised previously with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned to alleviate the risks. The particular potential vulnerability of consumers, as opposed to professional users, should be taken into account as should the increased vulnerability of certain categories of consumer such as children, the elderly or the disabled.

Amendment

(18) For the purposes of this Regulation risk assessment should be carried out to identify products which have the potential to affect adversely the public interests protected by [Regulation (EU) No xxxx (on consumer product safety)], sector-specific Union harmonisation legislation and other Union legislation on products that are subject to this Regulation. It should include, where available, data on risks that have materialised previously with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned to alleviate the risks. The particular potential vulnerability of consumers, as opposed to professional users, should be taken into *special* account as should the increased vulnerability of certain categories of consumer such as children, the elderly or the disabled.

Or. en

Amendment 79
Constance Le Grip

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) For the purposes of this Regulation risk assessment should be carried out to identify products which have the potential to affect adversely the public interests protected by [Regulation (EU) No xxxx (on consumer product safety)], sector-specific Union harmonisation legislation and other Union legislation on products that are subject to this Regulation. It should

Amendment

(18) For the purposes of this Regulation risk assessment should be carried out to identify products which have the potential to affect adversely the public interests protected by [Regulation (EU) No xxxx (on consumer product safety)], sector-specific Union harmonisation legislation and other Union legislation on products that are subject to this Regulation. It should

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include, where available, data on risks that have materialised previously with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned, ***in keeping with their duty of care***, to alleviate the risks. The particular potential vulnerability of consumers, as opposed to professional users, should be taken into account as should the increased vulnerability of certain categories of consumer such as children, the elderly or the disabled.

Or. fr

Amendment 80
Constance Le Grip

Proposal for a regulation
Recital 21

Text proposed by the Commission

(21) Market surveillance authorities should be given the power to destroy products, render inoperable or order their destruction by the relevant economic operator, if they deem it necessary and proportionate to ensure that such goods cannot pose any further threats.

Amendment

(21) Market surveillance authorities should be given the power to destroy products, render *them* inoperable or order their destruction by the relevant economic operator, ***regardless of whether that operator trades online or offline***, if they deem it necessary and proportionate to ensure that such goods cannot pose any further threats.

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels.

Amendment 81
Matteo Salvini

Proposal for a regulation
Recital 21

Text proposed by the Commission

(21) Market surveillance authorities should be given the power to destroy products, render inoperable or order their destruction by the relevant economic operator, if they deem it necessary and proportionate to ensure that such goods cannot pose any further threats.

Amendment

(21) Market surveillance authorities should be given the power to destroy products, render inoperable or order their destruction by the relevant economic operator, if they deem it necessary and proportionate to ensure that such goods cannot pose any further threats. ***The relevant economic operator should bear all the costs related to those actions.***

Or. en

Amendment 82
Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation
Recital 23

Text proposed by the Commission

(23) There should be effective, speedy and accurate exchange of information among the Member States and between the Member States and the Commission. It is therefore necessary to provide for effective tools for such exchange. The Union rapid information system (RAPEX) has proved its effectiveness and efficiency. RAPEX enables measures to be taken across the Union in relation to products that present a risk beyond the territory of a single Member State. To avoid unnecessary duplication, this system should be used for all alert notifications required by this Regulation relating to products presenting a risk.

Amendment

(23) There should be effective, speedy and accurate exchange of information among the Member States and between the Member States and the Commission. It is therefore necessary to provide for effective tools for such exchange. The Union rapid information system (RAPEX) has proved its effectiveness and efficiency. RAPEX enables measures to be taken across the Union in relation to products that present a ***serious*** risk beyond the territory of a single Member State. To avoid unnecessary duplication, this system should be used for all alert notifications required by this Regulation relating to products presenting a ***serious*** risk.

Or. en

Justification

In line with amendments to Articles 19 and 20.

Amendment 83 **Sirpa Pietikäinen**

Proposal for a regulation **Recital 23**

Text proposed by the Commission

(23) There should be effective, speedy and accurate exchange of information among the Member States and between the Member States and the Commission. It is therefore necessary to provide for effective tools for such exchange. The Union rapid information system (RAPEX) has proved its effectiveness and efficiency. RAPEX enables measures to be taken across the Union in relation to products that present a risk beyond the territory of a single Member State. To avoid unnecessary duplication, this system should be used for all alert notifications required by this Regulation relating to products presenting a risk.

Amendment

(23) There should be effective, speedy and accurate exchange of information among the Member States and between the Member States and the Commission. It is therefore necessary to provide for effective tools for such exchange. The Union rapid information system (RAPEX) has proved its effectiveness and efficiency. RAPEX enables measures to be taken across the Union in relation to products that present a risk beyond the territory of a single Member State. To avoid unnecessary duplication, this system should be used for all alert notifications required by this Regulation relating to products presenting a risk. ***RAPEX should also include notifications related to Food Contact Materials, moved there from the RASFF platform.***

Or. en

Amendment 84 **Josef Weidenholzer**

Proposal for a regulation **Recital 27**

Text proposed by the Commission

(27) A European Market Surveillance Forum composed of representatives from

Amendment

(27) A European Market Surveillance Forum composed of representatives from

market surveillance authorities should be established. The Forum should provide a means of involving all stakeholders concerned, including professional organisations and consumer organisations, in order to take advantage of available information relevant for market surveillance when establishing, implementing and updating market surveillance programmes.

market surveillance authorities should be established. The Forum should provide a means of involving all stakeholders concerned, including professional organisations and, **above all**, consumer organisations, in order to take advantage of available information relevant for market surveillance when establishing, implementing and updating market surveillance programmes.

Or. de

Amendment 85
Sirpa Pietikäinen

Proposal for a regulation
Recital 30

Text proposed by the Commission

(30) This Regulation should strike a balance between transparency through the release of the maximum possible amount of information to the public and maintaining confidentiality, for example for reasons of **personal data protection**, commercial secrecy or the protection of investigations, in accordance with rules on confidentiality pursuant to applicable national law or, as regards the Commission, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the

Amendment

(30) This Regulation should strike a balance between transparency through the release of the maximum possible amount of information to the public and maintaining confidentiality, for example for reasons of commercial secrecy or the protection of investigations, , in accordance with rules on confidentiality pursuant to applicable national law or, as regards the Commission, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. **Moreover, this Regulation should respect data protection principles, such as confidential handling of personal data, requirement to process data fairly and lawfully and for specific purpose, while ensuring their quality and allowing the individuals concerned to exercise their rights.** Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of

Community institutions and bodies and on the free movement of such data apply in the context of this Regulation.

personal data and on the free movement of such data and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data apply in the context of this Regulation.

Or. en

Amendment 86
Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation
Recital 33

Text proposed by the Commission

(33) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.

Amendment

(33) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive. ***The level thereof should be set as a proportion of the value of sales of the products concerned during the last full year of the infringement, depending on its seriousness, duration and intentional or recurring character of the infringement. In any case, penalties should not exceed 10% of the company's total turnover in the preceding accounting year. Where possible under national law, Member States should be encouraged to allocate the revenue from such penalties to market surveillance activities.***

Or. en

Amendment 87
Matteo Salvini

Proposal for a regulation
Recital 33

Text proposed by the Commission

(33) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.

Amendment

(33) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive ***and include administrative penalties harmonised Union-wide. To that end it is necessary to allow for the seriousness of the infringement, company size and the situation of SMEs in particular, and the roles played by individual businesses within the supply chain, with particular reference to the activity actually performed by the given economic operator in the production process and the ability of that operator to affect product safety. Member States should ensure that the proceeds obtained from such administrative penalties are used for market surveillance activities.***

Or. it

Amendment 88
Matteo Salvini

Proposal for a regulation
Recital 34

Text proposed by the Commission

(34) Market surveillance should be financed ***at least in part*** by ***fees*** charged to economic operators where they are required by market surveillance authorities to take corrective action or where those authorities are obliged to take action themselves.

Amendment

(34) Market surveillance should be financed ***chiefly by Member States and only to a very limited extent*** by ***penalties*** charged to economic operators ***responsible for placing on the market*** where they are required by market surveillance authorities to take corrective action or where those authorities are obliged to take action themselves. ***In such cases it will, however, be necessary to allow for the seriousness***

of the infringement, company size and the situation of SMEs in particular, and the roles played by individual businesses within the supply chain, with particular reference to the activity actually performed by the given economic operator in the production process and the ability of that operator to affect product safety.

Or. it

Amendment 89

Lara Comi

Proposal for a regulation

Recital 38

Text proposed by the Commission

(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards uniform conditions for the *carrying out* of checks by reference to particular product categories or sectors, including the scale of checks to be carried out and the adequacy of samples to be checked. Implementing powers should also be conferred as regards the modalities for the provision of information to market surveillance authorities by economic operators, as regards establishing uniform conditions for determining cases in which such information need not be provided. Implementing powers should also be conferred as regards the modalities and procedures for the exchange of information through RAPEX and as regards the adoption of temporary or permanent marketing restrictions on products presenting a serious risk, where appropriate, specifying the necessary control measures to be taken by the Member States for their effective implementation where other Union

Amendment

(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards uniform conditions for the *carrying-out* of checks by reference to particular product categories or sectors, including the scale of checks to be carried out and the adequacy of samples to be checked. Implementing powers should also be conferred as regards the modalities for the provision of information to market surveillance authorities by economic operators, as regards establishing uniform conditions for determining cases in which such information need not be provided.

Economic operators should not, in any event, be called upon to supply information other than that which they are required to know by virtue of their role within the supply chain.

Implementing powers should also be conferred as regards the modalities and procedures for the exchange of information through RAPEX and as regards the adoption of temporary or permanent marketing restrictions on products

legislation does not provide a specific procedure to address the risks in question. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of its implementing powers.

presenting a serious risk, where appropriate, specifying the necessary control measures to be taken by the Member States for their effective implementation where other Union legislation does not provide a specific procedure to address the risks in question. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of its implementing powers.

Or. it

Amendment 90
Matteo Salvini

Proposal for a regulation
Recital 38

Text proposed by the Commission

(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards uniform conditions for the *carrying out* of checks by reference to particular product categories or sectors, including the scale of checks to be carried out and the adequacy of samples to be checked. Implementing powers should also be conferred as regards the modalities for the provision of information to market surveillance authorities by economic operators, as regards establishing uniform conditions for determining cases in which such information need not be provided. Implementing powers should also be conferred as regards the modalities and procedures for the exchange of information through RAPEX and as regards the

Amendment

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Economic operators should not, in any event, be called upon to supply information other than that which they are required to know by virtue of their

adoption of temporary or permanent marketing restrictions on products presenting a serious risk, where appropriate, specifying the necessary control measures to be taken by the Member States for their effective implementation where other Union legislation does not provide a specific procedure to address the risks in question. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of its implementing powers.

role within the supply chain.

Implementing powers should also be conferred as regards the modalities and procedures for the exchange of information through RAPEX and as regards the adoption of temporary or permanent marketing restrictions on products presenting a serious risk, where appropriate, specifying the necessary control measures to be taken by the Member States for their effective implementation where other Union legislation does not provide a specific procedure to address the risks in question. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of its implementing powers.

Or. it

Amendment 91
Constance Le Grip

Proposal for a regulation
Recital 41

Text proposed by the Commission

(41) Since the objective of this Regulation, namely to ensure that products on the market covered by Union legislation fulfil the requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal **market** by providing a framework for coherent market surveillance in the Union, cannot be sufficiently achieved by the Member States as the attainment of this objective requires a very high degree of cooperation, interaction and uniformity of operation

Amendment

(41) Since the objective of this Regulation, namely to ensure that products on the **physical and digital markets** covered by Union legislation fulfil the requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the **physical and digital** internal **markets** by providing a framework for coherent market surveillance in the Union, cannot be sufficiently achieved by the Member States as the attainment of this objective requires a very high degree of cooperation,

among all of the competent authorities of all Member States, and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

interaction and uniformity of operation among all of the competent authorities of all Member States, and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels.

Amendment 92

Pablo Arias Echeverría

Proposal for a regulation

Recital 42 a (new)

Text proposed by the Commission

Amendment

(42a) This Regulation should comply with the precautionary principle in order to ensure a high level of human health, consumer and environmental protection.

Or. es

Amendment 93

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Recital 42 b (new)

Text proposed by the Commission

Amendment

(42b) This Regulation should comply with the precautionary principle in order to ensure a high level of human health, consumer and environmental protection.

Or. es

Amendment 94
Constance Le Grip

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission

Amendment

This Regulation lays down a framework for verifying that products meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests.

This Regulation lays down a framework for verifying that products ***available online or offline*** meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, ***fair trading practices***, consumer protection, the environment, ***intellectual property rights***, public security and other public interests.

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels. Lastly, if a product is authentic, consumers can be sure that it is safe and that it complies with the relevant standards.

Amendment 95
Norica Nicolai

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission

This Regulation lays down a framework for verifying that products meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests.

Amendment

This Regulation lays down a framework for verifying that products ***available on the market, either online or offline***, meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security, ***the level-playing field among market operators*** and other public interests.

Or. en

Justification

It should be clarified that this Regulation applies to products that are already placed on the market, as pre-market checks are performed by conformity assessment bodies. No distinction should be made according to the distribution channel. Moreover, one of the overarching goals of this regulation is to create a level-playing field between economic operators, which requires the verification of compliance with the requirements, as well as follow-up actions by market surveillance authorities.

Amendment 96
Heide Rühle

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission

This Regulation lays down a framework for verifying that products meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests.

Amendment

This Regulation lays down a framework for verifying that products ***placed or made available on the market*** meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security, ***a level-playing field among market operators*** and other public interests.

Or. en

Amendment 97
Christel Schaldemose

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission

This Regulation lays down a framework for verifying that products meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests.

Amendment

This Regulation lays down a framework for verifying that products meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests, ***and ensuring a level-playing field for economic operators.***

Or. en

Amendment 98
Pablo Arias Echeverría

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission

This Regulation lays down a framework for verifying that products meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests.

Amendment

This Regulation lays down a framework for verifying that products meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests, ***and for general compliance with EU legislation.***

Or. es

Amendment 99
Pablo Arias Echeverría

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

Text proposed by the Commission

(1) ‘product’ means **a product obtained through a manufacturing process**;

Amendment

(1) ‘product’ means **any product supplied or made available as part of a business activity, either in exchange for payment or free of charge**;

Or. es

Justification

Clarifies the term ‘product’. Deletes the wording ‘obtained through a manufacturing process’ as doubts surrounded the way this requirement might be interpreted (in the case of plants, wood, etc.). Proposes a description based on the one set out in the General Product Safety Directive (GPSD).

Amendment 100
Constance Le Grip

Proposal for a regulation
Article 3 – paragraph 1 – point 2

Text proposed by the Commission

(2) ‘making available on the market’ means any supply of a product for distribution, consumption or use on the **Union market** in the course of a commercial activity, whether in return for payment or free of charge;

Amendment

(2) ‘making available on the market’ means any supply of a product for distribution, consumption or use on the **Union’s physical and digital markets** in the course of a commercial activity, whether in return for payment or free of charge;

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels.

Amendment 101
Constance Le Grip

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

Text proposed by the Commission

(3) ‘placing on the market’ means the first making available of a product on the ***Union market***;

Amendment

(3) ‘placing on the market’ means the first making available of a product on the ***Union’s physical and digital markets***;

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels.

Amendment 102
Norica Nicolai, Jürgen Creutzmann

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

Text proposed by the Commission

Amendment

(7a) ‘intermediary service providers’ means any natural or legal person who enables the placing or making available on the market of a product via electronic means, such as by operating e-commerce platforms or hosting websites;

Or. en

Justification

Intermediary service providers, such as online hosts and registrars, who provide electronic platforms for economic operators from third countries to sell their products online (as defined in Article 3(7a) new), are often based on EU territory. Such intermediaries should be obliged to cooperate with market surveillance authorities and take corrective actions where required, like other economic operators, in order to prevent the selling of unsafe or otherwise non-compliant products online.

Amendment 103
Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation

Article 3 – paragraph 1 – point 8

Text proposed by the Commission

(8) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the **distributor**;

Amendment

(8) ‘economic operators’ means the manufacturer, the authorised representative, the importer, **the distributor** and the **intermediary service provider**;

Or. en

Justification

Intermediary service providers, such as online hosts and registrars, who provide electronic platforms for economic operators from third countries to sell their products online (as defined in Article 3(7a) new), are often based on EU territory. Such intermediaries should be obliged to cooperate with market surveillance authorities and take corrective actions where required, like other economic operators, in order to prevent the selling of unsafe or otherwise non-compliant products online.

Amendment 104

Constance Le Grip

Proposal for a regulation

Article 3 – paragraph 1 – point 11

Text proposed by the Commission

(11) ‘market surveillance’ means the activities carried out and measures taken by public authorities to ensure that products do not endanger health, safety or any other aspect of public interest protection and, in the case of products falling within the scope of Union harmonisation legislation, that they comply with the requirements set out in that legislation;

Amendment

(11) ‘market surveillance’ means the activities carried out and measures taken by public authorities to ensure that products available **online or offline** do not endanger health, safety or any other aspect of public interest protection and, in the case of products falling within the scope of Union harmonisation legislation, that they comply with the requirements set out in that legislation;

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market

surveillance needs to be equally robust for both conventional and online channels.

Amendment 105
Constance Le Grip

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

Text proposed by the Commission

(12) ‘market surveillance authority’ means an authority of a Member State responsible for carrying out market surveillance on its territory;

Amendment

(12) ‘market surveillance authority’ means an authority of a Member State responsible for carrying out ***physical and digital*** market surveillance on its territory;

Or. fr

Justification

Consumer products are marketed through various channels in the internal market. Market surveillance needs to be equally robust for both conventional and online channels.

Amendment 106
Pablo Arias Echeverría

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

Text proposed by the Commission

(12) ‘market surveillance authority’ means an authority of a Member State ***responsible for carrying out market surveillance on its territory***;

Amendment

(12) ‘market surveillance authority’ means an authority of a Member State ***competent for exercising the regulated powers under by this Regulation***;

Or. es

Justification

The duties of the market surveillance authorities laid down in this Regulation are not market surveillance activities in the strict sense of the term. Besides conducting product checks, they also have to collect complaints, alert users, enter data in the Information and Communication System for Market Surveillance (ICSMS) and work with economic actors to draw up codes of good practice, etc. These tasks amount to more than straightforward market surveillance.

Amendment 107
Heide Rühle

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

Text proposed by the Commission

Amendment

(12a) 'Non-compliant product' means a product which is not in conformity with the requirements laid down in Union harmonisation legislation that applies to it;

Or. en

Amendment 108
Ashley Fox

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

Text proposed by the Commission

Amendment

(12b) "non-compliant product" means a product which fails to meet the requirements of Union legislation

Or. en

Amendment 109
Heide Rühle

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

Amendment

(13) ‘product presenting a risk’ means a product ***having*** the potential to affect adversely health and safety of persons in general, health and safety in the workplace,

(13) ‘product presenting a ***safety*** risk’ means a product ***which has*** the potential to affect adversely health and safety of persons in general, health and safety in the

consumer protection, the environment and public security as well as other public interests to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

workplace, consumer protection, the environment and public security as well as other public interests to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

Or. en

Amendment 110

Raffaele Baldassarre, Andreas Schwab

Proposal for a regulation

Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘product presenting a risk’ means a product **having** the potential to affect adversely health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security as well as other public interests to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

Amendment

(13) ‘product presenting a **safety** risk’ means a product **which has** the potential to affect adversely health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security as well as other public interests to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements

Or. en

Justification

A difference should be made in the definition of risk, given that for the purposes of Market Surveillance, products that are non-compliant with EU law should be banned from the EU Market. However, some products that are not compliant may be also unsafe, but not all of them.

Amendment 111
Matteo Salvini

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘product presenting a risk’ means a product **having** the potential to affect adversely health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security as well as other public interests to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

Amendment

(13 'product presenting a **safety** risk' means a product **which has** the potential to affect adversely health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security as well as other public interests to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

Or. en

Amendment 112
Jürgen Creutzmann

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘product presenting a risk’ means a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security **as well as other public interests** to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

Amendment

(13) ‘product presenting a risk’ means a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

Justification

The deletion of 'other public interests' increases legal certainty, as its meaning is unclear.

