

Market surveillance of products *I**

European Parliament legislative resolution of 15 April 2014 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 (COM(2013)0075 – C7-0043/2013 – 2013/0048(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2013)0075),
 - having regard to Article 294(2) and Articles 33, 114 and 207 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0043/2013),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 22 May 2013¹,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection and the opinion of the Committee on International Trade (A7-0346/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 271, 19.9.2013, p. 86.

Amendment 1

Proposal for a regulation Recital 2

Text proposed by the Commission

(2) Market surveillance activities covered by this Regulation should not be directed exclusively towards the protection of health and safety but should also be applicable to the enforcement of Union legislation which seeks to safeguard other public interests, for example, by means of regulating the accuracy of measurement, electromagnetic compatibility **and energy efficiency**.

Amendment

(2) Market surveillance activities covered by this Regulation should not be directed exclusively towards the protection of health and safety but should also be applicable to the enforcement of Union legislation which seeks to safeguard other public interests, for example, by means of regulating the accuracy of measurement, electromagnetic compatibility, **energy efficiency and applicable environmental legislation**.

Amendment 2

Proposal for a regulation Recital 11 a (new)

Text proposed by the Commission

Amendment

(11a) This Regulation should apply to all forms of supply of products, including distance selling. Member States and the Commission should develop a common approach for the market surveillance of products sold online and, where appropriate, produce guidance on the respective roles and responsibilities of operators involved in the e-commerce supply chain in order to strengthen enforcement of the rules for products sold online.

Amendment 3

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 those 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.

Amendment 4

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 for assessing risks should be homogeneous in all Member States in order to ensure a 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.

Amendment 5

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 consumers' awareness 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, furthermore, explore the opportunities for making the submission of such complaints harmonised throughout the Union, for example through the creation of a central database where the complaints filed by consumers can be stored, as well as examine the possibility of making those complaints public, subject to the right of review and reply by the economic operators involved.

Amendment 6

Proposal for a regulation Recital 20

Text proposed by the Commission

(20) Obliging the authorities responsible for the control of products entering the Union market to carry out checks on an adequate scale therefore contributes to a safer Union market for products. In order to increase the effectiveness of such checks, *cooperation and exchange of information between those authorities and market surveillance authorities* concerning products presenting a risk *should be enhanced*.

Amendment

(20) Obliging the authorities responsible for the control of products entering the Union market to carry out checks on an adequate scale therefore contributes to a safer Union market for products. In order to increase the effectiveness of such checks, *those authorities and market surveillance authorities should be obliged to cooperate and exchange information* concerning products presenting a risk *and products that are non-compliant*.

Amendment 7

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, in particular the costs incurred by the market surveillance*

authority.

Amendment 8

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 ***and constantly updated*** 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 Rapid Alert System for Food and Feed (RASFF) platform.***

Amendment 9

Proposal for a regulation Recital 25

Text proposed by the Commission

(25) Given the size of the Union market for goods and as there are no internal borders, it is imperative that ***the*** market surveillance authorities of the Member States ***are willing and able*** to cooperate with each other effectively and to coordinate joint support and action. Accordingly, mechanisms for mutual assistance should be established.

Amendment

(25) Given the size of the Union market for goods and as there are no internal borders, it is imperative that ***this Regulation builds the framework for*** market surveillance authorities of the Member States to cooperate with each other effectively and to coordinate joint support and action. Accordingly, mechanisms for mutual assistance should be established, ***enforced, verified and duly financed.***

Amendment 10

Proposal for a regulation Recital 25 a (new)

Text proposed by the Commission

Amendment

(25a) The consistent application of this Regulation should be closely monitored by the Commission, which should also, where necessary, give recommendations to Member States where it finds that the powers and resources they have given to their market surveillance authorities are insufficient to meet the requirements of this Regulation properly.