Amendment 113

Raffaele Baldassarre, Andreas Schwab

Proposal for a regulation

Article 3 – paragraph 1 – point 13 a

Text proposed by the Commission

Amendment

(13a) 'product presenting a regulatory risk' means a product which fails to comply with applicable Union legislation;

Or. en

Justification

A difference should be made in the definition of risk, given that for the purposes of Market Surveillance, products that are non-compliant with EU law should be banned from the EU Market. However, some products that are not compliant may be also unsafe, but not all of them.

Amendment 114

Matteo Salvini

Proposal for a regulation

Article 3 – paragraph 1 – point 13 b (new)

Text proposed by the Commission

Amendment

(13b) 'product presenting a regulatory risk' means a product which fails to comply with applicable Union legislation;

Or. en

Amendment 115

Heide Rühle

Proposal for a regulation
Article 3 – paragraph 1 – point 13 c (new)

Text proposed by the Commission

Amendment

(13c) 'product presenting a regulatory risk' means a product which fails to comply with applicable Union legislation;

Or. en

Amendment 116
Raffaele Baldassarre, Andreas Schwab

Proposal for a regulation
Article 3 – paragraph 1 – point 13 d (new)

Text proposed by the Commission

Amendment

(13d) 'product presenting an emerging risk' means a product which is not subject to EU harmonised legislation and on which there is solid scientific evidence that it presents a newly developing risk or a known risk if it is sold for use in new or unfamiliar conditions not foreseen by the manufacturer.

Or. en

Justification

Market surveillance authorities should also tackle products presenting an emerging risk. The proposed definition aims at clarification in order to be easily applied in a harmonised manner across the EU

Amendment 117
Wim van de Camp

Proposal for a regulation
Article 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) 'product presenting a serious risk' means a product presenting a risk requiring rapid intervention and follow-up, including cases where the effects may not be immediate;

Amendment

(14) 'product presenting a serious risk' means a product presenting a 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 Union 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;***

Or. en

Amendment 118

Matteo Salvini

Proposal for a regulation

Article 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) 'product presenting a serious risk' means a product presenting a risk requiring rapid intervention and follow-up, including cases where the effects may not be immediate;

Amendment

(14) 'product presenting a serious risk' means a product presenting a 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 Union 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;***

Or. en

Amendment 119

Wim van de Camp

Proposal for a regulation

Article 3 – paragraph 1 – point 14 a (new)

Text proposed by the Commission

Amendment

(14a) 'product models' means products that are considered to be distinct as presenting identical or similar essential characteristics, with differences, if any, having no impact on their safety level, unless otherwise proven by the manufacturer and or the importer.

Or. en

Justification

The notion of model is a cornerstone of the work of market surveillance authorities. Testing and surveillance is carried out by models. However, a number of market players have either no models identification or multiply the number of models for products that are actually similar, which hampers the work of market surveillance authorities, and deters them from performing controls as it significantly increases the level of resources that they need for controls.

Amendment 120

Matteo Salvini

Proposal for a regulation

Article 3 – paragraph 1 – point 14 b (new)

Text proposed by the Commission

Amendment

(14b) 'product models' means products that are considered to be distinct as presenting identical or similar essential characteristics, with differences, if any, having no impact on their safety level, unless otherwise proven by the manufacturer and or the importer.

Or. en

Justification

The notion of model is a cornerstone of the work of market surveillance authorities. Testing and surveillance is carried out by models. However, a number of market players have either

no models identification or multiply the number of models for products that are actually similar, which hampers the work of market surveillance authorities, and deters them from performing controls as it significantly increases the level of resources that they need for controls.

Amendment 121
Preslav Borissov

Proposal for a regulation
Article 3 – paragraph 1 – point 14 c (new)

Text proposed by the Commission

Amendment

(14c) 'product model' means a product that is to be considered as representative of a distinct group of products presenting similar essential characteristics, with differences, if any, having no impact on their safety level;

Or. en

Justification

The notion of model is essential for the work of market surveillance authorities in order to help them to better identify products when carrying out testing.

Amendment 122
Heide Rühle

Proposal for a regulation
Article 3 – paragraph 1 – point 18

Text proposed by the Commission

Amendment

(18) 'Union harmonisation legislation' means Union legislation harmonising the conditions for the marketing of products;

(18) 'Union harmonisation legislation' means Union legislation harmonising the conditions for the marketing of products; ***it defines the essential requirements which products must comply with in order to be placed on the Union market;***

Or. en

Amendment 123
Constance Le Grip

Proposal for a regulation
Article 3 – paragraph 1 – point 18

Text proposed by the Commission

(18) ‘Union harmonisation legislation’ means Union legislation harmonising the conditions for ***the marketing of*** products;

Amendment

(18) ‘Union harmonisation legislation’ means Union legislation harmonising the conditions for ***making*** products ***available on the online and offline markets***;

Or. fr

Amendment 124
Heide Rühle

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products ***presenting*** a risk are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product.

Amendment

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products ***that are not compliant with the applicable Union legislation and which present*** a risk are not made available on the Union market and, where such products have been made available, effective ***and proportionate*** measures are taken to remove the risk presented by the product ***or to put an end to its non-compliance***.

Or. en

Amendment 125
Raffaele Baldassarre, Andreas Schwab

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product.

Amendment

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk, ***and products that are not compliant with the applicable Union legislation*** are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product ***and to put an end to its non-compliance***

Or. en

Amendment 126

Matteo Salvini

Proposal for a regulation

Article 4 – paragraph 2

Text proposed by the Commission

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product.

Amendment

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk, ***and products that are not compliant with the applicable Union legislation*** are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product ***and to put an end to its non-compliance.***

Or. en

Amendment 127

Pablo Arias Echeverría

Proposal for a regulation

Article 4 – paragraph 2

Text proposed by the Commission

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product.

Amendment

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk ***and, more generally, products that are not compliant with the applicable Union legislation***, are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product ***and to put an end to its non-compliance.***

Or. es

Justification

Market surveillance should also cover non-compliant products that do not present a risk.

Amendment 128

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 4 – paragraph 2

Text proposed by the Commission

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product.

Amendment

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk ***and, more generally, products that are not compliant with the applicable Union legislation***, are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product ***and to put an end to its non-compliance.***

Or. es

Amendment 129
Anja Weisgerber, Markus Ferber

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

Amendment

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year. The information reported shall include statistics regarding the number of controls carried out and shall be communicated to all Member States. Member States may make a summary of the results accessible to the public.

deleted

Or. de

Justification

The Information and Communication System on Market Surveillance (ICSMS) already exists. Because of the time involved, additional surveillance activities by Member States would adversely affect how well surveillance was carried out.

Amendment 130
Franz Obermayr

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

Amendment

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year. The information reported shall include statistics regarding the number of controls carried out and shall be communicated to all Member States. Member States *may*

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year. The information reported shall include statistics regarding the number of controls carried out, ***the number of products queried in relation to those controls, and***

make a summary of the results accessible to the public.

the number and type of remedial actions subsequently put in hand, and shall be communicated to all Member States. Member States *shall* make a summary of the results *and statistics* accessible to the public.

Or. de

Amendment 131
Ashley Fox

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every *year*. *The information reported shall include statistics regarding the number of controls carried out and shall be communicated* to all Member States. *Member States may make* a summary of *the results accessible* to the public.

Amendment

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every *three years*. *The Commission shall communicate this information* to all Member States. A summary of *this information may be made available* to the public.

Or. en

Amendment 132
Preslav Borissov

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year.

Amendment

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year.

The information reported shall include statistics regarding the number of controls carried *out* **and** shall be communicated to all Member States. *Member States may make a summary of the results* accessible to the public.

The information reported shall include statistics regarding the number of controls *of each type* carried **and their results**. *These statistics* shall be communicated to all Member States **and shall be made** accessible to the public.

Or. en

Amendment 133
Christel Schaldemose

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year. The information reported shall include statistics regarding the number of controls carried out **and** shall be communicated to all Member States. *Member States may make a summary of the results accessible* to the public.

Amendment

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year. The information reported shall include statistics regarding the number **and results** of controls *of each type* carried out. *These statistics* shall be communicated to all Member States **and shall be made available** to the public.

Or. en

Amendment 134
Pablo Arias Echeverría

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year.

Amendment

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year.

The information reported shall include statistics regarding the number of controls carried out and shall be communicated to all Member States. ***Member States may make a summary of the results accessible to the public.***

The information reported shall include statistics regarding the number of controls carried out and shall be communicated to all Member States ***via the Commission.***

Or. es

Amendment 135
Constance Le Grip

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls ***to the Commission every year.*** The information reported shall include statistics regarding the number of controls carried out and shall be communicated to all Member States. Member States may make a summary of the results accessible to the public.

Amendment

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report ***to the Commission every year*** on these activities and controls ***and on the control methods used.*** The information reported shall include statistics regarding the number of controls carried out and shall be communicated to all Member States. Member States may make a summary of the results accessible to the public.

Or. fr

Amendment 136
Ashley Fox

Proposal for a regulation
Article 4 – paragraph 4

Text proposed by the Commission

4. The results of the monitoring and assessment of market surveillance activities carried out pursuant to paragraph 3 shall be made available to

Amendment

deleted

the public, electronically and, where appropriate, by other means.

Or. en

Amendment 137

Franz Obermayr

Proposal for a regulation

Article 4 – paragraph 4

Text proposed by the Commission

4. The results of the monitoring and assessment of market surveillance activities carried out pursuant to paragraph 3 shall be made available to the public, electronically and, where appropriate, by other means.

Amendment

4. The results of the monitoring and assessment of market surveillance activities carried out pursuant to paragraph 3 shall be made available to the public, electronically and, where appropriate, by other means. ***This shall take place within three months after they have been communicated to the other Member States.***

Or. de

Amendment 138

Pablo Arias Echeverría

Proposal for a regulation

Article 4 – paragraph 4

Text proposed by the Commission

4. The results of the monitoring and assessment of market surveillance activities carried out pursuant to paragraph 3 shall be made available to the public, electronically and, where appropriate, by other means.

Amendment

4. The ***Member States shall make a summary of the*** results of the monitoring and assessment of market surveillance activities carried out pursuant to paragraph 3 available to the public, electronically and, where appropriate, by other means.

Or. es

Justification

The information on the controls must be forward by the Commission to the Member States. As there would seem to be no distinction between the information made available to the public under paragraph 3 and under paragraph 4, it is proposed that the two be linked.

Amendment 139 **Christel Schaldemose**

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

Text proposed by the Commission

1. Each Member State shall establish or designate market surveillance authorities ***and define their duties, powers and organisation.***

Amendment

1. Each Member State shall establish or designate market surveillance authorities.

Or. en

Amendment 140 **Christel Schaldemose**

Proposal for a regulation **Article 5 – paragraph 2**

Text proposed by the Commission

2. Market surveillance authorities shall be given the powers and entrusted with the resources and means ***necessary*** for the proper performance of their tasks.

Amendment

2. Market surveillance authorities shall be given the powers and entrusted with the resources and means for the proper ***and comprehensive*** performance of their tasks.

Or. en

Amendment 141 **Christel Schaldemose**

Proposal for a regulation **Article 5 – paragraph 3**

Text proposed by the Commission

3. Each Member State shall establish **appropriate** mechanisms to ensure that the market surveillance authorities that it has established or designated exchange information, cooperate and coordinate their activities both among themselves and with the authorities in charge of controls of products at the external borders of the Union.

Amendment

3. Each Member State shall establish **sufficient and comprehensive** mechanisms to ensure that the market surveillance authorities that it has established or designated exchange information, cooperate and coordinate their activities both among themselves and with the authorities in charge of controls of products at the external borders of the Union.

Or. en

Amendment 142
Christel Schaldemose

Proposal for a regulation
Article 5 – paragraph 5

Text proposed by the Commission

5. Member States shall inform the public of the existence, responsibilities and identity of national market surveillance authorities and how those authorities may be contacted.

Amendment

5. Member States shall inform the public of the existence, responsibilities, **powers, available resources, cooperation mechanisms** and identity of national market surveillance authorities and how those authorities may be contacted.

Or. en

Amendment 143
Sirpa Pietikäinen

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate

Amendment

1. Market surveillance authorities shall **organise their activities in such a way that maximum effectiveness can be achieved.**

scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

They shall perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. ***Where appropriate, along with these traditional market sampling mechanisms, the market surveillance authorities shall move to proactive auditing of supply chain processes at entities involved in the manufacturing, importing, trading, branding and retailing of consumer products.*** They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Or. en

Amendment 144
Christel Schaldemose

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Amendment

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products, ***irrespective of the distribution channels and selling techniques,*** on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. ***For the sample checks, they shall use 2 % of all products placed on the market per year as an indicative target for each Member State.*** They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Or. en

Amendment 145
Heide Rühle

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Amendment

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products, ***irrespective of the distribution channels and selling techniques***, on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Or. en

Amendment 146
Pablo Arias Echeverría

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Amendment

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products, ***irrespective of the distribution channels and selling techniques***, on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Justification

Amendment designed to clarify that checks are also to be performed on products sold online.

Amendment 147

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation**Article 6 – paragraph 1 – subparagraph 1***Text proposed by the Commission*

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Amendment

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products, ***irrespective of the distribution channels and selling techniques***, on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Amendment 148

Anja Weisgerber, Markus Ferber

Proposal for a regulation**Article 6 – paragraph 1 – subparagraph 1***Text proposed by the Commission*

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They

Amendment

1. Market surveillance authorities shall perform appropriate checks on the characteristics of ***safety- or health-related*** products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the

shall record these checks in the information and communication system for market surveillance referred to in Article 21.

basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Or. de

Justification

For all areas which are not health- or safety-related, it should be left to the discretion of Member States whether they carry out sampling checks.

Amendment 149

Preslav Borissov

Proposal for a regulation

Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

Amendment

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21, ***by precisely identifying the product, referring to its type, model, batch or serial number.***

Or. en

Amendment 150

Wim van de Camp

Proposal for a regulation

Article 6 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The market surveillance authorities shall

identify risks arising in connection with products covered by this Regulation and the characteristics of such risks by complying with any possible indications and instructions that may be given by the Commission. They shall record this information in the information and communication system for market surveillance referred to in Article 21. The Commission shall systematically analyse such information and, in case it has information that leads it to suspect a risk, or in case of divergent risk identification among the authorities of Member States, may request additional information from the national market surveillance authorities and, of its own initiative or at the request of a national market surveillance authority, proceed to carry out an identification of the risk itself. The Commission shall transmit its identification of the risk to the national market surveillance authorities.

Or. en

Justification

The proposed amendment aims at permitting a common basis for risk identification on the basis of which the national surveillance authorities carry out their checks. Homogeneous risk identification is necessary to avoid operators in third countries choosing a point of entry to the European Union where a lower risk may have been identified due to less stringent controls

Amendment 151

Ashley Fox

Proposal for a regulation

Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

In cases of known or emerging risk related to the objectives set out in Article 1 of this Regulation and concerning a particular product or a category of

deleted

products, the Commission may adopt implementing acts to establish uniform conditions for the carrying out of the checks performed by one or several market surveillance authorities in relation to that particular product or category of products and the characteristics of that known or emerging risk. These conditions may include requirements for a temporary increase of the scale and frequency of checks to be carried out and the adequacy of samples to be checked. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).

Or. en

Amendment 152

Pablo Arias Echeverría

Proposal for a regulation

Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

In cases of known or emerging risk related to the objectives set out in Article 1 of this Regulation and concerning a particular product or a category of products, the Commission may adopt implementing acts to establish uniform conditions for the carrying out of the checks performed by one or several market surveillance authorities in relation to that particular product or category of products and the characteristics of that known or emerging risk. These conditions may include requirements for a temporary increase of the scale and frequency of checks to be carried out and the adequacy of samples to be checked. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).

deleted

Justification

This subparagraph enables the Commission to adopt additional control measures to be carried out by the surveillance authorities in the event of a known or emerging risk concerning any product or category of products. This may place an unexpected and unplanned burden on the surveillance authorities and differs from the case referred to in Article 12.

Amendment 153
Sirpa Pietikäinen

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. **Where appropriate**, market surveillance authorities shall alert users in their territories ***within an adequate timeframe*** of products that those authorities have identified as presenting a risk.

Amendment

2. Market surveillance authorities shall ***without delay*** alert users in their territories of products that those authorities have identified as presenting a risk. ***Where available, this information shall also include data on manufacturer, retail channel, pricing, and period of sales.***

Justification

The market surveillance authorities should not be allowed any delays for informing consumers of products presenting a risk. This information should be supplemented with more detailed information, such as data on the retail channel, where available, to help consumers identify the risky products.

Amendment 154
Josef Weidenholzer

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. **Where appropriate**, market surveillance authorities shall alert users ***in their***

Amendment

2. **The competent** market surveillance authorities ***and, where appropriate,***

territories within an adequate timeframe of products that those authorities have identified as presenting a risk.

economic operators shall alert users *as quickly as possible to* products which those authorities *or operators* have identified as presenting a risk;

Or. de

Amendment 155
Preslav Borissov

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. Where appropriate, market surveillance authorities shall alert users in their territories *within an adequate timeframe* of products that those authorities have identified as presenting a risk.

Amendment

2. Where appropriate, market surveillance authorities shall alert users in their territories *without delay of the identity* of products that those authorities have identified as presenting a risk.

Or. en

Amendment 156
Christel Schaldemose

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. Where appropriate, market surveillance authorities shall alert users in their territories *within an adequate timeframe* of products that those authorities have identified as presenting a risk.

Amendment

2. Where appropriate, market surveillance authorities shall alert users in their territories *without delay of the identity* of products that those authorities have identified as presenting a risk.

Or. en

Amendment 157
Josef Weidenholzer

Proposal for a regulation

Article 6 – paragraph 2 – subparagraph 2

Text proposed by the Commission

They shall cooperate with economic operators to prevent or reduce risks caused by products made available by those operators. For this purpose, they shall encourage and promote voluntary action by economic operators including, where applicable, through the development of and adherence to codes of good practice.

Amendment

Market surveillance authorities shall cooperate with economic operators **and other competent national authorities** to prevent or reduce risks caused by products made available by those **economic** operators. For this purpose, they shall encourage and promote voluntary action by economic operators including, where applicable, through the development of and adherence to codes of good practice.

Or. de

Amendment 158

Pablo Arias Echeverría

Proposal for a regulation

Article 6 – paragraph 2 – subparagraph 2

Text proposed by the Commission

They shall cooperate with economic operators to prevent or reduce risks caused by products made available by those operators. For this purpose, they shall encourage and promote voluntary action by economic operators including, where applicable, through the development of and adherence to codes of good practice.

Amendment

The market surveillance authorities shall encourage and promote voluntary action by economic operators including, where applicable, through the development of and adherence to codes of good practice.

Or. es

Justification

Economic operators must work with the market surveillance authorities to limit or prevent the risks that may arise from any unsafe products they have placed on the market, in accordance with the General Product Safety Directive (GPSD). Cooperation between economic operators and surveillance authorities should be covered under Articles 8, 10 and 11 of the proposal for the Regulation on Consumer Product Safety.

Amendment 159
Christel Schaldemose

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission

3. Market surveillance authorities shall carry out their duties independently, impartially and without bias and shall fulfil their obligations under this Regulation; they shall exercise their powers in relation to economic operators in accordance with the principle of proportionality.

Amendment

3. Market surveillance authorities shall carry out their duties independently, impartially and without bias and shall fulfil their obligations under this Regulation; they shall exercise their powers in relation to economic operators in accordance with the principle of proportionality ***and with due regard to the precautionary principle as laid down in Article 191(2) of the Treaty (TFEU).***

Or. en

Amendment 160
Lara Comi

Proposal for a regulation
Article 6 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Market surveillance authorities shall take duly into account the seriousness of the risk and the precautionary principle.

They shall accordingly carry out sample checks on sufficient numbers of products enabling conformity and the real risk posed to be assessed.