Amendment 11

Proposal for a regulation Recital 26 a (new)

Text proposed by the Commission

Amendment

(26a) Injuries and accidents place a high social and economic burden on societies in general and on individuals. Injury and accident prevention can be enhanced primarily by improving injury surveillance. Based on the experience gained in the framework of the Joint Action on Monitoring Injuries in Europe (JAMIE) project, a genuine Pan-European Injuries Database should urgently be established, especially given the fact that the JAMIE project expires in 2014. Moreover, political commitment is necessary to ensure that the exchange of injury data among the Member States is an absolute priority.

Amendment 12

Proposal for a regulation Recital 27

Text proposed by the Commission

Amendment

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

(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 *serve as a platform for structured cooperation between the authorities of the Member States and should* provide a *continuous and permanent* means of involving all stakeholders concerned, including professional organisations, *business organisations* and consumer organisations, in order to take advantage of available information relevant for market surveillance when establishing, implementing and updating market surveillance programmes.

Amendment 13

Proposal for a regulation

Recital 28

Text proposed by the Commission

(28) The Commission should provide support for cooperation between market surveillance authorities and participate in the Forum. **The** Regulation should set out a list of tasks to be performed by the Forum. An executive secretariat should organise the Forum's meetings and provide other operational support for the accomplishment of its tasks.

Amendment

(28) The Commission should provide support for cooperation between market surveillance authorities and participate in the Forum. **This** Regulation should set out a list of tasks to be performed by the Forum. An executive secretariat should organise the Forum's meetings and provide other operational support for the accomplishment of its tasks. **To streamline the practices of market surveillance within the Union and to make market surveillance more effective, the Commission should consider proposing, when this Regulation is next reviewed, that the Forum is given the power to set binding recommendations as to the quality and practices of market surveillance.**

Amendment 14

Proposal for a regulation

Recital 29 a (new)

Text proposed by the Commission

Amendment

(29a) In view of the conflict between the increased number of products in

circulation within the internal market on the one hand, and the constraints on public resources that limit the possibility to drastically increase public market surveillance on an adequate scale on the other, the Commission should explore complementary, new and innovative, market-based solutions for more effective market surveillance on a larger scale, such as third party auditing of quality control systems and products. The Commission should include the results of those deliberations in the general evaluation report.

Amendment 15

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***¹⁴. 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***¹⁵ 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***¹⁶ apply in 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 Council¹⁴. ***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 Council¹⁵ and Regulation (EC) No 45/2001 of the European Parliament and of the Council¹⁶ apply in the context of this Regulation.

¹⁴ ***Regulation (EC) No 1049/2001 of the European Parliament and of the Council***

context of this Regulation.

¹⁴ OJ L 145, 31.5.2001, p. 43.

¹⁵ OJ L 281, 23.11.1995, p. 31.

¹⁶ OJ L 8, 12.1.2001, p. 1.

of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

¹⁵ *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 (OJ L 281, 23.11.1995, p. 31).*

¹⁶ *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 (OJ L 8, 12.1.2001, p. 1).*

Amendment 16

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 depend on the seriousness, duration and intentional or recurring character of the infringement, as well as the size of the undertakings, in terms of the number of persons employed by and annual turnover of the economic operators concerned, with particular regard to small and medium-sized enterprises (SMEs). Infringements should entail administrative penalties that are harmonised at Union level. Member States should be encouraged to allocate the revenues collected from such penalties to market surveillance activities.*

Amendment 17

Proposal for a regulation

Recital 33 a (new)

Text proposed by the Commission

Amendment

(33a) In order to enhance the deterrent effect of the penalties, the Commission should make them public. In addition, economic operators who are repeatedly found to have intentionally breached this Regulation should be placed on a public, Union-wide blacklist.

Amendment 18

Proposal for a regulation

Recital 34

Text proposed by the Commission

Amendment

(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.

(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. ***Member States should ensure that the revenues collected from fees charged in accordance with this Regulation are allocated to market surveillance activities.***

Amendment 19

Proposal for a regulation

Recital 37 a (new)

Text proposed by the Commission

Amendment

(37a) In order to facilitate the identification and traceability of products bearing a potential serious risk to health and safety and thus to maintain a high level of health and safety of consumers, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in order to establish a Pan-European Injuries

Database. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Amendment 20

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 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

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 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. ***In addition, implementing powers should be conferred to the Commission as regards the adoption of the general risk assessment methodology.*** Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹⁸.