Or. it

Amendment 161
Matteo Salvini

Proposal for a regulation
Article 6 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. Market surveillance authorities shall take duly into account the seriousness of the risk and the precautionary principle. They shall accordingly carry out sample checks on sufficient numbers of products enabling conformity and the real risk posed to be assessed.

Or. it

Amendment 162

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 6 – paragraph 3 c (new)

Text proposed by the Commission

Amendment

3c. Market surveillance authorities shall act taking due account of the seriousness of the risk and of the precautionary principle.

Or. es

Amendment 163

Bernadette Vergnaud

Proposal for a regulation

Article 6 – paragraph 4

Text proposed by the Commission

Amendment

4. Where it is necessary and justified for carrying out their duties, market surveillance authorities may enter the premises of economic operators and take any necessary samples of products.

4. Where it is necessary and justified for carrying out their duties, market surveillance authorities may enter the premises of economic operators ***without prior warning, examine, seize or take copies of any and all documents, gain access to IT systems*** and take any necessary samples of products.

Justification

In order to ensure consumer safety and combat fraud, surveillance authorities need to be given broader powers, which should include the right to carry out spot checks, seize documents and gain access to IT systems, given that only an electronic copy is now kept of most documents.

Amendment 164

Pablo Arias Echeverría

Proposal for a regulation

Article 6 – paragraph 4

Text proposed by the Commission

4. Where it is necessary and justified for carrying out their duties, market surveillance authorities may enter the premises of economic operators and take any necessary samples of products.

Amendment

4. Where it is necessary and justified for carrying out their duties, market surveillance authorities may enter the premises of economic operators, ***carry out appropriate documentary checks, make copies of relevant documents*** and take any necessary samples of products.

Justification

Granting additional powers to market surveillance authorities will ensure thorough performance of their duties.

Amendment 165

Maria Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 6 – paragraph 4

Text proposed by the Commission

4. Where it is necessary and justified for carrying out their duties, market surveillance authorities may enter the premises of economic operators and take

Amendment

4. Where it is necessary and justified for carrying out their duties, market surveillance authorities may enter the premises of economic operators, ***carry out appropriate documentary checks, make***

any necessary samples of products.

copies of relevant documents and take any necessary samples of products.

Or. es

Amendment 166
Josef Weidenholzer

Proposal for a regulation
Article 6 – paragraph 5 – point a

Text proposed by the Commission

(a) provide consumers and other interested parties with the opportunity to submit complaints on issues relating to product safety, market surveillance activities and risks arising in connection with products and follow up those complaints as appropriate;

Amendment

(a) provide consumers and other interested parties with the opportunity to submit complaints on issues relating to product safety, market surveillance activities and risks arising in connection with products and follow up those complaints as appropriate ***and within a reasonable time frame***;

Or. de

Amendment 167
Norica Nicolai

Proposal for a regulation
Article 6 – paragraph 5 – point c

Text proposed by the Commission

(c) follow and keep up to date with developments in scientific and technical knowledge concerning the safety of products.

Amendment

(c) follow and keep up to date with developments in scientific and technical knowledge concerning the safety ***and compliance*** of products ***with Union harmonised legislation***.

Or. en

Justification

This provision should not be limited to product safety only, but should be extended to any other issues that may be relevant for the compliance of products with Union harmonised

legislation.

Amendment 168
Christel Schaldemose

Proposal for a regulation
Article 6 – paragraph 5 – point c a (new)

Text proposed by the Commission

Amendment

(ca) monitor accidents and harm to health which are suspected to have been caused by those products.

Or. en

Amendment 169
Anna Hedh

Proposal for a regulation
Article 6 – paragraph 5 – point c b (new)

Text proposed by the Commission

Amendment

(cb) monitor accidents and harm to health which are related to those products;

Or. sv

Amendment 170
Heide Rühle

Proposal for a regulation
Article 6 – paragraph 5 – point c c (new)

Text proposed by the Commission

Amendment

(cc) Verify the compliance of products with the applicable Union legislation.

Or. en

Amendment 171
Heide Rühle

Proposal for a regulation
Article 6 – paragraph 5 – point c d (new)

Text proposed by the Commission

Amendment

(cd) be encouraged to participate in national standardisation activities aimed at the development or revision of standards requested by the Commission in accordance with Article 10 of Regulation (EU) No 1025/2012.

Or. en

Amendment 172
Norica Nicolai

Proposal for a regulation
Article 6 – paragraph 5 – point c e (new)

Text proposed by the Commission

Amendment

(ce) participate, where possible and relevant, in activities of standardisation organisations for the purposes of the development or revision of standards in accordance with Regulation (EU) No. 1025/2010.

Or. en

Justification

It would be useful for market surveillance authorities to be closely associated to the standardisation process, as this would help them in keeping up to date with developments in scientific and technical knowledge as required under point c) of this paragraph.

Amendment 173
Anna Hedh

Proposal for a regulation
Article 6 – paragraph 6

Text proposed by the Commission

6. Adequate procedures shall be established and made known to the public to enable market surveillance authorities to fulfil these obligations.

Amendment

6. Adequate procedures shall be established and made known to the public to enable market surveillance authorities to fulfil these obligations. ***In particular, market surveillance authorities shall make available to the public on request:***

(a) the identity of those products about which safety complaints have been received under point a of Article 6(5);

(b) the nature of the safety defect and risk perceived in the product by the complainant and any hazardous incident or injury reported;

(c) any comments on the complaint made by the economic operators;

(d) what follow up action the market surveillance authority has determined to be appropriate.

Or. en

Amendment 174
Franz Obermayr

Proposal for a regulation
Article 6 – paragraph 8

Text proposed by the Commission

8. ***The protection of*** confidentiality shall not prevent the dissemination to market surveillance authorities of information necessary to ensure effective market surveillance.

Amendment

8. Confidentiality shall not prevent the dissemination to the market surveillance authorities of information relevant for ensuring the effectiveness of market surveillance activities.

Or. de

Amendment 175
Pablo Arias Echeverría

Proposal for a regulation

Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

1. Each Member State shall draw up a general market surveillance programme and shall review that programme, and update it if necessary, at least every four years. The programme shall cover market surveillance organisation and related activities ***and take into account the specific needs of business generally, and SMEs in particular, when implementing Union harmonisation legislation and Regulation (EU) No [.../...] [on consumer product safety], and provide for guidance and assistance. It shall include the following:***

Amendment

1. Each Member State shall draw up a general market surveillance programme and shall review that programme, and update it if necessary, at least every four years. The programme shall cover market surveillance organisation and related activities.

Or. es

Justification

The application of EU legislation should not be conditional on the specific needs of enterprises. The aim of this clause, for everyone involved, is to ensure that products meet the requirements set out in EU legislation.

Amendment 176

Josef Weidenholzer

Proposal for a regulation

Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

1. Each Member State shall draw up a general market surveillance programme and shall review that programme, and update it if necessary, at least every four years. The programme shall cover market surveillance organisation and related activities and take into account the specific needs of ***business generally, and SMEs in particular***, when implementing Union

Amendment

1. Each Member State shall draw up a general market surveillance programme and shall review that programme, and update it if necessary, at least every four years. The programme shall cover market surveillance organisation and related activities and take into account the specific needs of ***consumers*** when implementing Union harmonisation legislation and

harmonisation legislation and Regulation (EU) No [...] [on consumer product safety], and provide for guidance and assistance. It shall include the following:

Regulation (EU) No [...] [on consumer product safety], and provide for guidance and assistance **for relevant operators**. It shall include the following:

Or. de

Amendment 177
Christel Schaldemose

Proposal for a regulation
Article 7 – paragraph 1 – introductory part

Text proposed by the Commission

1. Each Member State shall draw up a general market surveillance programme and shall review that programme, and update it if necessary, at least every four years. The programme shall cover market surveillance organisation and related activities and take into account the specific needs of business **generally, and SMEs in particular**, when implementing Union harmonisation legislation and Regulation (EU) No [...] [on consumer product safety], and provide for guidance and assistance. It shall include the following:

Amendment

1. Each Member State shall draw up a general market surveillance programme and shall review that programme, and update it if necessary, at least every four years. The programme shall cover market surveillance organisation and related activities and take into account the specific needs of business **and consumers** when implementing Union harmonisation legislation and Regulation (EU) No [...] [on consumer product safety], and provide for guidance and assistance. It shall include the following:

Or. en

Amendment 178
Ashley Fox

Proposal for a regulation
Article 7 – paragraph 1 – point b

Text proposed by the Commission

(b) the financial resources, staff, technical and other means attributed to the authorities;

Amendment

deleted

Or. en

Justification

This could restrict Member State flexibility in effectively organising its Market Surveillance activity.

Amendment 179

Pablo Arias Echeverría

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) the financial resources, staff, technical and other means attributed to the authorities; ***deleted***

Or. es

Justification

Providing guidance and assistance to economic operators is not a characteristic of surveillance authorities and may undermine their independence. It is proposed that point b) be deleted as the issues it covers are confidential ones.

Amendment 180

Norica Nicolai

Proposal for a regulation

Article 7 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the levels and modalities of calculation of fees applicable to economic operators pursuant to Articles 10 and 16 of this Regulation;

Or. en

Justification

In order to encourage the emergence of a common practice with regard to the fees charged to economic operators who make available on the market unsafe or otherwise non-compliant products, it seems appropriate to include information thereon in the general market

surveillance programmes, so that both the Commission and the other Member States are kept informed.

Amendment 181

Matteo Salvini

Proposal for a regulation

Article 7 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) testing laboratories specialised in the commodity categories to which products to be tested belong, in accordance with the criteria set out in Article 28;

Or. it

Amendment 182

Norica Nicolai

Proposal for a regulation

Article 7 – paragraph 3

Text proposed by the Commission

Amendment

3. The general and sector-specific programmes and their updates shall be communicated to the other Member States and the Commission **and**, subject to Article 6(6), shall be made accessible to the public electronically and, where appropriate, by other means.

3. The general and sector-specific programmes and their updates shall be ***drawn up after consultation with relevant stakeholders and shall be*** communicated to the other Member States and the Commission. Subject to Article 6(6), ***they*** shall be made accessible to the public electronically and, where appropriate, by other means.

Or. en

Justification

In order to ensure that the market surveillance programmes take into account the needs of businesses, consumers etc. it is appropriate for Member States to consult relevant stakeholders before drawing up such programmes.

Amendment 183

Pablo Arias Echeverría

Proposal for a regulation

Article 7 – paragraph 3

Text proposed by the Commission

3. The general and sector-specific programmes and their updates shall be communicated to the other Member States **and** the Commission and, subject to Article 6(6), shall be made accessible to the public electronically and, where appropriate, by other means.

Amendment

3. The general and sector-specific programmes and their updates shall be communicated to the other Member States **via** the Commission and, subject to Article 6(6), shall be made accessible to the public electronically and, where appropriate, by other means.

Or. es

Justification

It would be more efficient for the Commission to inform the Member States of the programmes.

Amendment 184

Sirpa Pietikäinen

Proposal for a regulation

Article 8 – paragraph 1

Text proposed by the Commission

1. On request, economic operators and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities any documentation and information that those authorities require for the purpose of carrying out their activities, in a language which can be easily understood by them.

Amendment

deleted

Or. en

Justification

The deletion links to amendments spelling out the obligations of different economic operators more specifically.

Amendment 185

Andreas Schwab, Birgit Collin-Langen, Sabine Verheyen

Proposal for a regulation

Article 8 – paragraph 1

Text proposed by the Commission

1. ***On*** request, economic operators and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities any documentation and information that those authorities require for the purpose of carrying out their activities, ***in a language which can be easily understood by them.***

Amendment

1. ***Following a reasoned*** request, economic operators and, where applicable, conformity assessment bodies shall make available to market surveillance authorities any documentation and information that those authorities require for the purpose of carrying out their activities. ***Where an economic operator has previously received the documentation and information concerned from another economic operator, and where it is classified as confidential under EU and Member State trade secrecy rules, confidentiality shall be ensured when that documentation and information is made available.***

Or. de

Amendment 186

Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation

Article 8 – paragraph 1

Text proposed by the Commission

1. ***On*** request, economic operators and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities ***any*** documentation

Amendment

1. ***Further to a reasoned*** request, economic operators and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities

and information that those authorities require for the purpose of carrying out their activities, in a language which can be easily understood by them.

all the** documentation and information that those authorities require for the purpose of carrying out their activities, in **electronic or physical format and in** a language which can be easily understood by them. **Such information shall include information that enables the precise identification of the product and facilitates the tracing of the product, as appropriate.

Or. en

Justification

This wording aims at avoiding putting unnecessary administrative burdens on economic operators by clarifying the information which may be requested by market surveillance authorities. The second paragraph of this article is redundant and the relevant part has therefore been integrated in this paragraph.

Amendment 187

Ashley Fox

Proposal for a regulation

Article 8 – paragraph 1

Text proposed by the Commission

1. On request, economic operators and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities any documentation and information that those authorities require for the purpose of carrying out their activities, in a language which can be easily understood by **them**.

Amendment

1. On request, economic operators and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities any **necessary** documentation and information that those authorities require for the purpose of carrying out their activities, in a language which can be easily understood by **end users as determined by the Member State concerned**.

Or. en

Amendment 188

Heide Rühle

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. On request, economic operators and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities any documentation and information that those authorities require for the purpose of carrying out their activities, in a language which can be easily understood by them.

Amendment

1. On request ***and without prejudice to Articles R2(9), R4(9) and R5(5) of Annex I of Decision 768/2008/EC***, economic operators and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities any documentation and information that those authorities require for the purpose of carrying out their activities, in a language which can be easily understood by them.

Or. en

Amendment 189
Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission

2. Economic operators shall ***provide all necessary information to*** market surveillance authorities ***including information that enables the precise identification of the product and facilitates the tracing of the product.***

Amendment

2. Economic operators shall ***cooperate with*** market surveillance authorities ***at their request, on any action taken to eliminate the risks presented by products that they have placed or made available on the market.***

Or. en

Justification

It is appropriate to foresee a cooperation obligation for economic operators in line with the provisions of other articles of this Regulation. This includes taking corrective measures and any other actions that may be needed to eliminate the risk. This is in line with the provisions of the New Legislative Framework.

Amendment 190
Wim van de Camp

Proposal for a regulation
Article 8 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Manufacturers and importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or on its packaging or in a document accompanying the product. The address shall indicate a single point at which the manufacturer or the importer can be contacted.

Or. en

Justification

While traceability requirements are relevant when products pose an identified risk, they should be limited to such products, hence the reference to products governed by specific safety requirements. Also due to the cost of the measure, a reasonable alternative on packs or accompanying material should always be allowed.

Amendment 191
Matteo Salvini

Proposal for a regulation
Article 8 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. Manufacturers and importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or on its packaging or in a document accompanying the product. The address shall indicate a single point at which the manufacturer or the importer can be contacted.

Or. en

Justification

While traceability requirements are relevant when products pose an identified risk, they should be limited to such products, hence the reference to products governed by specific safety requirements. Also due to the cost of the measure, a reasonable alternative on packs or accompanying material should always be allowed.

Amendment 192 **Constance Le Grip**

Proposal for a regulation **Article 8 – paragraph 2 c (new)**

Text proposed by the Commission

Amendment

2c. All information supplied or made available to market surveillance authorities under this article shall be presented in a clear and legible manner.

Or. fr

Amendment 193 **Raffaele Baldassarre, Andreas Schwab**

Proposal for a regulation **Article 8 a (new)**

Text proposed by the Commission

Amendment

Article 8a

General obligations of manufacturers

- 1. When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with relevant EU legislation.***
- 2. Manufacturers shall draw up the required technical documentation in accordance with their relevant EU harmonised legislation.***
- 3. Manufacturers who consider or have reason to believe that a product which***

they have placed on the market is not in conformity with the relevant EU harmonised legislation shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk for the health and safety of the consumer, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective measure taken.

4. Manufacturers established outside the Union shall appoint a single authorised representative established within the Union for the purposes of market surveillance

Or. en

Justification

Article 8 of the proposal should be completed with respect to the obligations of economic operators. In this context, and in accordance with Decision 768/2008/EC establishing a common framework for the marketing of products, Regulations EU 167/2013 on the approval and market surveillance of agricultural and forestry vehicles, Regulation EU 168/2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles and Directive 2009/48/EC on the safety of toys, specific obligations need to be spelled out for the different economic operators whose responsibilities differ according to their position in the supply chain.

Amendment 194
Sirpa Pietikäinen

Proposal for a regulation
Article 8 b (new)

Text proposed by the Commission

Amendment

Article 8b
Obligations of manufacturers

- 1. When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with relevant Union legislation.*
- 2. Proportionate to the possible risks of a product, manufacturers shall have in place adequate quality management systems to ensure the compliance and safety of their products. They shall carry out sample testing of products made available on the market, investigate complaints and keep a register of complaints, nonconforming products and product recalls, and shall keep distributors informed of any such monitoring.*
- 3. Manufacturers shall draw up the required technical documentation in accordance with the relevant Union harmonisation legislation.*
- 4. Manufacturers shall keep, for a period of ten years after the product has been placed on the market, the technical documentation and make it available to the market surveillance authorities, upon reasoned request.*
- 5. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing the identification of the product which is easily visible and legible, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.*
- 6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.*

7. Manufacturers who consider or have reason to believe that a product which they have placed on the market presents a risk, including non-compliance with the relevant Union harmonisation legislation, shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a serious risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the risk and of any corrective measure taken.

Or. en

Justification

A clarification of the obligations and responsibilities of different economic operators within the legislation.

Amendment 195

Raffaele Baldassarre, Andreas Schwab

Proposal for a regulation

Article 8 c (new)

Text proposed by the Commission

Amendment

Article 8c

General Obligations of the single authorised representatives

For the purposes of market surveillance, the single authorised representative shall perform the tasks specified in the mandate received from the manufacturer.

The obligations laid down in Article [8a first paragraph – General Obligations of the Manufacturer] and the drawing up of technical documentation shall not form part of the single authorised

representative's mandate.

The mandate shall allow the single authorised representative to do at least the following:

(a) keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities.

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product subject to Union harmonisation legislation;

(c) cooperate with the competent national authorities at their request, on any action taken to eliminate the risks posed by the products covered by their mandate.

Or. en

Amendment 196
Sirpa Pietikäinen

Proposal for a regulation
Article 8 d (new)

Text proposed by the Commission

Amendment

Article 8d

Authorised representatives

1. A manufacturer established outside the Union shall appoint an authorised representative established within the Union for the purposes of market surveillance

2. For the purpose of market surveillance, the authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) further to a reasoned request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product;

(b) cooperate with the market surveillance authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.

Or. en

Justification

A clarification of the obligations and responsibilities of authorised representatives, proposed to be appointed by the manufacturers established outside the EU. The amendment replaces Rapporteur's AM36

Amendment 197

Raffaele Baldassarre, Andreas Schwab

Proposal for a regulation

Article 8 e (new)

Text proposed by the Commission

Amendment

Article 8e

General Obligations of importers

1. Importers shall place on the market only compliant and safe products.

2. Before placing a product on the market, importers shall ensure that the manufacturer has drawn up the technical documentation, that the product bears the required marking and is accompanied by the required documents.

3. Where importers consider or have reason to believe that a product is not in conformity with relevant EU legislation, they shall not place it on the market. Furthermore, where they consider or have reason to believe that the product presents a serious risk, they shall inform the manufacturer and the market surveillance

authorities. For type-approved products, they shall also inform the approval authority that has granted the approval to that effect.

Or. en

Amendment 198
Sirpa Pietikäinen

Proposal for a regulation
Article 8 f (new)

Text proposed by the Commission

Amendment

Article 8f

Obligations of importers

- 1. Before placing a product on the market importers shall ensure that the product is compliant with relevant Union legislation.***
- 2. Where an importer considers or has reason to believe that a product presents a risk, including non-compliance with the relevant Union harmonisation legislation, he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product presents a serious risk, the importer shall inform the manufacturer and the market surveillance authorities of the Member State in which he is established to that effect.***
- 3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.***
- 4. Proportionate to the possible risks presented by a product, importers shall have in place adequate quality***

management systems to ensure the compliance and safety of their imported products. They shall carry out sample testing of marketed products, investigate complaints, and keep a register of complaints, of non-conforming products and of product recalls, and shall keep the manufacturer and distributors informed of such monitoring.