¹⁸ ***Regulation (EU) No 182/2011 of the European Parliament and of the Council***

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*¹⁸.

¹⁸ OJ L 55, 28.2.2011, p. 11.

of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of its implementing powers (OJ L 55, 28.2.2011, p. 13).

Amendment 21

Proposal for a regulation Recital 39 a (new)

Text proposed by the Commission

Amendment

(39a) The precautionary principle, as laid down in Article 191(2) TFEU, and outlined inter alia in the Commission Communication of 2 February 2000 entitled "On the precautionary principle", is a fundamental principle for the safety of products and for the safety of consumers and should be taken into due account by market surveillance authorities when assessing the safety of a product.

Amendment 22

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

Text proposed by the Commission

Amendment

The provisions of this Regulation are based on the precautionary principle.

Amendment 23

Proposal for a regulation Article 3 – point 1

Text proposed by the Commission

Amendment

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

(1) ‘product’ means a ***substance, mixture, preparation or good produced*** through a manufacturing process ***other than food, feed, products of human origin and products of plants and animals relating***

directly to their future reproduction;

Amendment 24

Proposal for a regulation Article 3 – point 5

Text proposed by the Commission

(5) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

Amendment

(5) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks ***with regard to the manufacturer's obligations under the relevant Union legislation;***

Amendment 25

Proposal for a regulation Article 3 – 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;

Amendment 26

Proposal for a regulation Article 3 – 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 this Regulation;***

Amendment 27

Proposal for a regulation Article 3 – point -13 (new)

Text proposed by the Commission

Amendment

(-13) 'non-compliant product' means a product which is not in conformity with the requirements laid down in applicable Union legislation;

Amendment 28

Proposal for a regulation Article 3 – 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, 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;

(13) ‘product presenting a 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;

Amendment 29

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

Text proposed by the Commission

Amendment

(13a) 'product presenting an emerging risk' means a product on which there is solid scientific evidence that it presents a newly developing risk or a known risk if the product is used in new or unfamiliar conditions which cannot be reasonably foreseen by the manufacturer.

Amendment 30

Proposal for a regulation Article 3 – 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 the marketing of products ***by laying down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;***

Amendment 31

**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 non-compliant products*** are not ***placed or*** made available on the Union market and, where such products have been ***placed or*** made available, effective ***and proportionate*** measures are taken to remove the risk presented by the product ***or to resolve non-compliance.***

Amendment 32

**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

Amendment

3. ***Member States shall report on the*** market surveillance activities and external border controls to the Commission every year. The information reported shall include statistics regarding the number ***and results*** of controls carried out and shall be communicated to all Member States. ***The Commission shall make that information***

be communicated to all Member States.
Member States may make a summary of the results accessible to the public.

available to the public *electronically and, where appropriate, by other means.*

Amendment 33

Proposal for a regulation Article 4 – paragraph 4

Text proposed by the Commission

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.

deleted

Amendment 34

Proposal for a regulation Article 5 – paragraph 1

Text proposed by the Commission

Amendment

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

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

Amendment 35

Proposal for a regulation Article 5 – paragraph 2

Text proposed by the Commission

Amendment

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

2. Each Member State shall grant market surveillance authorities the powers and **entrust them** with the resources and means necessary for the proper performance of their tasks **and shall report to the Commission thereon. The Commission shall evaluate whether those powers and resources are sufficient for the proper performance of that Member State's market surveillance obligations under this Regulation, and shall make the outcomes of its evaluations available to the public electronically and, where appropriate, by**

other means.

Amendment 36

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. Market surveillance authorities **shall** 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 37

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

4. Each Member State shall inform the Commission about its market surveillance authorities and their areas of competence, providing the necessary contact details, **and the Commission shall transmit this information to the other Member States and publish a list of market surveillance authorities.**

Amendment

4. Each Member State shall inform the Commission about its market surveillance authorities and their areas of competence, providing the necessary contact details. The Commission shall **make the list available to the public electronically and, where appropriate, by other means.**

Amendment 38

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.

Amendment 39

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 ***organise their activities in such a way that maximum effectiveness can be achieved.*** ***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. ***They shall, accordingly, carry out the sample checks on sufficient numbers of products made available on the market, enabling conformity and the real risk posed to be assessed.*** They shall record these checks in the information and communication system for market surveillance referred to in Article 21. ***Where appropriate, along with those traditional market sampling mechanisms, the market surveillance authorities shall endeavour to move to pro-active auditing of supply chain processes at entities involved in the manufacturing, importing, trading, branding and retailing of consumer products.***

Amendment 40

Proposal for a regulation

Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission

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

Amendment

In cases of known or emerging risk related to the objectives set out in Article 1 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, ***criteria for determination of 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).

amount of samples to be checked in relation to that particular product or category of products and the characteristics of that known or emerging risk. **Those** 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. **Those** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).

Amendment 41

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

Amendment 42

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.

Amendment 43

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, ***check, examine and obtain copies of any relevant documents*** and take any necessary samples of products.

Amendment 44

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 ***within a reasonable time frame***;

Amendment 45

Proposal for a regulation

Article 6 – paragraph 5 – point b

Text proposed by the Commission

(b) verify that corrective action has been taken;

Amendment

(b) verify that corrective action has been taken ***in a timely manner***;

Amendment 46

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

Amendment

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

products.

products *and compliance of products with applicable Union legislation;*

Amendment 47

Proposal for a regulation

Article 6 – paragraph 5 – point c a (new)

Text proposed by the Commission

Amendment

(ca) monitor accidents and damage to health which are suspected to have been caused by products;

Amendment 48

Proposal for a regulation

Article 6 – paragraph 5 – point c b (new)

Text proposed by the Commission

Amendment

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

Amendment 49

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ba) the levels and methods for calculation of fees applicable to economic operators pursuant to Articles 10 and 16;

Amendment 50

Proposal for a regulation

Article 7 – paragraph 2

Text proposed by the Commission

Amendment

2. Each Member State shall draw up sector-specific programmes and shall review *these* programmes, and update them if necessary, every year. *These*

2. Each Member State shall draw up sector-specific programmes *with the input of key stakeholders concerned, including professional organisations, business*

programmes shall cover all sectors in which authorities conduct market surveillance activities.

organisations and consumer organisations, and shall review **those** programmes, and update them if necessary, every year. **Those** programmes shall cover all sectors in which authorities conduct market surveillance activities.

Amendment 51

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. Subject to Article 6(6), **they** shall be made accessible to the public electronically and, where appropriate, by other means.

Amendment 52

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

Text proposed by the Commission

Amendment

The Commission shall evaluate the general and sector-specific programmes and, if appropriate, make recommendations to the Member States based on that evaluation. The Commission shall make the outcomes of its evaluations and, if applicable, its recommendations to Member States available to the public electronically and, where appropriate, by other means.

Amendment 53

Proposal for a regulation Article 8 – paragraph 1

Text proposed by the Commission

1. **On** request, economic operators and, where applicable, conformity assessment

Amendment

1. **Further to a reasoned** request, economic operators, **according to their**

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.***

respective role in the supply chain and, where applicable, conformity assessment bodies, ***shall*** make available to market surveillance authorities ***all the*** documentation and information that those authorities require for the purpose of carrying out their activities. ***Such information shall include information that enables the precise identification of the product and facilitates the tracing of the product, as appropriate. Where an economic operator has previously received the documentation and information concerned from another economic operator, and where it is classified as confidential under Union and Member State trade secrecy rules, market surveillance authorities shall ensure confidentiality when that documentation and information is made available.***

Amendment 54

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 or non-compliance of products that they have placed or made available on the market.***

Amendment 55

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

Text proposed by the Commission

Amendment

2a. All information supplied or made available to market surveillance authorities under this Article shall be clear, understandable and intelligible.

Amendment 56

Proposal for a regulation

Article 8 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. The obligations laid down in this Article shall also apply to intermediary service providers.