5. Importers who consider or have reason to believe that a product which they have placed on the market presents a risk, including non-compliance with the relevant Union harmonisation legislation, shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a serious risk, importers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the risk and of any corrective measure taken.

6. Importers shall keep, for a period of ten years after the product has been placed on the market, the technical documentation and make it available to the market surveillance authorities, upon reasoned request.

Or. en

Justification

A clarification of the obligations and responsibilities of different economic operators within the legislation.

Amendment 199

Raffaele Baldassarre, Andreas Schwab

Proposal for a regulation

Article 8 g (new)

Text proposed by the Commission

Amendment

Article 8g

General Obligations of distributors

1. When making a product available on the market, distributors shall act with due care in relation to the requirements set out in the Union legislation.

Before making a product available on the market, distributors shall verify that it bears the required statutory marking or type-approval mark, where applicable, and that it is accompanied by the required documents demonstrating compliance, including labelling information where applicable, and by instructions and safety information in the official language or languages of the Member State in which the product is to be made available on the market.

2. Distributors shall provide all necessary information to market surveillance authorities including information that enables the precise identification of the product and facilitates the tracing of the product.

Or. en

Amendment 200
Sirpa Pietikäinen

Proposal for a regulation
Article 8 h (new)

Text proposed by the Commission

Amendment

Article 8h

Obligations of distributors

1. Where a distributor considers or has a reason to believe that a product presents a risk, including non-compliance with the

relevant Union harmonisation legislation, he shall not make the product available on the market until it has been brought into conformity. Furthermore, where the product presents a serious risk, the distributor shall inform the manufacturer or the importer, as applicable, to that effect as well as the market surveillance authority of the Member State in which the distributor is established.

2. Distributors who consider or have reason to believe that a product which they have placed on the market presents a risk, including non-compliance with the relevant Union harmonisation legislation shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a serious risk, importers shall immediately inform the market surveillance authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the risk and of any corrective action taken.

3. Following a request of the technical documentation to the distributor, he shall take steps to either obtain the documentation himself and hand it to the authority or arrange that the documentation is sent directly by the manufacturer to the authority. In the latter case the distributor remains responsible and liable to sanctions in the event the documentation does not reach the authority. The distributor has the possibility, when having received a reasoned request, to contact the importer, manufacturer or authorised representative in order to obtain the documentation or to arrange that it is sent directly to the authority. The obligation for distributors to provide the technical documentation to an authority upon reasoned request does not include an obligation to keep it.

Justification

A clarification of the obligations and responsibilities of different economic operators within the legislation should be made. The clarification in point 4 permits the manufacturer to ensure that confidential business information contained in the technical documentation is not systematically shared with distributors, who are potential competitors, and remains confidential.

Amendment 201

Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation**Article 8 i (new)**

Text proposed by the Commission

Amendment

Article 8i***Formal non-compliance of products***

1. Where market surveillance authorities identify one of the following cases of formal non-compliance in relation to a product subject to Union harmonisation legislation, they shall require the relevant economic operator to rectify that formal non-compliance:

(a) the CE marking or other markings required by Union harmonisation legislation have not been affixed or have been affixed incorrectly;

(b) the EU declaration of conformity, where required, has not been drawn up or has been drawn up incorrectly;

(c) the technical documentation is incomplete or unavailable;

(d) the required labelling or instructions for use are incomplete or missing.

2. If the economic operator fails to rectify the formal non-compliance referred to in paragraph 1, market surveillance authorities shall ensure that the product is withdrawn or recalled.

Justification

It is not appropriate to create an automatic causal link between a formal non-compliance circumstance and the existing of a material risk. It is therefore proposed to treat cases of formal non-compliance separately, which doesn't exclude a risk assessment being carried out.

Amendment 202

Heide Rühle

Proposal for a regulation

Article 9 – title

Text proposed by the Commission

Products presenting a risk

Amendment

Procedures for dealing with non-compliant products or Products presenting a risk

Or. en

Amendment 203

Ashley Fox

Proposal for a regulation

Article 9 – title

Text proposed by the Commission

Products presenting a risk

Amendment

Non-compliant products and products presenting a risk

Or. en

Amendment 204

Ashley Fox

Proposal for a regulation

Article 9 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out a risk assessment in relation to **that** product **taking account of** the considerations and criteria set out in Article 13.

Amendment

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may **be non-compliant or** present a risk, they shall carry out a risk assessment in relation to **the** product **concerned covering the requirements laid down in the applicable Union legislation and, where necessary,** the considerations and criteria set out in Article 13.

Or. en

Amendment 205
Heide Rühle

Proposal for a regulation
Article 9 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out **a risk assessment** in relation to that product taking account of the considerations and criteria set out in Article 13.

Amendment

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk **or is otherwise not compliant with the applicable Union legislation,** they shall carry out **an evaluation** in relation to that product taking account of the considerations and criteria set out in Article 13.

Or. en

Amendment 206

Raffaele Baldassarre, Andreas Schwab

Proposal for a regulation

Article 9 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13.

Amendment

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk **and may be non-compliant with the applicable Union legislation**, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13

Or. en

Amendment 207

Josef Weidenholzer

Proposal for a regulation

Article 9 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13.

Amendment

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities **learn or** have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13.

Or. de

Amendment 208

Pablo Arias Echeverría

Proposal for a regulation

Article 9 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13.

Amendment

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13 ***of this Regulation and in Article 6 of the Regulation on Consumer Product Safety.***

Or. es

Justification

The risk assessment should reflect the considerations and criteria set out in Article 13, but this does not cover the assessment of (safety) risks posed by non-harmonised products not covered by any standards. It is therefore proposed that the article be supplemented with a reference to Article 6 of the Regulation on Consumer Product Safety (RCPS), which covers such a scenario.

Amendment 209

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 9 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market

Amendment

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market

surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13.

surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13 *of this Regulation and in Article 6 of the Regulation on Consumer Product Safety*.

Or. es

Amendment 210
Heide Rühle

Proposal for a regulation
Article 9 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Without prejudice to Article R31 and in line with Article R34 of Annex I of Decision 768/2008/EC, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the conformity marking has been affixed in violation of Article [R11] or of Article [R12] of Decision 768/2008/EC;

(b) the conformity marking has not been affixed;

(c) the EC declaration of conformity has not been drawn up;

(d) the EC declaration of conformity has not been drawn up correctly;

(e) technical documentation is either not available or not complete.

Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate

measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market.

Or. en

Amendment 211

Pablo Arias Echeverría

Proposal for a regulation

Article 9 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Market surveillance authorities shall take **due** consideration of any readily available test result and risk assessment that has already been carried out or issued in relation to the product by an economic operator or any other person or authority including the authorities of other Member States.

Amendment

Market surveillance authorities shall take consideration of any readily available **and comprehensible** test result and risk assessment that has already been carried out or issued in relation to the product by an economic operator or any other person or authority including the authorities of other Member States.

Or. es

Justification

‘Due’ is deleted as this may give rise to differing interpretations, while ‘comprehensible’ is added following ‘readily available’ with reference to interpreting the results of the risk assessment.

Amendment 212

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 9 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Market surveillance authorities shall take due consideration of any readily available test result and risk assessment that has already been carried out or issued in

Amendment

Market surveillance authorities shall take due consideration of any readily available **and comprehensible** test result and risk assessment that has already been carried

relation to the product by an economic operator or any other person or authority including the authorities of other Member States.

out or issued in relation to the product by an economic operator or any other person or authority including the authorities of other Member States.

Or. es

Amendment 213
Josef Weidenholzer

Proposal for a regulation
Article 9 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Market surveillance authorities shall take due consideration of any readily available test result and risk assessment that has already been carried out or issued in relation to the product by an economic operator or any other person or authority including the authorities of other Member States.

Amendment

Market surveillance authorities shall take due consideration of any readily available **and objective** test result and risk assessment that has already been carried out or issued in relation to the product by an economic operator or any other person or authority including the authorities of other Member States.

Or. de

Amendment 214
Heide Rühle

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

2. In relation to a product that is subject to Union harmonisation legislation, formal non-compliance with that legislation shall give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases:

(a) the CE marking or other markings required by Union harmonisation legislation have not been affixed or have

Amendment

deleted

- been affixed incorrectly;*
- (b) the EU declaration of conformity, where required, has not been drawn up or has been drawn up incorrectly;*
- (c) the technical documentation is incomplete or unavailable;*
- (d) the required labelling or instructions for use are incomplete or missing.*

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities shall ensure that the product is withdrawn or recalled.

Or. en

Amendment 215
Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

Amendment

2. In relation to a product that is subject to Union harmonisation legislation, formal non-compliance with that legislation shall give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases:

deleted

- (a) the CE marking or other markings required by Union harmonisation legislation have not been affixed or have been affixed incorrectly;*
- (b) the EU declaration of conformity, where required, has not been drawn up or has been drawn up incorrectly;*
- (c) the technical documentation is*

incomplete or unavailable;

(d) the required labelling or instructions for use are incomplete or missing.

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities shall ensure that the product is withdrawn or recalled.

Or. en

Justification

It doesn't seem appropriate to consider formal non-compliance as a sufficient reason to believe the product may present a risk. It is therefore proposed to treat cases of formal non-compliance separately. The text has been adjusted and moved to a new article 8a.

Amendment 216

Anja Weisgerber, Markus Ferber

Proposal for a regulation

Article 9 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission

In relation to a product that is subject to Union harmonisation legislation, formal non-compliance with that legislation **shall** give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases:

Amendment

In relation to a product that is subject to Union harmonisation legislation, formal non-compliance with that legislation **may** give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases:

Or. de

Justification

It is for the market surveillance authorities to decide whether a product presents risks.

Amendment 217

Pablo Arias Echeverría

Proposal for a regulation

Article 9 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission

In relation to a product ***that is subject to Union harmonisation legislation***, formal non-compliance with ***that*** legislation shall give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases:

Amendment

In relation to a product, formal non-compliance with ***EU*** legislation shall give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases:

Or. es

Justification

Formal non-compliance should be extended to include all products, including non-harmonised ones, since the RCPC sets out the obligation on the availability of technical documentation attesting to the safety of the product to be placed on the market, the identification of the economic operators and the provision, where necessary, of instructions and warnings.

Amendment 218

Sirpa Pietikäinen

Proposal for a regulation

Article 9 – paragraph 2 – subparagraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(aa) the product or any presentation of the product bears without authorisation a trade mark that is identical or similar to a registered trade mark for this product, thereby not allowing to guarantee its authenticity or origin;

Or. en

Amendment 219

Constance Le Grip

Proposal for a regulation

Article 9 – paragraph 2 – subparagraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the product or any presentation of the product bears, without authorisation, a trade mark that is identical or similar to the registered trade mark for this product, thereby preventing its authenticity or origin from being firmly established;

Or. fr

Amendment 220

Anja Weisgerber, Markus Ferber

Proposal for a regulation

Article 9 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Amendment

Regardless whether the risk assessment shows that the product in fact presents a risk, **market surveillance authorities shall require** the economic operator **to** rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities **shall** ensure that the product is withdrawn or recalled.

Regardless whether the risk assessment shows that the product in fact presents a risk, the economic operator **shall** rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities **may** ensure that the product is withdrawn or recalled. **For minor infringements, a warning may be issued or a penalty payment imposed.**

Or. de

Justification

It should be made possible for market surveillance authorities penalise minor infringements.

Amendment 221

Ashley Fox

Proposal for a regulation

Article 9 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities ***shall ensure that the product is withdrawn or recalled.***

Amendment

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities ***may, if appropriate, withdraw or recall the product in question until the non-compliance is rectified.***

Or. en

Justification

Products which are subject only to minor infringements should not be dealt with in the same way as products which present a general risk.

Amendment 222

Othmar Karas

Proposal for a regulation

Article 9 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities shall ensure that the product is withdrawn or recalled.

Amendment

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities shall ensure that the product is withdrawn or recalled. ***Warnings and penalties can be applied in case of infringements.***

Or. en

Amendment 223

Lara Comi

Proposal for a regulation

Article 9 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities shall ensure that the product is withdrawn or recalled.

Amendment

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator ***responsible for placing the product on the market*** to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities shall ensure that the product is withdrawn or recalled.

Or. it

Amendment 224

Matteo Salvini

Proposal for a regulation

Article 9 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities shall ensure that the product is withdrawn or recalled.

Amendment

Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator ***responsible for placing the product on the market*** to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities shall ensure that the product is withdrawn or recalled.

Or. it

Amendment 225

Lara Comi

Proposal for a regulation

Article 9 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Without prejudice to Article 10(4), where market surveillance authorities find that a product does present a risk they shall without delay specify the necessary corrective action to be taken by the relevant economic operator to address the risk within a specified period. Market surveillance authorities may recommend or agree with the relevant economic operator the corrective action to be taken.

Amendment

Without prejudice to Article 10(4), where market surveillance authorities find that a product does present a risk they shall without delay specify the necessary corrective action to be taken by the relevant economic operator ***responsible for placing the product on the market*** to address the risk within a specified period. Market surveillance authorities may recommend or agree with the relevant economic operator ***responsible for placing the product on the market*** the corrective action to be taken.

Or. it

Amendment 226
Matteo Salvini

Proposal for a regulation
Article 9 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Without prejudice to Article 10(4), where market surveillance authorities find that a product does present a risk they shall without delay specify the necessary corrective action to be taken by the relevant ***economic operator*** to address the risk within a specified period. Market surveillance authorities may recommend or agree with the relevant ***economic operator*** the corrective action to be taken.

Amendment

Without prejudice to Article 10(4), where market surveillance authorities find that a product does present a risk they shall without delay specify the necessary corrective action to be taken by the relevant ***party responsible for placing the product on the market*** to address the risk within a specified period. Market surveillance authorities may recommend or agree with the relevant ***party responsible for placing the product on the market*** the corrective action to be taken.

Or. it

Amendment 227
Pablo Arias Echeverría

Proposal for a regulation

Article 9 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Without prejudice to Article 10(4), where market surveillance authorities find that a product does present a risk they shall without delay specify the necessary corrective action to be taken by the relevant economic operator to address the risk within a specified period. **Market surveillance authorities may recommend or agree with the relevant economic operator the corrective action to be taken.**

Amendment

Without prejudice to Article 10(4), where market surveillance authorities find that a product does present a risk they shall without delay specify the necessary corrective action to be taken by the relevant economic operator to address the risk within a specified period **in which he can implement that action and present his case, submitting any relevant statements.**

Or. es

Justification

This paragraph contains three very different concepts in terms of the surveillance authorities establishing corrective measures: 'specify' to the EO – 'recommend' to the EO and 'agree with' the EO. This would give rise to very different interpretations of this crucial matter of the adoption of measures concerning products that present a risk. It is proposed that the last sentence be deleted. It is the surveillance authority that should take action to limit the marketing of such products and the EO himself that should decide what steps to take to prevent his product presenting a risk and whether this can be remedied or if the product must be destroyed, depending on the product and the nature of its non-compliance. Furthermore, the set period provided for should be viewed as one for considering the situation and deciding what measures should be adopted and, if necessary, in which the EO can present his case to prove that his product is safe, submitting any relevant statements and documentation. Not all EOs have the same level of liability and it is difficult for distributors to make a risk assessment.

Amendment 228

Lara Comi

Proposal for a regulation

Article 9 – paragraph 3 – subparagraph 2

Text proposed by the Commission

The **economic operator** shall ensure that all necessary corrective action is taken in respect of all the products concerned that it

Amendment

The **party responsible for placing on the market** shall ensure that all necessary corrective action is taken in respect of all

has made available on the market throughout the Union.

the products concerned that it has made available on the market throughout the Union.

Or. it

Amendment 229
Matteo Salvini

Proposal for a regulation
Article 9 – paragraph 3 – subparagraph 2

Text proposed by the Commission

The *economic operator* shall ensure that all necessary corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Union.

Amendment

The *party responsible for placing on the market* shall ensure that all necessary corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Union.

Or. it

Amendment 230
Lara Comi

Proposal for a regulation
Article 9 – paragraph 3 – subparagraph 3 – introductory part

Text proposed by the Commission

The *economic operator* shall provide all necessary information to market surveillance authorities pursuant to Article 8, and in particular the following information:

Amendment

The *party responsible for placing on the market* shall provide all necessary information to market surveillance authorities pursuant to Article 8, and in particular the following information:

Or. it

Amendment 231
Matteo Salvini

Proposal for a regulation

Article 9 – paragraph 3 – subparagraph 3 – introductory part

Text proposed by the Commission

The ***economic operator*** shall provide all necessary information to market surveillance authorities pursuant to Article 8, and in particular the following information:

Amendment

The ***party responsible for placing on the market*** shall provide all necessary information to market surveillance authorities pursuant to Article 8, and in particular the following information:

Or. it

Amendment 232

Lara Comi

Proposal for a regulation

Article 9 – paragraph 3 – subparagraph 4

Text proposed by the Commission

Where possible, market surveillance authorities shall ***identify the manufacturer or importer of*** the product ***and*** take action in relation to ***that economic operator in addition to*** the distributor.

Amendment

Where ***it is not possible to identify the party responsible for placing*** the product ***on the market***, market surveillance authorities shall take action in relation to the distributor.

Or. it

Amendment 233

Matteo Salvini

Proposal for a regulation

Article 9 – paragraph 3 – subparagraph 4

Text proposed by the Commission

Where possible, market surveillance authorities shall ***identify the manufacturer or importer of*** the product ***and*** take action in relation to ***that economic operator in addition to*** the distributor.

Amendment

Where ***it is not possible to identify the party responsible for placing*** the product ***on the market***, market surveillance authorities shall take action in relation to the distributor.

Or. it

Amendment 234
Lara Comi

Proposal for a regulation
Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. Corrective action to be taken by ***economic operators*** in relation to a product presenting a risk may include:

Amendment

4. Corrective action to be taken by ***those responsible for placing on the market*** in relation to a product presenting a risk may include:

Or. it

Amendment 235
Matteo Salvini

Proposal for a regulation
Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. Corrective action to be taken by ***economic operators*** in relation to a product presenting a risk may include:

Amendment

4. Corrective action to be taken by ***those responsible for placing on the market*** in relation to a product presenting a risk may include:

Or. it

Amendment 236
Pablo Arias Echeverría

Proposal for a regulation
Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. Corrective action to be taken ***by economic operators*** in relation to a product presenting a risk may include:

Amendment

4. Corrective action to be taken in relation to a product presenting a risk may include:

Justification

This would appear to be a list of corrective measures concerning products presenting a risk that economic operators can take voluntarily or may be imposed by the market surveillance authorities, and to derive from Article 8.1 of the GDPS. The inclusion of the term 'by economic operators' in the introductory part therefore creates confusion and should be deleted.

Amendment 237**Pablo Arias Echeverría****Proposal for a regulation****Article 9 – paragraph 4 – point b – introductory part***Text proposed by the Commission*

(b) in the case of a product that is liable to present a risk only in certain conditions or only to certain persons and where such risk is not addressed by requirements of Union **harmonisation** legislation:

Amendment

(b) in the case of a product that is liable to present a risk only in certain conditions or only to certain persons and where such risk is not addressed by requirements of Union legislation:

Justification

This does not make it clear that the Regulation applies to all products, and it is therefore proposed that the word 'harmonisation' be eliminated.

Amendment 238**Christel Schaldemose****Proposal for a regulation****Article 9 – paragraph 4 – point b – point iii***Text proposed by the Commission*

(iii) alerting the persons at risk to the risk, **in good time and in an appropriate form**, including by publication of special warnings;

Amendment

(iii) alerting the persons at risk to the risk, **without undue delay**, including by publication of special warnings;

Amendment 239

Pablo Arias Echeverría

Proposal for a regulation

Article 9 – paragraph 4 – point b – point iii

Text proposed by the Commission

(iii) alerting the persons at risk to the risk, ***in good time*** and in an appropriate form, including by publication of special warnings;

Amendment

(iii) alerting the persons at risk to the risk, ***immediately*** and in an appropriate form, including by publication of special warnings;

Or. es

Justification

Point b) iii) the term 'in good time' should be replaced with the term 'immediately', which is the one used in the current General Directive on Product Safety (GDPS).