Amendment 57

Proposal for a regulation

Article 9 – title

Text proposed by the Commission

Amendment

Products presenting a risk

Non-compliant products and products presenting a risk

Amendment 58

Proposal for a regulation

Article 9 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

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.

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 that product taking account of the considerations and criteria set out in Article 13 ***of this Regulation and in Article 6 of Regulation (EU) No .../.... of the European Parliament and of the Council***^{1*}.

¹ ***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 L...).***

** OJ: please insert the number of Regulation (2013/0049(COD)) in the text and the number, date of adoption and the publication reference of the Regulation in the footnote.*

Amendment 59

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.

Amendment 60

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 Union legislation **may** give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases:

Amendment 61

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 essentially similar to a registered trade mark for that product,

thereby not allowing its authenticity or origin to be guaranteed;

Amendment 62

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***.

Amendment 63

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:

Amendment 64

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:

Amendment 65

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;

Amendment 66

Proposal for a regulation

Article 9 – paragraph 4 – point d – point i

Text proposed by the Commission

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

Amendment

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

Amendment 67

Proposal for a regulation

Article 9 – paragraph 4 – point d – point ii

Text proposed by the Commission

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

Amendment

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

Amendment 68

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

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).

Amendment

deleted

Amendment 69

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.

Amendment 70

Proposal for a regulation

Article 10 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

All of the expenses incurred by the market surveillance authority in the course of the application of the first subparagraph shall be borne by the relevant economic operator unless the market surveillance authority considers it to be disproportionate, in which case it may decide that the cost shall be borne only partly by the economic operator.

Amendment 71

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

Amendment

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.

deleted

Amendment 72

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.

Amendment 73

Proposal for a regulation

Article 10 – paragraph 8 – subparagraph 1

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 ***shall*** charge fees on ***the relevant*** economic operators which ***are caught placing or making available non-compliant products and products presenting a risk on the Union market. Such fees shall*** 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 74

Proposal for a regulation

Article 10 – paragraph 8 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The fees shall be calculated on the basis of the actual costs of each market surveillance activity, and shall be applied to the economic operators subject to such market surveillance activities. Such fee

shall not exceed the actual costs of the market surveillance activity performed and may partly or entirely reflect the time taken by the staff of the market surveillance authorities to perform the market surveillance controls.

Amendment 75

Proposal for a regulation Article 11 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. Within **30** days of communication by the Commission to the Member States, pursuant to Article 20(4), of measures taken pursuant to Article 10(**1**) **or (4)** 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.

Amendment 76

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 a maximum of 30 days** the national measures, taking account of all available scientific or technical evidence.

Amendment 77

Proposal for a regulation

Article 11 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. If an objection is raised pursuant to paragraph 1 by a Member State or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall inform all the Member States through the RAPEX contact points.

Amendment 78

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

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission ***shall*** decide by implementing acts ***within three months*** whether the national measures are justified and similar measures should be taken by all Member States that have not already done so. In ***that*** 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 79

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

Amendment

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.

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***

Such a decision shall be without prejudice to procedures provided in that Regulation.

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.***

Amendment 80

Proposal for a regulation Article 13 – paragraph 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 and, where appropriate, Commission guidelines on the application of that methodology to a specific category of products. The Commission shall, by means of implementing acts, adopt the general risk assessment methodology. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).***

Amendment 81

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, **inspection and calibration** reports or certificates attesting conformity and issued by a conformity assessment body **accredited in accordance with Regulation (EC) No 765/2008, including assessments drawn up pursuant to Regulation (EC) No 1907/2006, for instance in connection with registration, authorisation, restrictions or reporting;**

Amendment 82

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

Text proposed by the Commission

Amendment

2a. In the absence of criteria referred to in points (a), (b) and (c) of paragraph 2 of this Article, account shall be taken of Article 6 of Regulation (EU) No ... *;

OJ: please insert the number of Regulation (2013/0049(COD)).

Amendment 83

**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

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 action under this Regulation where there is evidence that, despite such conformity or

compliance, the product presents a risk.

compliance, the product presents a risk. ***In that case, the market surveillance authority shall demonstrate that the product presents a risk.***

Amendment 84

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.