Amendment 240

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 9 – paragraph 4 – point b – point iii

Text proposed by the Commission

(iii) alerting the persons at risk to the risk, ***in good time*** and in an appropriate form, including by publication of special warnings;

Amendment

(iii) alerting the persons at risk to the risk, ***immediately*** and in an appropriate form, including by publication of special warnings;

Or. es

Amendment 241

Pablo Arias Echeverría

Proposal for a regulation

Article 9 – paragraph 4 – point d – point i

Text proposed by the Commission

Amendment

(i) preventing the product from being placed or made available on the market;

(i) preventing ***immediately*** the product from being placed or made available on the market;

Or. es

Justification

Inclusion of the word 'immediately', since the products in question present a serious risk, as in the GDPS.

Amendment 242

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 9 – paragraph 4 – point d – point i

Text proposed by the Commission

Amendment

(i) preventing the product from being placed or made available on the market;

(i) preventing ***immediately*** the product from being placed or made available on the market;

Or. es

Amendment 243

Josef Weidenholzer

Proposal for a regulation

Article 9 – paragraph 4 – point d – point ii

Text proposed by the Commission

Amendment

(ii) withdrawing or recalling the product and alerting the public to the risk presented;

(ii) withdrawing or recalling the product and ***immediately*** alerting the public, ***in an appropriate form,*** to the risk presented;

Or. de

Amendment 244
Heide Rühle

Proposal for a regulation
Article 9 – paragraph 5

Text proposed by the Commission

Amendment

5. The Commission may adopt implementing acts establishing the modalities for the provision of information in accordance with the third subparagraph of paragraph 3, while ensuring the effectiveness and proper functioning of the system. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).

deleted

Or. en

Amendment 245
Constance Le Grip

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission

Amendment

1. Where the identity of the relevant economic operator cannot be ascertained by the market surveillance authorities or where an economic operator has not taken the necessary corrective action pursuant to Article 9(3) within the period specified, market surveillance authorities shall take all necessary measures to deal with the risk presented by the product.

1. Where the identity of the relevant economic operator cannot be ascertained by the market surveillance authorities or where an economic operator ***has failed in its duty of care or*** has not taken the necessary corrective action pursuant to Article 9(3) within the period specified, market surveillance authorities shall take all necessary measures to deal with the risk presented by the product.

Or. fr

Amendment 246
Wim van de Camp

Proposal for a regulation

Article 10 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. ***They may require the relevant economic operator to bear the cost of such action.***

Amendment

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. ***All of the expenses incurred by the surveillance authority in the scope of the application of this provision (destruction of products, work performed, etc.) shall be borne by the economic operator unless the surveillance authority considers this decision to be disproportionate, in which case it may decide that the cost shall be borne by the economic operator only partly.***

Or. en

Justification

If the cost of tests/destruction is first paid by MSAs, and then re-invoiced to rogue players, there will remain a risk on MSAs until payment by the economic operator. Costs should be directly invoiced to rogue market players by service providers performing tests or destruction to avoid the freezing effects of the financial risk on MSAs. More importantly, it will reduce market surveillance authorities' uncertainty regarding their own expenses, allowing them to take the right measures without having unnecessary concerns about the allocation of their resources.

Amendment 247

Josef Weidenholzer

Proposal for a regulation

Article 10 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. ***They may require the relevant economic operator to***

Amendment

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. ***The cost of action taken by market surveillance***

bear the cost of such action.

*authorities shall be borne by the relevant economic operator **unless the market surveillance concerned regards that as disproportionate.***

Or. de

Amendment 248

Norica Nicolai

Proposal for a regulation

Article 10 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. ***They may require*** the relevant economic operator ***to*** bear the cost of such action.

Amendment

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. ***Where*** the relevant economic operator ***has been identified, he shall*** bear the ***entire*** cost of such action.

Or. en

Justification

In case the destruction of a product or other measures to make it inoperable are needed in order to put away the risk, the economic operator responsible for making that product available on the EU market should bear the full cost of the operation. This would have a deterrent effect on economic operators and would also ease the financial burden on market surveillance authorities.

Amendment 249

Preslav Borissov

Proposal for a regulation

Article 10 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem

Amendment

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem

it necessary and proportionate. ***They may require*** the relevant economic operator ***to*** bear the cost of such action.

it necessary and proportionate. The relevant economic operator ***shall*** bear the cost of such action.

Or. en

Amendment 250
Matteo Salvini

Proposal for a regulation
Article 10 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. They may require the ***relevant*** economic operator to bear the cost of such action.

Amendment

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. They may require the economic operator ***responsible for placing that product on the market*** to bear the cost of such action.

Or. it

Amendment 251
Pablo Arias Echeverría

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Prior to taking any measure under paragraph 1 in relation to an economic operator who has failed to take the necessary corrective action, market surveillance authorities shall allow him at least 10 days within which to be heard.

Amendment

deleted

Or. es

Justification

It is general practice, when a product is identified that may present a risk, to inform the

economic operator and grant him a period to present his case, in which he can remedy problems and make counterclaims, as is laid down in Article 21 of Regulation 765/2008/EC. The deadline for this is already set under Article 9.3, making it wrong for another deadline to be set for economic operators who in the first instance have not taken the requisite corrective action specified by the surveillance authorities.

Amendment 252
Constance Le Grip

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Prior to taking any measure under paragraph 1 in relation to an economic operator who has failed ***to take*** the necessary corrective action, market surveillance authorities shall allow him at least 10 days within which to be heard.

Amendment

3. Prior to taking any measure under paragraph 1 in relation to an economic operator who has failed ***in his duty of care or has not taken*** the necessary corrective action, market surveillance authorities shall allow him at least 10 days within which to be heard.

Or. fr

Amendment 253
Heide Rühle

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission

4. Where market surveillance authorities consider that a product presents a serious risk, they shall take all necessary measures and may do so without first requiring the economic operator to take corrective action pursuant to Article 9(3) and without giving the operator the opportunity to be heard beforehand. In such cases the economic operator shall be heard as soon as practicable.

Amendment

4. Where market surveillance authorities consider that a product presents a serious risk ***and the economic operator cannot be identified or is unwilling to take the necessary measures***, they shall take all necessary measures and may do so without first requiring the economic operator to take corrective action pursuant to Article 9(3) and without giving the operator the opportunity to be heard beforehand. In such cases the economic operator shall be heard as soon as practicable.

Amendment 254

Pablo Arias Echeverría

Proposal for a regulation

Article 10 – paragraph 5 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

(a) be communicated without delay to the economic operator ***together with information about the remedies available under the law of the Member State concerned;***

(a) be communicated without delay to the economic operator;

Or. es

Justification

It is unnecessary to require the surveillance authority to notify the economic operator of the remedies available to rectify cases of non-compliance. The surveillance authorities inform him of the way/s in which the product does not comply with the relevant legislation. It is the economic operator who should decide how to remedy that non-compliance. It is proposed that the last phrase be deleted.

Amendment 255

Anja Weisgerber, Markus Ferber

Proposal for a regulation

Article 10 – paragraph 6

Text proposed by the Commission

Amendment

6. Market surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal

deleted

data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

Or. de

Justification

The Information and Communication System on Market Surveillance (ICSMS) already exists. Because of the time involved, additional surveillance activities by Member States would adversely affect how well surveillance was carried out.

Amendment 256

Heide Rühle

Proposal for a regulation

Article 10 – paragraph 6

Text proposed by the Commission

6. Market surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to ***protect commercial secrets***, preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

Amendment

6. Market surveillance authorities shall, ***without undue delay***, publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

Or. en

Amendment 257

Anna Hedh

Proposal for a regulation

Article 10 – paragraph 6

Text proposed by the Commission

6. Market surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. ***This information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.***

Amendment

6. Market surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk - ***as referred to in Article 6(6)*** - on a dedicated website, ***without delay***, to the fullest extent necessary to protect the interests of users of products in the Union.

Or. en

Amendment 258
Josef Weidenholzer

Proposal for a regulation
Article 10 – paragraph 6

Text proposed by the Commission

6. Market surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to protect ***commercial secrets, preserve*** personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

Amendment

6. Market surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to protect personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

Or. de

Amendment 259

Pablo Arias Echeverría

Proposal for a regulation

Article 10 – paragraph 6

Text proposed by the Commission

6. **Market** surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

Amendment

6. ***In the case of products found to present a risk, market*** surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

Or. es

Justification

It should be specified that the information to be published on the internet relates to products which present a risk.

Amendment 260

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 10 – paragraph 6

Text proposed by the Commission

6. **Market** surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union.

Amendment

6. ***In the case of products found to present a risk, market*** surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the

This information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

Or. es

Amendment 261

Heide Rühle

Proposal for a regulation

Article 10 – paragraph 8

Text proposed by the Commission

8. Market surveillance authorities may charge fees on economic operators which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraphs 1 or 4.

Amendment

8. Market surveillance authorities may charge fees on economic operators which ***are caught placing or making available non-compliant products and products presenting a risk on the Union market. Such fees should*** wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraphs 1 or 4.

Or. en

Amendment 262

Matteo Salvini

Proposal for a regulation

Article 10 – paragraph 8

Text proposed by the Commission

8. Market surveillance authorities may charge fees on economic operators which ***wholly or*** partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraphs 1

Amendment

8. Market surveillance authorities may charge fees on economic operators ***responsible for placing on the market*** which partly cover the costs of their activities, including testing carried out for the risk assessment, where they take

or 4.

measures in accordance with paragraphs 1 or 4. *The fees shall be calculated on the basis of the actual cost of each market surveillance activity and shall be charged to those economic operators which are responsible for placing on the market and subject to the market surveillance activities in question according to their role within the supply chain, taking into account company size and the situation of SMEs in particular as well as the activity actually performed by the given economic operator in the production process and the ability of that operator to affect product safety.*

Such fees may not exceed the actual costs of the market surveillance activities carried out and may fully or partially reflect the time spent by market surveillance authority personnel in carrying out the above-mentioned checks.

Or. it

Amendment 263

Heide Rühle

Proposal for a regulation

Article 10 – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8a. Where a product is found to be non-compliant for which an outside body was tasked with carrying out parts of the conformity assessment procedure, the market surveillance authority concerned should act to review and, where necessary, limit or rescind that body's accreditation, licence or appointment.

Or. de

Amendment 264
Christel Schaldemose

Proposal for a regulation
Article 10 – paragraph 8 b (new)

Text proposed by the Commission

Amendment

8b. Any funds or revenues obtained through such fees shall be earmarked to the financing of the activities of market surveillance authorities.

Or. en

Amendment 265
Pablo Arias Echeverría

Proposal for a regulation
Article 11 – paragraph 1

Text proposed by the Commission

Amendment

1. Within **60** days of communication by the Commission to the Member States, pursuant to Article 20(4), of measures taken pursuant to paragraphs 1 or 4 of Article 10 by the original notifying Member State, a Member State may object to those measures where they relate to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question.

1. Within **15** days of communication by the Commission to the Member States, pursuant to Article 20(4), of measures taken pursuant to paragraphs 1 or 4 of Article 10 by the original notifying Member State, a Member State may object to those measures where they relate to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question.

Or. es

Justification

A 60-day deadline for objecting to measures adopted is too long and is detrimental to economic operators themselves. This period, added to the Commission's decision-making time frame, is sufficient for the supervisory authorities to have taken precautionary action to

limit the marketing of the product or prevented the import thereof and ensured its return to its point of origin. The information provided by the notifying Member State along with the notification (test report, grounds for action and risk assessment) is enough to determine in a brief period whether or not the measure is adequate. There is no need to wait 60 days. The adoption of two time frames is recommended to ensure that these provisions are not detrimental to economic operators: a short (15-day) deadline for objections to be entered, together with the Commission's (60-day) decision-making time frame.

Amendment 266

Pablo Arias Echeverría

Proposal for a regulation

Article 11 – paragraph 3

Text proposed by the Commission

3. Where an objection is raised by a Member State pursuant to paragraph 1 or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall without delay enter into consultation with the relevant economic operator(s) and shall evaluate the national measures, taking account of all available scientific or technical evidence.

Amendment

3. Where an objection is raised by a Member State pursuant to paragraph 1 or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall without delay enter into consultation with ***the notifying Member State and*** the relevant economic operator(s) and shall evaluate, ***within 60 days at the most***, the national measures, taking account of all available scientific or technical evidence.

Or. es

Justification

It is essential to consult the notifying Member State, given that it holds all the supporting documentation relating to the measure.

Amendment 267

Pablo Arias Echeverría

Proposal for a regulation

Article 11 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. If an objection is raised within 15 days by the Commission or a Member State in accordance with paragraph 1, the

Commission shall inform all the Member States through the RAPEX contact points.

Or. es

Justification

It is essential for the market supervisory authorities to be informed of any objections to measures adopted in respect of products deemed to be unsafe and notified through RAPEX.

Amendment 268

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 11 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. If an objection is raised in accordance with paragraph 1 by the Commission or a Member State, the Commission shall inform all the Member States through the RAPEX contact points.

Or. es

Amendment 269

Heide Rühle

Proposal for a regulation

Article 11 – paragraph 4

Text proposed by the Commission

Amendment

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission **may** decide by implementing acts whether the national measures are justified and similar measures should be taken by all Member States that have not already done so. In this case, it shall address the decision to the Member States concerned and immediately

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission **shall** decide by implementing acts **within 3 months** whether the national measures are justified and similar measures should be taken by all Member States that have not already done so. In this case, it shall address the decision to the Member States concerned and

communicate it to all Member States and the relevant economic operator or operators.

immediately communicate it to all Member States and the relevant economic operator or operators.

Or. en

Amendment 270
Norica Nicolai

Proposal for a regulation
Article 11 – paragraph 4

Text proposed by the Commission

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission *may* decide by implementing acts whether the national measures are justified and similar measures should be taken by all Member States that have not already done so. In this case, it shall address the decision to the Member States concerned and immediately communicate it to all Member States and the relevant economic operator or operators.

Amendment

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission *shall* decide *without undue delay* by implementing acts whether the national measures are justified and similar measures should be taken by all Member States that have not already done so. In this case it shall address the decision to the Member States concerned and immediately communicate it to all Member States and the relevant economic operator or operators.

Or. en

Justification

Legal certainty should be ensured for economic operators. Therefore there should always be a timely decision on whether the measures taken are justified or not.

Amendment 271
Matteo Salvini

Proposal for a regulation
Article 12 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Where it is evident that a product, or a specific category or group of products,

Amendment

1. Where it is evident that a product, or a specific category or group of products,

when used in accordance with the product's intended purpose or under conditions which can be reasonably foreseeable, presents a serious risk the Commission may, by means of implementing acts, take any appropriate measures depending on the gravity of the situation, including measures prohibiting, suspending or restricting the placing or making available on the market of such products or laying down special conditions for their marketing, in order to ensure a high level of protection of the public interest, provided that the risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned or by any other procedure under Union legislation. By those implementing acts, the Commission may lay down the appropriate control measures to be taken by Member States to ensure their effective implementation.

when used in accordance with the product's intended purpose or under conditions which can be reasonably foreseeable, presents a serious risk the Commission may, by means of implementing acts, take any appropriate measures depending on the gravity of the situation, including measures prohibiting, suspending or restricting the placing or making available on the market of such products or laying down special conditions for their marketing. ***In addition to the measures specifically set forth in this Regulation, the Commission may take any other appropriate emergency measures*** in order to ensure a high level of protection of the public interest, provided that the risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned or by any other procedure under Union legislation.

By those implementing acts, the Commission may lay down the appropriate control ***and precautionary*** measures to be taken by Member States to ensure their effective implementation. ***The market surveillance authorities shall identify risks arising in connection with products covered by this Regulation and the characteristics of such risks by complying with any possible indications and instructions that may be given by the Commission in relation to the actual methods, grids and criteria to be used in performing risk assessment.***

The market surveillance authorities shall record this information in the information and communication system for market surveillance referred to in Article 21.

As appropriate, such implementing acts shall include the definition of the product models on which the tests are to be performed, regardless of those defined by the economic operator, as well as the risk assessment criteria.

The implementing acts referred to in the

first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 32(2).

Or. en

Justification

For a more effective market surveillance of the Commission's emergency decisions and to share best practices on the most dangerous categories of non-food products (art 12 of proposed Regulation market surveillance), the proposal is that the EU Commission is granted the right to make use of the existing tools of the food legal framework.

Amendment 272
Josef Weidenholzer

Proposal for a regulation
Article 12 – paragraph 1 – subparagraph 2

Text proposed by the Commission

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 32(2).

Amendment

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 32(2) *and with the recommendations of the committee referred to in Article 19(1), first paragraph, of Regulation (EU) No. ... of the European Parliament and of the Council of ... on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC**.

** OJ: Please insert the number, date and reference details for the Consumer Product Safety Regulation (2013/0049(COD)).*

Or. de

Amendment 273
Pablo Arias Echeverría

Proposal for a regulation

Article 12 – paragraph 1 – subparagraph 3

Text proposed by the Commission

On duly justified imperative grounds of urgency ***relating to the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security and other public interests***, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 32(3).

Amendment

On duly justified imperative grounds of urgency, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 32(3).

Or. es

Amendment 274

Pablo Arias Echeverría

Proposal for a regulation

Article 12 – paragraph 1 – subparagraph 3 a (new)

Text proposed by the Commission

Amendment

In respect of consumer products presenting health and safety risks, the measures adapted under the previous paragraphs shall be implemented in accordance with Article XXX of the CPSR.

Or. es

Justification

EU measures concerning products presenting serious risks should be set out in the CPSR. However, given the scope thereof, it is proposed that they be limited to consumer products presenting health and safety risks.

Amendment 275

Andreas Schwab, Birgit Collin-Langen, Sabine Verheyen

Proposal for a regulation
Article 12 – paragraph 2

Text proposed by the Commission

2. For products **and risks** subject to Regulation (EC) No 1907/2006, a decision taken by the Commission pursuant to paragraph 1 of this Article shall be valid for up to two years and may be extended for additional periods of up to two years. Such a decision shall be without prejudice to procedures provided in that Regulation.

Amendment

2. For products subject to Regulation (EC) No 1907/2006, ***the Commission may take a decision, pursuant to paragraph 1 of this Article, only if it has justifiable grounds for believing that urgent action is essential to protect human health or the environment.*** A decision taken by the Commission pursuant to paragraph 1 of this Article shall be valid for up to two years and may be extended for additional periods of up to two years. Such a decision shall be without prejudice to procedures provided in that Regulation. ***The Commission shall immediately inform the Member States and the European Chemicals Agency thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based. If the provisional measure adopted by the Commission involves restricting the placing on the market or use of a substance, the Commission shall initiate a Community restrictions procedure by submitting to European Chemicals Agency a dossier, in accordance with Annex XV to Regulation (EC) No 1907/2006, within three months of the date of the Commission decision.***

Or. de

Justification

Brought into line with the restrictions procedure under Article 129 of the REACH Regulation so as to prevent duplicated regulatory action. If the Commission decision involves restricting the placing on the market or use of a substance, the decision should result in initiation of a Community restrictions procedure.

Amendment 276
Pablo Arias Echeverría

Proposal for a regulation
Article 13 – title

Text proposed by the Commission

Amendment

Risk assessment

Safety assessment

Or. es

Amendment 277
Norica Nicolai

Proposal for a regulation
Article 13 – paragraph - 1 (new)

Text proposed by the Commission

Amendment

-1. The Commission shall adopt by means of implementing acts a general risk assessment methodology and, where relevant, guidelines for the application of that methodology to specific categories of products. Such implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).

Or. en

Justification

There should be a common approach to risk assessment as outlined in the Commission's multiannual action plan for the surveillance of products in the EU. This will help avoiding situations where market surveillance authorities in different Member States get to different conclusions following the risk assessment of the same product. This amendment builds on the Rapporteur's amendment 43 by turning the possibility for the Commission of adopting such implementing acts into an obligation.

Amendment 278
Norica Nicolai

Proposal for a regulation

Article 13 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Risk assessment shall be based on available scientific or technical evidence.