Amendment 85

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

Text proposed by the Commission

Amendment

4a. The Commission may, on 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.

Amendment 86

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

Text proposed by the Commission

Amendment

4b. 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/EC¹ and take into account all available scientific and technical evidence relating to the risks under consideration.

¹*Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment (OJ L 66, 4.3.2004, p. 45).*

Amendment 87

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 essentially similar to a registered trade mark for that product, thereby not allowing its authenticity or origin to be guaranteed.

Amendment 88

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), (ba) and (c) of the second subparagraph 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.

Amendment 89

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 shall be proportionate to the seriousness of the non-compliance.

Amendment 90

Proposal for a regulation Article 14 – paragraph 5

Text proposed by the Commission

Amendment

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.

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.

Amendment 91

Proposal for a regulation Article 15 – paragraph 1

Text proposed by the Commission

Amendment

1. A product the release of which has been suspended by the authorities in charge of external border controls pursuant to Article 14 shall be released if, within three working days of the suspension of release, those authorities have not been requested by the market surveillance authorities to continue the suspension or they have been informed by the market surveillance authorities that the product does not present a risk, and provided that all the other requirements and formalities pertaining to such release have been fulfilled.

1. A product the release of which has been suspended by the authorities in charge of external border controls pursuant to Article 14 shall be released if, within three working days of the ***notification of*** suspension of release, those authorities have not been requested by the market surveillance authorities to continue the suspension or they have been informed by the market surveillance authorities that the product does not present a risk, and provided that all the other requirements and formalities pertaining to such release have been fulfilled.

Amendment 92

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, **inspection and calibration** reports or certificates attesting conformity and issued by a conformity assessment body **accredited in accordance with Regulation (EC) No 765/2008**, 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 93

Proposal for a regulation

Article 16 – paragraph 6 – subparagraph 1

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 **to the person declaring the product 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.

Amendment 94

Proposal for a regulation

Article 16 – paragraph 6 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The fees shall be calculated on the basis of the actual costs of each market surveillance activity, and applied to the person declaring the product for free circulation subject to such market

surveillance activities. Such fees shall not exceed the actual costs of the market surveillance activity performed and may partly or entirely reflect the time taken by the staff of the market surveillance authorities to perform the market surveillance controls.

Amendment 95

Proposal for a regulation Article 18 – paragraph 1

Text proposed by the Commission

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 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.

Amendment

1. Within **30** 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.

Amendment 96

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 30 days**, evaluate the **national measures**, taking account of all available scientific or technical evidence.

Amendment 97

Proposal for a regulation

Article 18 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. If an objection is raised within 30 days pursuant to paragraph 1 by a Member State or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall inform all the Member States through the RAPEX contact points.

Amendment 98

Proposal for a regulation

Article 19 – paragraph 4

Text proposed by the Commission

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.

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.***

Amendment 99

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

deleted

risk presented by a product do not go beyond the territory of its Member State.

Amendment 100

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 for product identification and traceability;

Amendment 101

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 level of the risk and a summary of safety and risk assessment findings;

Amendment 102

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 Union legislation;

Amendment 103

Proposal for a regulation

Article 20 – paragraph 2 – subparagraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) whether the product is known to be counterfeit.

Amendment 104

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 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.

Amendment 105

Proposal for a regulation

Article 20 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. Information on a product contained in a notification in RAPEX shall be updated, where appropriate.

Amendment 106

Proposal for a regulation

Article 21 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission

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, in particular the following information:

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 into ICSMS*** in particular the following information:

Amendment 107

Proposal for a regulation

Article 21 – paragraph 1 – subparagraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) the identification of risks and their characteristics;

Amendment 108

Proposal for a regulation

Article 21 – paragraph 1 – subparagraph 1 – point e

Text proposed by the Commission

(e) any non-compliance with Union **harmonisation** legislation other than measures or corrective action notified under RAPEX in accordance with Article 20;

Amendment

(e) any non-compliance with Union legislation other than measures or corrective action notified under RAPEX in accordance with Article 20;

Amendment 109

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 those systems, where appropriate.

Amendment 110

Proposal for a regulation

Article 21 – paragraph 1 – subparagraph 3

Text proposed by the Commission

ICSMS **may** also be made available, where necessary or appropriate, for use by the authorities in charge of controls at the external borders.

Amendment

ICSMS **shall** also be made available, where necessary or appropriate, for use by the authorities in charge of controls at the external borders.

Amendment 111

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

Amendment

3. Market surveillance authorities shall recognise the validity and make use of test, **inspection or calibration** reports prepared by or for their counterparts in other

entered into ICSMS.

Member States and entered into ICSMS.

Amendment 112

Proposal for a regulation Article 21 a (new)

Text proposed by the Commission

Amendment

Article 21a

Pan-European Injuries Database

1. The Commission shall adopt delegated acts, in accordance with Article 31a, establishing a Pan-European Injuries Database (Database) which would cover all types of injuries, and in particular those related to products used at home and for leisure, transportation and work activities by*. The Database shall be coordinated and operated by the Commission.

2. The relevant market surveillance authorities of the Member States shall contribute to the establishment of the Database and deliver comprehensive injury data. In consultation with the Member States, the Commission shall draw up and publish detailed guidance on the relevant data to be included in the Database, as well as the methods for electronic communication of the data.

Not later than two years after the establishment of the Database, the Commission shall report to the European Parliament and the Council on the functioning of the Database.

**** OJ: please insert the date: two years after the date of entry into force of this Regulation.***

Amendment 113

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 **applicant countries**, third countries or international organisations with which the Commission and 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.**

Amendment 114

**Proposal for a regulation
Article 23 – paragraph 1**

Text proposed by the Commission

1. There shall be efficient cooperation and exchange of information among the market surveillance authorities of the Member States, among the different authorities within **each** Member **State** and between market surveillance authorities and the Commission and the relevant Union agencies regarding market surveillance programmes and all issues relating to products presenting a risk.

Amendment

1. There shall be efficient cooperation and exchange of information among the market surveillance authorities of the Member States, among the different authorities within **and among the** Member **States** and between market surveillance authorities and the Commission and the relevant Union agencies regarding market surveillance programmes and all issues relating to products presenting a risk.

Amendment 115

**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.

Amendment 116

Proposal for a regulation Article 25 – paragraph 5

Text proposed by the Commission

5. The EMSF may invite experts and other third parties to attend meetings or provide written contributions.

Amendment

5. The EMSF may invite experts and other third parties to attend meetings or provide written contributions ***on a regular and continuous basis. Business organisations, SMEs, consumers, laboratories and conformity assessment bodies at Union level may be consulted on the annual market surveillance programme.***

Amendment 117

Proposal for a regulation Article 25 – paragraph 6

Text proposed by the Commission

6. The EMSF may establish standing or temporary sub-groups which shall include the administrative cooperation groups for market surveillance set up for the implementation of Union harmonisation legislation. Organisations representing the interests of industry, ***small and medium-sized enterprises***, consumers, laboratories and conformity assessment bodies at Union level ***may*** be invited to participate in such sub-groups as observers.

Amendment

6. The EMSF may establish standing or temporary sub-groups which shall include the administrative cooperation groups for market surveillance set up for the implementation of Union harmonisation legislation. Organisations representing the interests of industry, ***SMEs***, consumers, laboratories and conformity assessment bodies at Union level ***shall*** be invited to participate in such sub-groups as observers ***on a regular and continuous basis.***

Amendment 118

Proposal for a regulation Article 27 – paragraph 1 – point c

Text proposed by the Commission

(c) to ***organise*** joint market surveillance and joint testing projects;

Amendment

(c) to ***facilitate the organisation of*** joint market surveillance and joint testing projects;

Amendment 119

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;

Amendment 120

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, **including controls at borders**;

Amendment 121

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 **SMEs, consumer protection**, and other stakeholders;

Amendment 122

Proposal for a regulation

Article 27 – point l a (new)

Text proposed by the Commission

Amendment

(la) to organise specific and regular market surveillance actions on products that are distributed on-line;

Amendment 123

Proposal for a regulation

Article 27 – paragraph 1 – point 1 b (new)

Text proposed by the Commission

Amendment

(1b) to ensure adequate involvement of and cooperation with customs authorities;

Amendment 124

Proposal for a regulation

Article 27 – paragraph 1 – point 1 c (new)

Text proposed by the Commission

Amendment

(1c) to contribute to a streamlining of administrative and enforcement practices with regard to market surveillance in the Member States.