Amendment

1. Risk assessment shall be based on available scientific or technical evidence ***and shall be carried out in accordance with the general risk assessment methodology developed by the Commission in accordance with the previous paragraph and, where relevant, according to the guidelines on the application of thereof to specific categories of products.***

Or. en

Justification

There should be a common approach to risk assessment as outlined in the Commission's multiannual action plan. The basis for this already exists and the update should be done as soon as possible so that risk assessment under this Regulation is carried out following a common methodology. This will help avoiding situations where market surveillance authorities in different Member States get to different conclusions following the risk assessment of the same product.

Amendment 279

Preslav Borissov

Proposal for a regulation

Article 13 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Risk assessment shall be based on available scientific or technical evidence.

Amendment

1. Risk assessment shall be based on available scientific or technical evidence. ***Risk assessment shall be carried out in accordance with the general risk assessment methodology established and used by the Commission and, as appropriate, in accordance with the application made by the Commission for a specific category of products.***

Or. en

Justification

Once the Commission has applied its general methodology for a specific category of products, in particular by pre-completing the information in the interpretation guidance it has drawn up, the surveillance authorities should comply with it.

Amendment 280 **Wim van de Camp**

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

Text proposed by the Commission

1. Risk assessment shall be based on available scientific or technical evidence.

Amendment

1. Risk assessment shall be based on available scientific or technical evidence.
Risk assessment shall be carried out in accordance with the general risk assessment methodology established by the Commission and, as appropriate, in accordance with the application made by the Commission for a specific category of products.

Or. en

Justification

The common understanding of approach to risk assessment contemplated by the Commission should apply immediately on the date of entry into force of the Regulation and not simply be featured in a non-binding document such as the multi-annual action plan. Once the Commission has applied its general methodology for a specific category of products, in particular by pre-completing the information in the interpretation guidance it has drawn up, the surveillance authorities should comply therewith.

Amendment 281 **Nora Berra**

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

Text proposed by the Commission

1. Risk assessment shall be based on

Amendment

1. Risk assessment shall be based on available scientific or technical evidence.

available scientific or technical evidence.

Risk assessment shall be carried out in accordance with the general risk assessment methodology established by the Commission and, as appropriate, in accordance with the application made by the Commission for a specific category of products.

Or. en

Amendment 282
Matteo Salvini

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

Text proposed by the Commission

1. Risk assessment shall be based on available scientific or technical evidence.

Amendment

1. Risk assessment shall be based on available scientific or technical evidence.
Risk assessment shall be carried out in accordance with the general risk assessment methodology established by the Commission and, as appropriate, in accordance with the application made by the Commission for a specific category of products.

Or. en

Justification

The common understanding of approach to risk assessment contemplated by the Commission should apply immediately on the date of entry into force of the Regulation and not simply be featured in a non-binding document such as the multi-annual action plan. Once the Commission has applied its general methodology for a specific category of products, in particular by pre-completing the information in the interpretation guidance it has drawn up, the surveillance authorities should comply therewith.

Amendment 283
Othmar Karas

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

Text proposed by the Commission

1. Risk assessment shall be based on available scientific or technical evidence.

Amendment

1. Risk assessment shall be based on available scientific or technical evidence, ***such as the Risk Assessment Guidelines for Consumer Products from the RAPEX Guidelines (Commission Decision 2010/15/EU).***

Or. en

(Commission Decision 2010/15/EU)

Amendment 284

Christel Schaldemose

Proposal for a regulation

Article 13 – paragraph 1 – subparagraph 2

Text proposed by the Commission

For products subject to Regulation (EC) No 1907/2006, risk assessment shall be carried out as appropriate in accordance with the relevant parts of Annex I to that Regulation.

Amendment

For products subject to Regulation (EC) No 1907/2006, risk assessment shall be carried out as appropriate in accordance with the relevant parts of ***Article 57 and*** Annex I to that Regulation.

Or. en

Amendment 285

Andreas Schwab, Birgit Collin-Langen, Sabine Verheyen

Proposal for a regulation

Article 13 – paragraph 2 – point a

Text proposed by the Commission

(a) any requirements laid down in or pursuant to Union harmonisation legislation that apply to the product and relate to the potential risk under consideration, taking full account of test reports or certificates attesting conformity and issued by a conformity assessment

Amendment

(a) any requirements laid down in or pursuant to Union harmonisation legislation that apply to the product and relate to the potential risk under consideration, taking full account of test reports or certificates attesting conformity and issued by a conformity assessment

body;

body, *including assessments drawn up pursuant to Regulation (EC) No 1907/2006, e.g. in connection with registration, authorisation, restrictions or reporting*;

Or. de

Justification

Brought into line with the REACH Regulation so as to prevent duplicated regulatory action. The REACH Regulation provides the main framework for risk assessment in respect of substances, and, for that reason, account has to be taken of such assessments.

Amendment 286

Pablo Arias Echeverría

Proposal for a regulation

Article 13 – paragraph 2 – point a

Text proposed by the Commission

(a) any requirements laid down in or pursuant to Union harmonisation legislation that apply to the product and relate to the potential risk under consideration, taking **full** account of test reports or certificates attesting conformity and issued by a conformity assessment body;

Amendment

(a) any requirements laid down in or pursuant to Union harmonisation legislation that apply to the product and relate to the potential risk under consideration, taking account of test reports or certificates attesting conformity and issued by a conformity assessment body;

Or. es

Justification

It is proposed that, for the sake of clarity, the word ‘full’ be deleted, since it signifies ‘complete’ or ‘absolute’ and could give rise to confusion. Test reports and certificates are in any case taken into account in their entirety and not in part.

Amendment 287

Pablo Arias Echeverría

Proposal for a regulation
Article 13 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. In the absence of requirements laid down in paragraphs (a), (b) and (c), account must be taken of the provisions of Article 6 of the Regulation on Consumer Product Safety;

Or. es

Justification

Firstly, a name change is proposed for the sake of terminological alignment with the CPSR. Secondly, the wording does not cover risk assessment. Non-harmonised products that are not regulated by any standards are also excluded, necessitating a reference to the CPSR and more particularly Article 6 thereof.

Amendment 288
Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission

Amendment

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. ***However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is new evidence that, despite such conformity or compliance, the product presents a risk.***

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate.

Or. en

Justification

Points a, b, c referred to in this paragraph are circumstances where the absence of risk can

be presumed in accordance with Union legislation. It is not appropriate for an administrative authority to challenge the relevance of the legislation as a matter of legal certainty for economic operators.

Amendment 289

Pablo Arias Echeverría

Proposal for a regulation

Article 13 – paragraph 3

Text proposed by the Commission

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is *new* evidence that, despite such conformity or compliance, the product presents a risk.

Amendment

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is evidence that, despite such conformity or compliance, the product presents a risk.

Or. es

Amendment 290

María Irigoyen Pérez, Vicente Miguel Garcés Ramón

Proposal for a regulation

Article 13 – paragraph 3

Text proposed by the Commission

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is *new* evidence that, despite such conformity or compliance, the product presents a risk.

Amendment

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is evidence that, despite such conformity or compliance, the product presents a risk.

Amendment 291
Heide Rühle

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is new evidence that, despite such conformity or compliance, the product presents a risk.

Amendment

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is new evidence that, despite such conformity or compliance ***with the criteria referred to in points (b) and (c) of paragraph 2***, the product presents a ***serious*** risk. ***In that case the market surveillance authorities shall demonstrate that the product presents a serious risk and notify its decision pursuant to Article 19.***

Amendment 292
Christel Schaldemose

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this

Amendment

3. Compliance with ***any of*** the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking

Regulation where there is new evidence that, despite such conformity or compliance, the product presents a risk.

action under this Regulation where there is new evidence that, despite such conformity or compliance, the product presents a risk.

Or. en

Amendment 293
Josef Weidenholzer

Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission

4. The feasibility of obtaining higher levels of protection of the public interest concerned and the availability of other products presenting a lesser risk shall not be **a** reason to consider that a product presents a risk.

Amendment

4. The feasibility of obtaining higher levels of protection of the public interest concerned and the availability of other products presenting a lesser risk shall not be **sufficient** reason to consider that a product presents a risk.

Or. de

Amendment 294
Preslav Borissov

Proposal for a regulation
Article 13 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The Commission may, of its own initiative or at the request of a market surveillance authority, have a risk assessment carried out by a European Union reference laboratory, in accordance with Article 28. Such assessment shall be binding on all stakeholders.

Or. en

Justification

The proposal to use the European Union's reference laboratories to resolve differences in assessment of risk by Member States permits making up for the absence of an independent authority in the field of non-food products, while permitting a uniform assessment of risk across the European Union.

Amendment 295 **Wim van de Camp**

Proposal for a regulation **Article 13 – paragraph 4 b (new)**

Text proposed by the Commission

Amendment

4b. The Commission may, of its own initiative or at the request of a surveillance authority, have a risk assessment carried out by a European Union reference laboratory, in accordance with Article 28. Such assessment shall be binding on all stakeholders.

Or. en

Justification

The proposal to use the European Union's reference laboratories to resolve differences in the assessment of risk by Member States permits making up for the absence of an independent authority in the field of non-food products while permitting a uniform assessment of risk across the territory of the European Union.

Amendment 296 **Matteo Salvini**

Proposal for a regulation **Article 13 – paragraph 4 c (new)**

Text proposed by the Commission

Amendment

4c. The Commission may, of its own initiative or at the request of a surveillance authority, have a risk assessment carried out by a European

Union reference laboratory, in accordance with Article 28. Such assessment shall be binding on all stakeholders.

Or. en

Justification

The proposal to use the European Union's reference laboratories to resolve differences in the assessment of risk by Member States permits making up for the absence of an independent authority in the field of non-food products while permitting a uniform assessment of risk across the territory of the European Union.

Amendment 297

Sirpa Pietikäinen

Proposal for a regulation

Article 13 – paragraph 4 d (new)

Text proposed by the Commission

Amendment

4d. In cases where Member State risk assessment practices differ and result in divergent interpretations as to the necessity of measures in respect of similar products, the Commission shall provide guidance on appropriate risk assessment practices. The Commission shall be assisted by the scientific committees established under Commission Decision 2004/210/EC and take into account all available scientific and technical evidence relating to the risks under consideration.

Or. en

Justification

A procedure should be established for the cases where the results of risk assessments undertaken by different Member States differ from one another.

Amendment 298

Josef Weidenholzer

Proposal for a regulation
Article 13 – paragraph 4 e (new)

Text proposed by the Commission

Amendment

4e. At the request of a market surveillance authority or on its own initiative, the Commission may have risk assessments carried out by reference laboratories in accordance with Article 28. Those risk assessments shall be binding on all parties.

Or. de

Amendment 299
Norica Nicolai

Proposal for a regulation
Article 14 – paragraph 3 – subparagraph 2 – introductory part

Text proposed by the Commission

Amendment

In relation to a product which must comply with Union harmonisation legislation when it is released for free circulation, formal non-compliance with that legislation shall give the authorities of Member States sufficient reason to ***believe that the product may present a risk*** in any of the following cases:

In relation to a product which must comply with Union harmonisation legislation when it is released for free circulation, formal non-compliance with that legislation shall give the authorities of Member States sufficient reason to ***suspend the release of a product*** in any of the following cases:

Or. en

Justification

Formal non-compliance doesn't automatically entail that the product concerned presents a risk. Nevertheless, this should be a sufficient reason for suspension and the economic operator should be required to put an end to the formal non-compliance, after which the products can be released upon decision of the market surveillance authorities, as foreseen in Article 15.

Amendment 300

Anja Weisgerber, Markus Ferber

Proposal for a regulation

Article 14 – paragraph 3 – subparagraph 2 – introductory part

Text proposed by the Commission

In relation to a product which must comply with Union harmonisation legislation when it is released for free circulation, formal non-compliance with that legislation ***shall*** give the authorities of Member States sufficient reason to believe that the product may present a risk in any of the following cases:

Amendment

In relation to a product which must comply with Union harmonisation legislation when it is released for free circulation, formal non-compliance with that legislation ***may*** give the authorities of Member States sufficient reason to believe that the product may present a risk in any of the following cases:

Or. de

Justification

It is for the market surveillance authorities to decide whether a product presents risks.

Amendment 301

Pablo Arias Echeverría

Proposal for a regulation

Article 14 – paragraph 3 – subparagraph 2 – introductory part

Text proposed by the Commission

In relation to a product which must comply with Union ***harmonisation*** legislation when it is released for free circulation, formal non-compliance with that legislation shall give the authorities of Member States sufficient reason to believe that the product may present a risk in any of the following cases:

Amendment

In relation to a product which must comply with Union legislation when it is released for free circulation, formal non-compliance with that legislation shall give the authorities of Member States sufficient reason to believe that the product may present a risk in any of the following cases:

Or. es

Justification

Under the CPSR, formal requirements in respect of non-harmonised products are similar to those applicable to harmonised products: importers are required to identify themselves,

provide technical documentation, verify the identity of the manufacturers and take note of relevant instructions and warnings. Failure to meet any of these requirements could constitute formal non-compliance, which we propose be treated in the same way as in the case of that relating to harmonised products.

Amendment 302
Constance Le Grip

Proposal for a regulation
Article 14 – paragraph 3 – subparagraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the product or any presentation of the product bears, without authorisation, a trade mark that is identical or similar to the registered trade mark for this product, thereby preventing its authenticity or origin from being firmly established;

Or. fr

Amendment 303
Sirpa Pietikäinen

Proposal for a regulation
Article 14 – paragraph 3 – subparagraph 2 – point b b (new)

Text proposed by the Commission

Amendment

(bb) the product or any presentation of the product bears without authorisation a trade mark that is identical or similar to a registered trade mark for this product, thereby not allowing to guarantee its authenticity or origin;

Or. en

Amendment 304
Jürgen Creutzmann

Proposal for a regulation
Article 14 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Where products are not intended to be placed on the market in the Member State in which they are released for free circulation, the language in which the information set out in points (a), (b) and (c) of paragraph 3 is presented shall not give the authorities in charge of external border controls sufficient reason to believe that the product may present a risk.

Or. en

Justification

Small items (e.g. cosmetics) are often re-labelled after their release for free circulation and before being placed in the market. Customs authorities have sometimes wrongly suspended the release of such products because they were not labelled in their national languages. This misunderstanding should be avoided. Nevertheless, importers and distributors will still have to check that instructions and safety information are in the language of the Member State where they make the products available.

Amendment 305
Christel Schaldemose

Proposal for a regulation
Article 14 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. The corrective measures of the market surveillance authorities must be proportionate to the seriousness of the non-compliance.

Or. en

Amendment 306
Pablo Arias Echeverría

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission

5. In the case of perishable products, the authorities in charge of external border controls shall, as far as possible, ***seek to*** ensure that any requirements they may impose with regard to the storage of products or the parking of vehicles used for transport are not incompatible with the preservation of those products.

Amendment

5. In the case of perishable products, the authorities in charge of external border controls shall, as far as possible, ***facilitate measures to*** ensure that any requirements they may impose with regard to the storage of products or the parking of vehicles used for transport are not incompatible with the preservation of those products

Or. es

Justification

Economic operators themselves have the possibility of organising the proper storage and preservation of perishable products using facilities on customs premises. The authorities in charge of external border controls are able to help facilitate the necessary measures but not ensure that they are actually taken.

Amendment 307
Anja Weisgerber, Markus Ferber

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission

2. If the market surveillance authorities conclude that a product the release of which was suspended due to formal non-compliance in accordance with the second sub-paragraph of paragraph 3 of Article 14 does not in fact present a risk, ***the economic operator shall nevertheless rectify the formal*** non-compliance before the product is released.

Amendment

2. If the market surveillance authorities conclude that a product the release of which was suspended due to formal non-compliance in accordance with the second sub-paragraph of paragraph 3 of Article 14 does not in fact present a risk, ***they shall take measures, on the basis of the proportionality principle, to bring a criminal prosecution for*** non-compliance before the product is released.

Or. de

Justification

It should be made possible for market surveillance authorities penalise minor infringements.

Amendment 308

Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation

Article 15 – paragraph 3

Text proposed by the Commission

3. Compliance with the requirements of any Union harmonisation legislation that apply to the product upon its release which relate to the potential risk under consideration, taking full account of test reports or certificates attesting conformity and issued by a conformity assessment body, shall raise a presumption on the part of market surveillance authorities that the product does not present a risk. ***However, this shall not prevent those authorities from instructing the authorities in charge of external border controls not to release the product where there is evidence that, despite such compliance, the product does in fact present a risk.***

Amendment

3. Compliance with the requirements of any Union harmonisation legislation that apply to the product upon its release which relate to the potential risk under consideration, taking full account of test reports or certificates attesting conformity and issued by a conformity assessment body, shall raise a presumption on the part of market surveillance authorities that the product does not present a risk.

Or. en

Justification

It is not appropriate for border control authorities to be able to overturn a presumption that the product doesn't present any risk, especially because it is unclear in which circumstances this could be done. Such a provision could lead to legal uncertainty and abuse.

Amendment 309

Pablo Arias Echeverría

Proposal for a regulation

Article 15 – paragraph 3

Text proposed by the Commission

3. Compliance with the requirements of any Union harmonisation legislation that apply to the product upon its release which relate to the potential risk under consideration, taking **full** account of test reports or certificates attesting conformity and issued by a conformity assessment body, shall raise a presumption on the part of market surveillance authorities that the product does not present a risk. However, this shall not prevent those authorities from instructing the authorities in charge of external border controls not to release the product where there is evidence that, despite such compliance, the product does in fact present a risk.

Amendment

3. Compliance with the requirements of any Union harmonisation legislation that apply to the product upon its release which relate to the potential risk under consideration, taking account of test reports or certificates attesting conformity and issued by a conformity assessment body, shall raise a presumption on the part of market surveillance authorities that the product does not present a risk. However, this shall not prevent those authorities from instructing the authorities in charge of external border controls not to release the product where there is evidence that, despite such compliance, the product does in fact present a risk.

Or. es

Justification

It is proposed that, for the sake of clarity, the word 'full' be deleted, since it signifies 'complete' or 'absolute' and could give rise to confusion. Test reports and certificates are in any case taken into account in their entirety and not in part.

Amendment 310
Wim van de Camp

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission

6. Market surveillance authorities **may** charge fees which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, **where they take measures in accordance with paragraph 1.**

Amendment

6. Market surveillance authorities **shall request subcontractors to directly charge the cost of their services to the economic operator concerned unless the market surveillance authority considers this measure to be disproportionate, where they take measures in accordance with paragraph 1. Market surveillance**

authorities may charge fees which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, **and work performed**.

Or. en

Justification

Pursuant to Article 10 of this Proposal for a Regulation, the market surveillance authorities may charge the economic operator concerned for the cost of destroying or otherwise rendering inoperable a product presenting a risk. While the destruction of a product is costly, so are laboratory tests, as stressed by the Commission in its multi-annual action plan. As a result it is consistent with Article 10 to have the economic operator who places an unsafe product on the market bear the cost of such tests.

Amendment 311

Matteo Salvini

Proposal for a regulation

Article 16 – paragraph 6

Text proposed by the Commission

6. Market surveillance authorities **may** charge fees which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, **where they take measures in accordance with paragraph 1.**

Amendment

6. Market surveillance authorities **shall request subcontractors to directly charge the cost of their services to the economic operator concerned unless the market surveillance authority considers this measure to be disproportionate, where they take measures in accordance with paragraph 1. Market surveillance authorities may** charge fees which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, **and work performed**.

Or. en

Justification

Pursuant to Article 10 of this Proposal for a Regulation, the market surveillance authorities may charge the economic operator concerned for the cost of destroying or otherwise rendering inoperable a product presenting a risk. While the destruction of a product is costly, so are laboratory tests, as stressed by the Commission in its multi-annual action plan. As a result it is consistent with Article 10 to have the economic operator who places an unsafe

product on the market bear the cost of such tests.

Amendment 312
Heide Rühle

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission

6. Market surveillance authorities **may** charge fees which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraph 1.

Amendment

6. Market surveillance authorities **shall** charge fees ***on economic operators declaring the non-compliant products and products presenting a risk for free circulation*** which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraph 1.

Or. en

Amendment 313
Franz Obermayr

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission

6. Market surveillance authorities may charge fees which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraph 1.

Amendment

6. Market surveillance authorities may charge fees which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraph 1. ***Subcontractors commissioned by market surveillance authorities to destroy or test products may also charge fees which wholly or partly cover the costs of their activities. The manufacturer or importer examined shall be directly invoiced for fees.***

Or. de

Amendment 314

Ashley Fox

Proposal for a regulation

Article 17

Text proposed by the Commission

Amendment

Article 17

deleted

Personal imports

1. Where a product enters the Union accompanied by, and in the physical possession of, a natural person and reasonably appears to be destined for the personal use of that person, its release shall not be suspended pursuant to Article 14(3) except where the use of the product can endanger the health and life of persons, animals or plants.

2. A product shall be deemed to be destined for the personal use of a natural person bringing it into the Union if it is of an occasional nature and exclusively intended for use by that person or his family and does not by its nature or quantity indicate any commercial intent.

Or. en

Amendment 315

Pablo Arias Echeverría

Proposal for a regulation

Article 18 – paragraph 1

Text proposed by the Commission

Amendment

1. Within **60** days of communication by the Commission to the Member States, pursuant to Article 20(4), of any refusal to release a product for free circulation by the original notifying Member State, a Member State may object to that refusal

1. Within **15** days of communication by the Commission to the Member States, pursuant to Article 20(4), of any refusal to release a product for free circulation by the original notifying Member State, a Member State may object to that refusal

where it relates to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question.

where it relates to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question.

Or. es

Justification

A 60-day deadline for objecting to measures adopted is too long and is detrimental to economic operators themselves. This period, added to the Commission's decision-making time frame, is sufficient for the supervisory authorities to have taken precautionary action to limit the marketing of the product or prevented the import thereof and ensured its return to its point of origin. The information provided by the notifying Member State along with the notification (test report, grounds for action and risk assessment) is enough to determine in a brief period of time whether or not the measure is adequate. There is no need to wait 60 days.

Amendment 316

Pablo Arias Echeverría

Proposal for a regulation

Article 18 – paragraph 3

Text proposed by the Commission

3. Where an objection is raised by a Member State under paragraph 1 or the Commission considers that the refusal may be contrary to Union legislation, the Commission shall without delay enter into consultation with the relevant economic operator(s) and shall evaluate the **refusal**, taking account of all available scientific or technical evidence.

Amendment

3. Where an objection is raised by a Member State under paragraph 1 or the Commission considers that the refusal may be contrary to Union legislation, the Commission shall without delay enter into consultation with **the notifying Member State and** the relevant economic operator(s) and shall, **within a maximum period of 60 days** evaluate the national measures, taking account of all available scientific or technical evidence.

Or. es

Justification

The adoption of two time frames is recommended to ensure that these provisions are not

detrimental to economic operators: a short (15-day) deadline for objections to be entered, together with the Commission's (60-day) decision-making time frame. It is essential to consult the notifying Member State, given that it holds all the supporting documentation relating to the measure.

Amendment 317

Pablo Arias Echeverría

Proposal for a regulation

Article 18 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. If an objection is entered within 15 days in accordance with paragraph 1 by the Commission or a Member State, the Commission shall inform all the Member States through the RAPEX contact points.

Or. es

Justification

It is essential for the market supervisory authorities to be informed of any objections to measures adopted in respect of products deemed to be unsafe and notified through RAPEX.

Amendment 318

Heide Rühle

Proposal for a regulation

Article 19 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a **risk** in accordance with this Regulation.

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a **serious risk to the health and safety of consumers** in accordance with this Regulation.

Or. en

Amendment 319

Ashley Fox

Proposal for a regulation

Article 19 – paragraph 1

Text proposed by the Commission

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a risk in accordance with this Regulation.

Amendment

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a **serious** risk in accordance with this Regulation.

Or. en

Amendment 320

Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation

Article 19 – paragraph 1

Text proposed by the Commission

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a risk in accordance with this Regulation.

Amendment

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a **serious** risk in accordance with this Regulation.

Or. en

Justification

To ensure the efficiency of RAPEX, its scope should be confined to products that present a serious risk, while the rest should be handled through ICSMS. This would help Member States to react in a more efficient manner to notifications by distinguishing between dangerous products and products that are simply non-compliant or present limited risks and therefore don't require urgent action to safeguard consumer safety. The current provision could overburden RAPEX and threaten its efficiency.

Amendment 321

Anja Weisgerber, Markus Ferber

Proposal for a regulation

Article 19 – paragraph 1

Text proposed by the Commission

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a risk in accordance with this Regulation.

Amendment

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a **considerable** risk in accordance with this Regulation.

Or. de

Justification

Use should be made of RAPEX only if a product presents a serious risk. In all other cases, ICSMS should continue to be used so as to contain the mass of data. Furthermore, a vast volume of RAPEX reports may create the erroneous impression that far too many defective products are produced in Europe. That might be harmful to European firms' image.

Amendment 322

Josef Weidenholzer

Proposal for a regulation

Article 19 – paragraph 4

Text proposed by the Commission

4. Participation in RAPEX shall be open to applicant countries, third countries or international organisations within the framework of and in accordance with agreements between the Union and those countries or organisations. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Union.

Amendment

4. Participation in RAPEX shall be open to applicant countries, third countries or international organisations within the framework of and in accordance with agreements between the Union and those countries or organisations. Any such agreements shall be based on reciprocity and include provisions on confidentiality **and personal-data protection** corresponding to those applicable in the Union.

Or. de

Amendment 323
Sirpa Pietikäinen

Proposal for a regulation
Article 19 – paragraph 4

Text proposed by the Commission

4. Participation in RAPEX shall be open to applicant countries, third countries or international organisations within the framework of and in accordance with agreements between the Union and those countries or organisations. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Union.

Amendment

4. Participation in RAPEX shall be open to applicant countries, third countries or international organisations within the framework of and in accordance with agreements between the Union and those countries or organisations. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Union ***as well as special provisions on personal data protection, as required by Article 25 of Directive 95/46/EC and Article 9 of Regulation (EC) No 45/2001.***

Or. en

Justification

In addition to the general provisions on confidentiality, also specific provisions on personal data protection must be adhered to.

Amendment 324
Christel Schaldemose

Proposal for a regulation
Article 19 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The Commission shall publish a weekly overview of the products posing a serious risk as reported by the national authorities. The weekly overview shall cover measures taken by national authorities as well as measures taken voluntarily by economic operators.

Amendment 325
Heide Rühle

Proposal for a regulation
Article 20 – title

Text proposed by the Commission

Notification through RAPEX of products
presenting a risk

Amendment

Notification through RAPEX of products
presenting a **serious** risk

Or. en

Amendment 326
Ashley Fox

Proposal for a regulation
Article 20 – title

Text proposed by the Commission

Notification through RAPEX of products
presenting a risk

Amendment

Notification through RAPEX of products
presenting a **serious** risk

Or. en

Amendment 327
Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation
Article 20 – title

Text proposed by the Commission

Notification through RAPEX of products
presenting a risk

Amendment

Notification through RAPEX of products
presenting a **serious** risk

Or. en

Justification

To ensure the efficiency of RAPEX, its scope should be confined to products that present a serious risk, while the rest should be handled through ICSMS. This would help Member States to react in a more efficient manner to notifications by distinguishing between dangerous products and products that are simply non-compliant or present limited risks and therefore don't require urgent action to safeguard consumer safety. The current provision could overburden RAPEX and threaten its efficiency.

Amendment 328 **Heide Rühle**

Proposal for a regulation **Article 20 – paragraph 1 – subparagraph 1 – point a**

Text proposed by the Commission

(a) any corrective action taken by economic operators *pursuant to Article 9(3)*;

Amendment

(a) any corrective action taken by economic operators;

Or. en

Amendment 329 **Norica Nicolai**

Proposal for a regulation **Article 20 – paragraph 1 – subparagraph 1 – point a**

Text proposed by the Commission

(a) any corrective action taken by economic operators pursuant to Article 9(3);

Amendment

(a) any corrective action taken by economic operators pursuant to *points (c) and (d) of Article 9(4)*;

Or. en

Justification

Limitation of the use of RAPEX to the notification of cases of products presenting a serious risk only.

Amendment 330
Pablo Arias Echeverría

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) measures adopted in response to cases of formal non-compliance which have not been rectified and could result in serious risk (Art. 9(2))

Or. es

Justification

The purpose of RAPEX is risk prevention, which is the reason for including measures adopted in respect of products possibly presenting risks. The notification report does not appear to contain any reference to measures adopted by economic operators in respect of dangerous products on the market. Moreover, the General Product Safety Directive (GPSD) requires RAPEX notification of such measures and the reason for their exclusion is therefore unclear. In this way, they will be published online and can be accessed by consumers or other interested parties. It is also necessary to notify measures taken in response to formal non-compliance which could cause a serious risk (absence of safety warnings, pictograms, instructions, etc) where the economic operator has failed to rectify the omission.

Amendment 331
Pablo Arias Echeverría

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 1 – point b b (new)

Text proposed by the Commission

Amendment

(bb) measures notified by economic operators to the market supervisory authorities in accordance with Articles 8(9), 10(7) and 11(5) of the Regulation on Consumer Product Safety (CPSR).

Or. es

Amendment 332
Heide Rühle

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) the arguments put forward by the relevant economic operator.

Or. en

Amendment 333
Christel Schaldemose

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

The first subparagraph shall not apply where the RAPEX contact point has reason to believe that the effects of the risk presented by a product do not go beyond the territory of its Member State.

deleted

Or. en

Amendment 334
Ashley Fox

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

The first subparagraph shall not apply where the RAPEX contact point has reason to believe that the effects of the risk presented by a product do not go beyond the territory of its Member State.

The first subparagraph shall not apply where the RAPEX contact point has reason to believe that the effects of the ***serious*** risk presented by a product do not go beyond the territory of its Member State.

Or. en

Amendment 335

Pablo Arias Echeverría

Proposal for a regulation

Article 20 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

(a) *the nature and level of the risk, including a summary of the results of the risk assessment;*

(a) *the data necessary to identify the product;*

Or. es

Amendment 336

Pablo Arias Echeverría

Proposal for a regulation

Article 20 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) the nature *of any non-compliance with Union harmonisation legislation;*

(b) the nature *and risk level and summary of safety and risk assessment findings;*

Or. es

Justification

It is necessary to formulate safety and risk assessment rules applicable to the product.

Amendment 337

Josef Weidenholzer

Proposal for a regulation

Article 20 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission

Amendment

(c) the data necessary *to identify the* product;

(c) the data necessary *for* product *identification and traceability;*

Amendment 338
Pablo Arias Echeverría

Proposal for a regulation
Article 20 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission

Amendment

(c) the data necessary to identify the product;

(c) the nature of any infringement of EU legislation;

Or. es

Justification

It is not clear that non-compliance in respect of non-harmonised products must be identified and notified through RAPEX also. It is therefore proposed that general reference be made to EU legislation.

Amendment 339
Pablo Arias Echeverría

Proposal for a regulation
Article 20 – paragraph 2 – subparagraph 1 – point d

Text proposed by the Commission

Amendment

(d) the origin and the supply chain of the product;

(d) the nature of the measure or corrective action taken and whether voluntary or compulsory;

Or. es

Amendment 340
Pablo Arias Echeverría

Proposal for a regulation
Article 20 – paragraph 2 – subparagraph 1 – point f

Text proposed by the Commission

Amendment

(f) the nature of the measure or corrective action taken and whether voluntary, approved, required;

(f) the origin and the supply chain of the product;

Or. es

Justification

Measures taken regarding a product presenting a risk may be compulsory or voluntary but are in both cases invariably approved and necessary. This does not therefore need to be stated. It also appears necessary to set out the requisite information y in a logical order and a number of modifications are accordingly proposed. The information should relate firstly to product identification and then, in the following order, risk, non-compliance with legislation, measures adopted, date of adoption, etc.

Amendment 341
Christel Schaldemose

Proposal for a regulation
Article 20 – paragraph 2 – subparagraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) website and alternative contact details for consumers;

Or. en

Amendment 342
Christel Schaldemose

Proposal for a regulation
Article 20 – paragraph 2 – subparagraph 1 – point f b (new)

Text proposed by the Commission

Amendment

(fb) whether the product is known to be counterfeit;

Or. en

Amendment 343
Sirpa Pietikäinen

Proposal for a regulation
Article 20 – paragraph 2 – subparagraph 1 – point g a (new)

Text proposed by the Commission

Amendment

(ga) Whether the product is known to be counterfeit

Or. en

Amendment 344
Ashley Fox

Proposal for a regulation
Article 20 – paragraph 3

Text proposed by the Commission

Amendment

3. Where a notification relates to a product found not to comply with Union harmonisation legislation, the information provided shall also indicate whether the non-compliance is due to any of the following:

deleted

(a) the failure of the product to satisfy the requirements of the applicable legislation;

(b) shortcomings in the harmonised standards referred to in that legislation which confer a presumption of conformity with those requirements.

Where a measure or corrective action referred to in paragraph 1 relates to a product that has undergone conformity assessment by a notified body, the market surveillance authorities shall ensure that the relevant notified body is informed of the corrective action or measures taken.

Or. en

Amendment 345
Heide Rühle

Proposal for a regulation
Article 20 – paragraph 4

Text proposed by the Commission

4. On receiving a notification, the Commission shall communicate it **to** the other Member States. If the notification does not satisfy the requirements set out in paragraphs 1, 2 and 3, the Commission may suspend it.

Amendment

4. On receiving a notification, the Commission shall communicate it ***without delay to the economic operator and*** the other Member States. If the notification does not satisfy the requirements set out in paragraphs 1, 2 and 3, the Commission may suspend it.

Or. en

Amendment 346
Ashley Fox

Proposal for a regulation
Article 20 – paragraph 4

Text proposed by the Commission

4. On receiving a notification, the Commission shall communicate it to the other Member States. If the notification does not satisfy the requirements set out in paragraphs 1, 2 and 3, the Commission may suspend it.

Amendment

4. On receiving a notification, the Commission shall communicate it to the other Member States. If the notification does not satisfy the ***administrative*** requirements set out in paragraphs 1, 2 and 3, the Commission may suspend it.

Or. en

Amendment 347
Andreas Schwab, Birgit Collin-Langen, Sabine Verheyen

Proposal for a regulation
Article 20 – paragraph 4

Text proposed by the Commission

4. On receiving a notification, the Commission shall communicate it to the other Member States. If the notification does not satisfy the requirements set out in paragraphs 1, 2 and 3, the Commission may suspend it.

Amendment

4. On receiving a notification, the Commission shall communicate it to **the relevant economic operator and** the other Member States. If the notification does not satisfy the requirements set out in paragraphs 1, 2 and 3, the Commission may suspend it.

Or. de

Justification

The economic operators concerned should be informed at least at the same time as the RAPEX notification is published so that they can also take appropriate action.

Amendment 348

Pablo Arias Echeverría

Proposal for a regulation

Article 20 – paragraph 5

Text proposed by the Commission

5. The Member States shall **immediately** inform the Commission of the action or measures taken following receipt of a notification and shall provide any supplementary information, including the results of any tests or analyses carried out or possible differences in views. The Commission shall immediately transmit this information to other Member States.

Amendment

5. The Member States shall **as soon as possible** inform the Commission of the action or measures taken following receipt of a notification and shall provide any supplementary information, including the results of any tests or analyses carried out or possible differences in views. The Commission shall immediately transmit this information to other Member States..

Or. es

Justification

Following receipt of a notification, the market supervisory authorities must verify the presence of the product on their market and contact the economic operator (if known). If at that time the economic operator does not consent to product withdrawal, a few days must be allowed for consultation, making it extremely difficult to notify the Commission ‘immediately’, let alone inform it of the results of any tests etc. We should try not to detract from the meaning of the word ‘immediately’, which is of major significance for the purposes of this regulation.

On the other hand, in order to obtain a response from market supervisory authorities, account must be taken of the deadlines stipulated in Articles 11 and 18 for the Commission and Member States to respond to the measures notified or the time frame that must be allowed for consultation with economic operators under Article 10(3) (at least 10 days), having allowed also for a supplementary time frame under Article 9(3).

Amendment 349

Heide Rühle

Proposal for a regulation

Article 20 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. It shall be possible to update the information related to a product notified to the RAPEX system.

Or. en

Amendment 350

Andreas Schwab, Birgit Collin-Langen, Sabine Verheyen

Proposal for a regulation

Article 20 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5b. Where appropriate, information on a product in a RAPEX notification shall be updated.

Or. de

Justification

Updating of RAPEX information on a notified product should be possible, for example, where that information is no longer valid.

Amendment 351

Heide Rühle

Proposal for a regulation

Article 21 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission

The Commission shall maintain an information and communication system for market surveillance (ICSMS) for the collection and structured storage of information on issues relating to market surveillance, ***in particular the following information:***

Amendment

The Commission shall maintain an information and communication system for market surveillance (ICSMS) for the collection and structured storage of information on issues relating to market surveillance. ***Member States shall collect and enter in ICSMS in particular the following information:***

Or. en

Amendment 352

Heide Rühle

Proposal for a regulation

Article 21 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The Commission shall provide an interface solution through which ICSMS can be connected to RAPEX for data interchange between these systems, when appropriate.

Or. en

Amendment 353

Pablo Arias Echeverría

Proposal for a regulation

Article 21 – paragraph 1 – subparagraph 1 – point e

Text proposed by the Commission

Amendment

(e) any non-compliance with Union ***harmonisation*** legislation other than measures or corrective action notified under RAPEX in accordance with Article

(e) any non-compliance with Union legislation other than measures or corrective action notified under RAPEX in accordance with Article 20;

Justification

Information regarding the surveillance of both harmonised and non-harmonised products should be stored.

Amendment 354

Pablo Arias Echeverría

Proposal for a regulation**Article 21 – paragraph 1 – subparagraph 1 – point f**

Text proposed by the Commission

Amendment

(f) any objection raised by a Member State in accordance with Articles 11(1) or 18(1) and the follow-up. ***deleted***

Justification

Duplication should be avoided. Objections are entered following RAPEX notification once measures have been adopted. Exchanges of information in this connection are part of the process. A further ICSMS entry is not considered necessary.

Amendment 355

Ashley Fox

Proposal for a regulation**Article 21 – paragraph 1 – subparagraph 2**

Text proposed by the Commission

Amendment

ICSMS shall contain a record of references to the notifications of measures or corrective action made under RAPEX in accordance with Article 20.

ICSMS shall contain a record of references to the notifications of measures or corrective action made under RAPEX in accordance with Article 20. ***The Commission will develop an interface between ICSMS and RAPEX which will automatically transfer information about***

serious risk to the RAPEX system.

Or. en

Amendment 356

Pablo Arias Echeverría

Proposal for a regulation

Article 21 – paragraph 3

Text proposed by the Commission

3. Market surveillance authorities shall ***recognise the validity*** and make use of test reports prepared by or for their counterparts in other Member States and entered into ICSMS.

Amendment

3. Market surveillance authorities shall ***as far as possible take into account*** and make use of test reports prepared by or for their counterparts in other Member States and entered into ICSMS

Or. es

Justification

This is excessive. While product information is an advantage in dealings with economic operators, if the latter do not accept it, the market surveillance authorities must once more obtain samples from the market, bearing in mind that products from another market may come from a different batch or consignment and not present the same characteristics. Furthermore, the last paragraph of Article 9(1) already stipulates that account must be taken of test results from other market surveillance authorities, this being a general requirement and not specifically relating to ICSMS reports.

Amendment 357

Christel Schaldemose, Evelyne Gebhardt, Anna Hedh

Proposal for a regulation

Article 21 a (new)

Text proposed by the Commission

Amendment

Article 21a

Pan-European Injuries Database

1. A Pan-European Injuries Database (IDB), which would cover all types of injuries, and namely those related to

products used at home and for leisure, transportation and work activities, shall be set up and coordinated by the European Commission.

2. The relevant market surveillance authorities established by the Member States shall contribute to the establishment of the database and deliver injury data to the database that is comprehensive and in accordance with European and national laws on data protection.