Amendment 125

Proposal for a regulation

Article 28 – paragraph 2 – point d a (new)

Text proposed by the Commission

Amendment

(da) be accredited pursuant to the provisions of Regulation (EC) No 765/2008.

Amendment 126

Proposal for a regulation

Article 28 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) contributing to the resolution of disputes between the authorities of Member States, economic operators and conformity assessment bodies;

(b) settling any disputes arising out of a divergent risk assessment among the market surveillance authorities of ***different*** Member States, ***the*** economic operators and ***the*** conformity assessment bodies;

Amendment 127

Proposal for a regulation

Article 31 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The Member States shall lay down the rules ***on*** penalties applicable to infringements of the provisions of this Regulation that impose obligations on economic operators and to infringements of provisions of any Union harmonisation legislation on products covered by this Regulation that impose obligations on economic operators where that legislation does not provide for penalties, and shall take all measures necessary to ensure that they are implemented. ***The penalties provided for must be effective, proportionate and dissuasive.*** Member States shall notify those provisions to the Commission by ***[insert date - 3 months prior to the date of application of this Regulation]*** and shall notify it without delay of any subsequent amendment affecting them.

Amendment

1. The Member States shall lay down the rules ***establishing appropriate*** penalties applicable to infringements of the provisions of this Regulation that impose obligations on economic operators and to infringements of provisions of any Union harmonisation legislation on products covered by this Regulation that impose obligations on economic operators where that legislation does not provide for penalties, and shall take all measures necessary to ensure that they are implemented. Member States shall notify those provisions to the Commission by ... * and shall notify it without delay of any subsequent amendment affecting them.

**** OJ: please insert the date: three months prior to the date of application of this Regulation.***

Amendment 128

Proposal for a regulation

Article 31 – paragraph 1 – subparagraph 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 provided for shall be effective, proportionate and dissuasive. The penalties shall have regard to the ***seriousness, the duration and, where applicable, the intentional character of the infringement.*** ***In addition,*** the penalties ***shall take into account whether*** the relevant economic operator has previously committed a similar infringement.

Amendment 129

Proposal for a regulation

Article 31 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Administrative penalties applicable to infringements shall at least offset the economic advantage sought through the infringement, but shall not exceed 10 % of the annual turnover or an estimate thereof. The penalties imposed may be higher than 10 % of the annual turnover or an estimate thereof, where it is necessary to offset the economic advantage sought through the infringement. The penalties may include criminal sanctions for serious infringements.

Amendment 130

Proposal for a regulation

Article 31 – paragraph 1 b – subparagraph 1 (new)

Text proposed by the Commission

Amendment

1b. The Member States shall inform the Commission of the type and the size of the penalties imposed under this Regulation, identify the actual infringements of this Regulation, and indicate the identity of economic operators for which penalties have been imposed. The Commission shall make that information available to the public without undue delay electronically and, where appropriate, by other means.

Amendment 131

Proposal for a regulation

Article 31 – paragraph 1 b – subparagraph 2 (new)

Text proposed by the Commission

Amendment

The Commission, on the basis of the information received under the first subparagraph, shall publish and update a

Union-wide blacklist of economic operators who are repeatedly found to intentionally infringe this Regulation.

Amendment 132

**Proposal for a regulation
Article 31 a (new)**

Text proposed by the Commission

Amendment

Article 31a

Exercise of the delegation

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 21a shall be conferred on the Commission for an indeterminate period of time from ...*.

3. The delegation of power referred to in Article 21a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 21a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the

** OJ: please insert the date: the date of entry into force of this Regulation.*

Amendment 133

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, ***energy efficiency***, public security and other public interests, taking into account its impact on business and in particular on ***SMEs***. ***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.***