3. The Commission shall support the co-ordination of the collection of data from Member States and the operation of the database.

Or. en

Amendment 358
Josef Weidenholzer

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission

The Commission and Member States may exchange confidential information, including information exchanged through RAPEX, with regulatory authorities of third countries or international organisations with which the Commission and the Member State or group of Member States have concluded bilateral or multilateral confidentiality arrangements based on reciprocity.

Amendment

The Commission and Member States may exchange confidential information, including information exchanged through RAPEX, with regulatory authorities of third countries or international organisations with which the Commission and the Member State or group of Member States have concluded bilateral or multilateral confidentiality arrangements based on reciprocity. ***Where an exchange of information concerns personal data, Directive 95/46/EC shall apply.***

Or. de

Amendment 359
Sirpa Pietikäinen

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission

The Commission and Member States may exchange confidential information, including information exchanged through RAPEX, with regulatory authorities of third countries or international organisations with which the Commission and the Member State or group of Member States have concluded bilateral or multilateral confidentiality arrangements based on reciprocity.

Amendment

The Commission and Member States may exchange confidential information, including information exchanged through RAPEX, with regulatory authorities of third countries or international organisations with which the Commission and the Member State or group of Member States have concluded bilateral or multilateral confidentiality arrangements based on reciprocity. ***Any such arrangements shall include provisions on confidentiality corresponding to those applicable in the Union as well as special provisions on personal data protection, as required by Article 25 of Directive 95/46/EC and Article 9 of Regulation (EC) No 45/2001.***

Or. en

Amendment 360
Pablo Arias Echeverría

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission

The Commission and Member States may exchange confidential information, including information exchanged through RAPEX, with regulatory authorities of third countries or international organisations with which the Commission and the ***Member State or group of*** Member States have concluded bilateral or multilateral confidentiality arrangements based on reciprocity.

Amendment

The Commission, ***together with the*** Member States may exchange confidential information, including information exchanged through RAPEX, with regulatory authorities of third countries or international organisations with which the Commission and Member States have concluded bilateral or multilateral confidentiality arrangements based on reciprocity.

Justification

RAPEX data, including confidential data, belongs to all Member States. Accordingly, they should all be party to the relevant agreements. This will avoid the case arising where one Member State does not wish to conclude agreements with a given third country and another Member State would be willing to do so and is thereby able to obtain all information not provided by the first Member State. Any exchanges must take place through the Commission.

Amendment 361

Ashley Fox

Proposal for a regulation

Article 23 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. Market surveillance authorities shall, on receipt of a duly motivated request from a market surveillance authority in another Member State, provide ***any relevant information or documentation and carry out checks, inspections or investigations and report on them and on any follow-up action taken*** to the requesting authority.

Amendment

2. Market surveillance authorities shall, on receipt of a duly motivated request from a market surveillance authority in another Member State, provide ***assistance on an appropriate scale*** to the requesting authority.

Or. en

Amendment 362

Pablo Arias Echeverría

Proposal for a regulation

Article 23 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. Market surveillance authorities shall, on receipt of a duly motivated request from a market surveillance authority in another Member State, ***provide any relevant information or documentation and*** carry out ***checks, inspections or investigations*** and report ***on them and*** on any follow-up

Amendment

2. Market surveillance authorities shall, on receipt of a duly motivated request from a market surveillance authority in another Member State ***which has exhausted other channels*** carry out ***the*** inspections ***considered necessary*** and report on any follow-up action taken to the requesting

action taken to the requesting authority.

authority.

Or. es

Justification

This is excessive. In general, mutual assistance is provided through RAPEX. However, under certain circumstances, such measures may be necessary, and it is therefore proposed that they be taken once other channels have been exhausted.

Amendment 363

Pablo Arias Echeverría

Proposal for a regulation

Article 24 – paragraph 1

Text proposed by the Commission

1. Market surveillance authorities may cooperate with the competent authorities of third countries with a view to exchanging information and technical support, promoting and facilitating access to Union information exchange systems ***including*** the RAPEX system in accordance with Article 19(4), and promoting activities relating to conformity assessment and market surveillance.

Amendment

1. Market surveillance authorities may cooperate with the competent authorities of third countries with a view to exchanging information and technical support, promoting and facilitating access to Union information exchange systems, ***excluding*** the RAPEX system, in accordance with Article 19(4), and promoting activities relating to conformity assessment and market surveillance.

Or. es

Justification

Although the criteria are the same as those of the Commission regarding third country access to RAPEX, they may be interpreted differently by individual Member States. Given that this is a question of major importance involving confidential information from all Member States, it is proposed that authorisation be given by the Commission (under Article 22) and that the RAPEX system be excluded from this provision. Alternatively both articles could be reworded to ensure respect for confidential RAPEX information belonging to all the Member States.

Amendment 364

Josef Weidenholzer

Proposal for a regulation
Article 24 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Where, in an exchange of information, personal data are exchanged, Directive 95/46/EC shall apply.

Or. de

Amendment 365
Christel Schaldemose

Proposal for a regulation
Article 25 – paragraph 5

Text proposed by the Commission

Amendment

5. The EMSF may invite experts and other third parties to attend meetings or provide written contributions.

5. The EMSF may invite experts and other third parties to attend meetings or provide written contributions. **Organisations representing the interests of industry, small and medium-sized enterprises, consumers, laboratories and conformity assessment bodies at Union level may be consulted on the yearly market surveillance programme.**

Or. en

Amendment 366
Pablo Arias Echeverría

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) to **organise** joint market surveillance and joint testing projects;

(c) to **facilitate the organisation of** joint market surveillance and joint testing projects;

Justification

The purpose of the EMSF is to facilitate the organisation of joint market surveillance, training programmes and information campaigns.

Amendment 367

Pablo Arias Echeverría

Proposal for a regulation

Article 27 – paragraph 1 – point e

Text proposed by the Commission

(e) to **organise** training programmes and exchanges of national officials;

Amendment

(e) to **facilitate the organisation of** training programmes and exchanges of national officials;

Justification

The purpose of the EMSF is to facilitate the organisation of joint market surveillance, training programmes and information campaigns.

Amendment 368

Christel Schaldemose

Proposal for a regulation

Article 27 – paragraph 1 – point g

Text proposed by the Commission

(g) to organise information campaigns and joint visit programmes;

Amendment

(g) to organise information campaigns and joint visit programmes, **including controls at borders**;

Amendment 369

Pablo Arias Echeverría

Proposal for a regulation

Article 27 – paragraph 1 – point g

Text proposed by the Commission

(g) to **organise** information campaigns and joint visit programmes;

Amendment

(g) to **facilitate the organisation of** information campaigns and joint visit programmes;

Or. es

Justification

The purpose of the EMSF is to facilitate the organisation of joint market surveillance, training programmes and information campaigns.

Amendment 370
Josef Weidenholzer

Proposal for a regulation
Article 27 – paragraph 1 – point j

Text proposed by the Commission

(j) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation, taking due account of the interests of **business, in particular small and medium-sized enterprises**, and other stakeholders;

Amendment

(j) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation, taking due account of the interests of **consumers** and other stakeholders;

Or. de

Amendment 371
Pablo Arias Echeverría

Proposal for a regulation
Article 27 – paragraph 1 – point j

Text proposed by the Commission

(j) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation, taking due account of the interests of business, in particular small and medium-sized enterprises, and other stakeholders;

Amendment

(j) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation, taking due account of the interests of business, in particular small and medium-sized enterprises, **consumer protection**, and other stakeholders;

Justification

Business interests should not affect the effective and uniform application of this regulation and, this being so, the necessary adjustments must be made to take due account of consumer protection.

Amendment 372
Josef Weidenholzer

Proposal for a regulation
Article 27 – paragraph 1 – point k

Text proposed by the Commission

(k) to provide advice and assist the Commission, at *its* request, in *its* assessment of any issue relating to the implementation of this Regulation;

Amendment

(k) to provide advice and assist the Commission, ***Member States and the European Parliament***, at ***their*** request, in ***their*** assessment of any issue relating to the implementation of this Regulation;

Or. de

Amendment 373
Pablo Arias Echeverría

Proposal for a regulation
Article 27 – paragraph 1 – point l a (new)

Text proposed by the Commission

Amendment

(la) to contribute to the creation of a European network of product safety laboratories.

Or. es

Justification

It is proposed that the EMSF contribute to the creation of an EU laboratory network (see Article 28).

Amendment 374
Christel Schaldemose

Proposal for a regulation
Article 27 – paragraph 1 – point l b (new)

Text proposed by the Commission

Amendment

***(lb) to organise specific and regular
market surveillance campaigns on
products that are distributed on-line;***

Or. en

Amendment 375
Christel Schaldemose

Proposal for a regulation
Article 27 – paragraph 1 – point l c (new)

Text proposed by the Commission

Amendment

***(lc) to ensure adequate involvement of
and cooperation with customs authorities;***

Or. en

Amendment 376
Christel Schaldemose

Proposal for a regulation
Article 27 – paragraph 1 – point l d (new)

Text proposed by the Commission

Amendment

***(ld) to contribute to a streamlining of
administrative and enforcement practices
with regard to market surveillance in the
Member States;***

Or. en

Amendment 377

Ashley Fox

Proposal for a regulation

Article 28

Text proposed by the Commission

Amendment

Article 28

deleted

European Union reference laboratories

1. For specific products or a category or group of products or for specific risks related to a category or group of products, the Commission may by means of implementing acts designate Union reference laboratories that satisfy the criteria set out in paragraph 2.

2. Each Union reference laboratory shall satisfy the following criteria:

(a) have suitably qualified staff with adequate training in the analytical techniques used in their area of competence and an adequate knowledge of standards and practices;

(b) possess the equipment and reference material needed to carry out the tasks assigned to them;

(c) act in the public interest in an impartial and independent manner;

(d) ensure that the staff respect the confidential nature of certain subjects, results or communications.

3. Within the area of their designation, Union reference laboratories shall where appropriate have the following tasks:

(a) carrying out product testing in relation to market surveillance activities and investigations;

(b) contributing to the resolution of disputes between the authorities of Member States, economic operators and

conformity assessment bodies;

(c) providing independent technical or scientific advice to the Commission and the Member States;

(d) developing new techniques and methods of analysis;

(e) disseminating information and providing training.

Or. en

Justification

There is no clear justification for Union designated reference laboratories. Such functions already exist in several Member States and could be utilised by colleagues who do not have access to them in their own Member State. The proposed tasks of “contributing to the resolution of disputes” and “providing independent technical or scientific advice” can easily be fulfilled by appointing an existing body in a third Member State.

Amendment 378

Pablo Arias Echeverría

Proposal for a regulation

Article 28

Text proposed by the Commission

Amendment

Article 28

deleted

European Union reference laboratories

1. For specific products or a category or group of products or for specific risks related to a category or group of products, the Commission may by means of implementing acts designate Union reference laboratories that satisfy the criteria set out in paragraph 2.

2. Each Union reference laboratory shall satisfy the following criteria:

(a) have suitably qualified staff with adequate training in the analytical techniques used in their area of competence and an adequate knowledge of standards and practices;

(b) possess the equipment and reference material needed to carry out the tasks assigned to them;

(c) act in the public interest in an impartial and independent manner;

(d) ensure that the staff respect the confidential nature of certain subjects, results or communications.

3. Within the area of their designation, Union reference laboratories shall where appropriate have the following tasks:

(a) carrying out product testing in relation to market surveillance activities and investigations;

(b) contributing to the resolution of disputes between the authorities of Member States, economic operators and conformity assessment bodies;

(c) providing independent technical or scientific advice to the Commission and the Member States;

(d) developing new techniques and methods of analysis;

(e) disseminating information and providing training.

Or. es

Justification

It is not necessary to designate reference laboratories. This would create problems of independence, funding and impartiality. Notified bodies already exist for each directive in the form of laboratories specialised in each product category and meeting periodically to establish uniform EU dispute settlement criteria. The new laboratories would simply duplicate their work. With regard to funding, the costly analyses already being carried out would also be costly for the new reference laboratories and the question arises as to who would foot the bill. With a view to establishing common criteria for non-harmonised products, we consider it preferable to use different laboratories. Article 27(m) (new) seeks to lay the foundations for a European laboratory network, pooling the resources of the Member States in the field of product safety analysis and making findings available to all market surveillance authorities. This would encompass the analytical resources of all EU laboratories, provide information on the different product testing procedures carried out by each and ensure adequate EU capacity in this area, thereby helping to enhance product quality and safety.

Amendment 379
Christel Schaldemose

Proposal for a regulation
Article 28 – paragraph 2 – introductory part

Text proposed by the Commission

2. Each Union reference laboratory shall satisfy the following criteria:

Amendment

2. Each Union reference laboratory ***must be independent and*** shall satisfy the following criteria:

Or. en

Amendment 380
Josef Weidenholzer

Proposal for a regulation
Article 28 – paragraph 2 – point -a (new)

Text proposed by the Commission

Amendment

(-a) It shall be accredited and inspected by the Commission.

Or. de

Amendment 381
Christel Schaldemose

Proposal for a regulation
Article 28 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The independence of Union reference laboratories of commercial interests and conflicts of interest must be ensured through the procedures as stated in Chapter II of Regulation 765/2008 with regard to national accreditation bodies.

Or. en

Amendment 382
Sirpa Pietikäinen

Proposal for a regulation
Article 31 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The penalties provided for must be effective, proportionate and dissuasive.

Where the infringement has been committed intentionally, these penalties shall include, inter alia, administrative penalties for the relevant economic operator of up to 10 % of its total annual turnover in the preceding business year;

Or. en

Justification

The amendment modifies the Rapporteur's AM62, and clarifies that heavy penalties should follow in the case the infringement of the Regulation is committed intentionally. The overall limit is similar to the one in force in the Union antitrust legislation.

Amendment 383
Pablo Arias Echeverría

Proposal for a regulation
Article 31 – paragraph 2

Text proposed by the Commission

Amendment

The penalties referred to in the first subparagraph shall have regard to the size of the undertakings and in particular to the situation of small and medium-sized enterprises. The penalties may be increased if the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements.

deleted

Or. es

Justification

Same as CPSR proposal, since this is considered to be the responsibility of the Member States.

Amendment 384

Ashley Fox

Proposal for a regulation

Article 31 – paragraph 2

Text proposed by the Commission

Amendment

The penalties referred to in the first subparagraph shall have regard to the size of the undertakings and in particular to the situation of small and medium-sized enterprises. The penalties may be increased if the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements.

deleted

Or. en

Justification

The proposed text by the Commission contradicts the previous paragraph since (as specified in the previous paragraph) it is clearly for Member States to define the appropriate sanctions.

Amendment 385

Heide Rühle

Proposal for a regulation

Article 31 – paragraph 2

Text proposed by the Commission

Amendment

The penalties referred to in the first subparagraph shall have regard to the size of the undertakings and in particular to the situation of small and medium-sized enterprises. The penalties may be increased if the relevant economic

When defining penalties authorities should take into account the revenue that was made in the internal market with the non-compliant product, economic damage caused to other operators selling similar or comparable products in the Union,

operator has previously committed a similar infringement and may include criminal sanctions for serious infringements.

seriousness of the non-compliance, recurrence of the non-compliance, intentionality of the economic operator placing the product on the market.

Or. en

Amendment 386

Norica Nicolai, Jürgen Creutzmann

Proposal for a regulation

Article 31 – paragraph 2

Text proposed by the Commission

The penalties referred to in the first subparagraph shall *have regard to the size of the undertakings and in particular to the situation of small and medium-sized enterprises*. The penalties may be increased if the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements.

Amendment

The level of the penalties referred to in the first subparagraph shall *be established as a proportion of the value of sales of the products concerned during the last full year of the infringement, depending on its seriousness, duration and intentional character*. The penalties may be increased if the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements. *In any case, the penalties shall not exceed 10% of the company's total turnover in the preceding business year.*

Or. en

Justification

The proposed wording is based on the conditions applying to fines for infringements of EU competition rules. Although fines need to have a dissuasive effect, it is appropriate to establish a cap at 10% of the total turnover during the preceding accounting year in order to avoid driving companies out of business.

Amendment 387

Christel Schaldemose

Proposal for a regulation

Article 31 – paragraph 2

Text proposed by the Commission

The penalties referred to in the first subparagraph shall have regard to the *size* of the ***undertakings and in particular to the situation of small and medium-sized enterprises***. The penalties may be increased if the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements.

Amendment

The penalties referred to in the first subparagraph shall have regard to the ***seriousness of the infringement and the amount of undue revenue derived from it***. The penalties may be increased if the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements.

Or. en

Amendment 388
Matteo Salvini

Proposal for a regulation
Article 31 – paragraph 2

Text proposed by the Commission

The penalties referred to in the first subparagraph shall have regard to the size of the undertakings and in particular to the situation of ***small and medium-sized enterprises***. The penalties may be increased if the ***relevant*** economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements.

Amendment

The penalties referred to in the first subparagraph shall have regard to ***the seriousness of the infringement***, the size of the undertakings and in particular to the situation of ***SMEs, and to the roles played by individual undertakings within the supply chain, with particular reference to the activity actually performed by the given economic operator in the production process and the ability of that operator to affect product safety***. The penalties may be increased if the economic operator responsible ***for placing on the market*** has previously committed a similar infringement and may include criminal sanctions for serious infringements.

Or. it

Amendment 389
Franz Obermayr

Proposal for a regulation
Article 33

Text proposed by the Commission

No later than [five] years after the date of application, the Commission shall assess the application of this Regulation and transmit an evaluation report to the European Parliament and the Council. That report shall assess if this Regulation achieved its objectives, in particular with regard to ensuring more effective and efficient enforcement of product safety rules and Union harmonisation legislation, improving cooperation between market surveillance authorities, strengthening the controls of products entering the Union and better protecting the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests, taking into account its impact on business and in particular on small and medium-sized enterprises.

Amendment

No later than [five] years after the date of application, the Commission shall assess the application of this Regulation and transmit an evaluation report to the European Parliament and the Council. That report shall assess if this Regulation achieved its objectives, in particular with regard to ensuring more effective and efficient enforcement of product safety rules and Union harmonisation legislation, improving cooperation between market surveillance authorities, strengthening the controls of products entering the Union and better protecting the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests, taking into account its impact on business and in particular on small and medium-sized enterprises. ***In addition to checks by market surveillance authorities, there should be mandatory checks by independent third parties and, in particular, sampling by such testing bodies of a representative number of products.***

Or. de

Amendment 390
Wim van de Camp

Proposal for a regulation
Article 33

Text proposed by the Commission

No later than [five] years after the date of application, the Commission shall assess the application of this Regulation and transmit an evaluation report to the European Parliament and the Council. That report shall assess if this Regulation

Amendment

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achieved its objectives, in particular with regard to ensuring more effective and efficient enforcement of product safety rules and Union harmonisation legislation, improving cooperation between market surveillance authorities, strengthening the controls of products entering the Union and better protecting the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests, taking into account its impact on business and in particular on small and medium-sized enterprises. ***In addition, that report shall explore new and innovative, market-based solutions that could effectively complement the market surveillance actions carried out by the market surveillance authorities, and shall include, but not be limited to, exploring the potential of compulsory third party auditing schemes, together with compulsory third party collection and sampling of products tested.***

Or. en

Justification

The proposal is to set forth compulsory third party auditing schemes together with compulsory third party collection and sampling for the products concerned. A key consideration for effectiveness is to ensure that third party auditing is based on representative samples of products.

Amendment 391

Matteo Salvini

Proposal for a regulation

Article 33

Text proposed by the Commission

No later than [five] years after the date of application, the Commission shall assess the application of this Regulation and transmit an evaluation report to the

Amendment

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Or. en

Justification

The proposal is to set forth compulsory third party auditing schemes together with compulsory third party collection and sampling for the products concerned. A key consideration for effectiveness is to ensure that third party auditing is based on representative samples of products.

Amendment 392 **Christel Schaldemose**

Proposal for a regulation **Article 34 – paragraph 1 – point q**

Text proposed by the Commission

(q) Articles **39**, 40, 42 to 45 of Directive

Amendment

(q) Articles 40, 42 to 45 of Directive

2009/48/EC;

2009/48/EC;

Or. en