ORGALIME

Position Paper

Brussels, 11 October 2010

Alignment of 10 product harmonisation directives with Decision 768/2008/EC (NLF)

Orgalime welcomes the New Legislative Framework and therefore supports the Commission in its intention to align 10 product harmonisation directives as closely as possible with the New Legislative Framework (Regulation 765/2008/EC and Decision 768/2008/EC), in order to avoid any unjustified discrepancies.

However, for the alignment to introduce this simplification in the regulatory environment and to reflect the drive towards smart regulation, we call on the Commission to clarify in the Blue Guide or in other guidance documents a number of elements contained in the reference provisions set out in Decision 768/2008/EC. Without this clarification, the alignment could trigger conflicting interpretations with burdensome consequences for the industries concerned, including the 90% of small and medium sized companies which Orgalime represents. We present our requests hereunder.

1. General comments

Directives covering exclusively non-consumer/professional products

Some of the Directives, such as the ATEX Directive 94/9/EC, the Lifts Directive 95/16/EC and the Civil Explosives Directive, cover exclusively professional, non-consumer products. For these directives the alignment would introduce obligations for economic operators that are not relevant or applicable. For instance the obligation to carry out sample checks of marketed products (an obligation taken from the GPSD for consumer products) is generally inapplicable as the professional products covered by these Directives do not circulate freely on the market. Moreover, this obligation would conflict with the private contractual arrangements between the manufacturer and his professional customers. Therefore we urge the Commission to remove all the obligations for economic operators that are only applicable to consumer products from the alignment of those directives that cover exclusively non-consumer/professional products.

Cost efficiency of pre-marketing requirements for post-market surveillance

Orgalime is generally supportive of the new pre-marketing obligations for economic operators and notified bodies and the more stringent conformity assessment procedures embedded in Decision 768/2008/EC. However, the alignment of the relevant provisions of the 10 Directives will not alone solve the problems caused by rogue trading. Therefore, we call on the Commission to ensure that the administrative burden and compliance costs, that the new obligations will give rise to lawful

www.Orgalime.org

Orgalime aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@Orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

manufacturers, will not add to the imbalance caused by unfair competition from unlawful market operators.

Market surveillance and border controls that are carried out with an equal level of efficiency and effectiveness throughout the European Economic Area are the only way to efficiently protect the safety of consumers and workers, the competitiveness and reputation of lawful manufacturers, and the success of energy and environment policies from unsafe or otherwise non-compliant products.

2. Specific comments: request for clarification in horizontal guidance

Translation requirements

According to Articles R2.9 and R4.9 of Decision No 768/2008/EC, manufacturers and importers *"shall, further to a **reasoned request** from a **competent national authority**, provide it with all the information and **documentation** necessary to demonstrate the conformity of the product, in a **language which can be easily understood** by that authority. They shall cooperate with that authority, at the request of the latter, on any action to avoid the risks posed by products which they have placed on the market".*

Translation into different languages of the whole technical file, which can contain several hundreds of pages, would generate significant administrative burdens and costs for manufacturers, especially SMEs, without clear added value for the authorities concerned.

Therefore, Orgalime urges the Commission to clarify that:

1) A "reasoned request" usually means that the authority must define the proven or claimed non-conformity. Therefore, translation of the technical file should be limited to those parts of the documentation that are relevant to assess the non-conformity or demonstrate whether the non-conformity has been addressed.
2) Translation into "*a language which can be easily understood*" by the competent national authority is meant to indicate that the manufacturer does *not* have to translate the technical file necessarily into the national language of the relevant authority, but that the language chosen is subject to negotiation with the authority and could be a third language such as English.
3) The "competent national authority" means the relevant market surveillance authority of the Member State where the manufacturer or the importer is established. Considering the obligation for cooperation contained in Article 24 of Regulation 765/2008, this authority should be given the lead in dealing with a specific case of non-compliance vis-à-vis the manufacturer or importer.

Traceability requirements

Manufacturers (Decision, Art. R2.6) and importers (Art. R4.3) "*shall indicate their name, registered trade name or registered trade mark **and** the **address** at which they can be contacted on the product or, **where that is not possible**, on its packaging or in a document accompanying the product. The address must indicate a **single point** at which the manufacturer can be contacted".*

Orgalime asks the Commission to clarify the meaning of the expression "*where that is not possible*", as it could be interpreted in various ways and may jeopardise the efficiency of market surveillance.

Moreover, the enforcement of this obligation should take into account the logistical realities of the distribution chain in order to be effective. The obligation to affix the "*registered trade name or registered trade mark and the address*", including the indication of a single contact point, could in our view be fulfilled by the indication of a **URL address** where all practical details are made available by the manufacturer, his authorised representative and/or the importer.

Furthermore, Orgalime requests that the interpretation of additional identification requirements as required in article R12.1 Module F 6.1 and in the annexes of some product specific directives (e.g

Orgalime aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@Orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

NAWID and MID) allows manufacturers to choose the most appropriate means (e.g. labels) or software identification (e.g display).

Obligations of importers

The obligations of importers were subject to much debate when the NLF was discussed in the European Parliament and the Council. The final wording in Article R4.2 of the Decision, i.e.: "*…importers shall **ensure** that the appropriate conformity assessment procedure has been carried out by the manufacturer*" and "*They shall **ensure** that the manufacturer has drawn up the technical documentation etc…*" may lead to different interpretations of what is needed to be done to *'ensure'*.

It should be clarified that this formulation is not meant to imply the need for importers to systematically resort to additional control procedures or (third-party) testing. Rather, its objective is to make sure that importers are aware of their responsibility to sell only compliant products on the EU market. Therefore Orgalime calls on the Commission to clarify that the term "to ensure" refers to actions of the importer that aim to ascertain that the manufacturer has fulfilled all his obligations. The obligation "to ensure" can thus be fulfilled by referring to the applicable EU legislation in the contract, by ensuring that the importer has access to the technical file or that the manufacturer has signed an obligation to provide the documentation at the request of market surveillance authorities. Furthermore, the importer must check that the product bears the required marking(s) and is accompanied by the required documents.

Proportionality of conformity assessment

Article 4.4 of the Decision states that "*for custom-made products and small series production, the technical and administrative conditions relating to conformity assessment procedures shall be **alleviated**"*. The application of this provision may lead to diverging procedures for conformity assessment depending on the kind or size of the undertaking involved. Similar concerns are raised by Article R17.6(c) of the Decision, which requires conformity assessment bodies (CABs) to perform their activities taking "*due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question*" etc.

In Orgalime's view, product safety must not be dependent on the size of the manufacturer or undertaking, and there should be no special rules for SMEs as far as CE marking and the underlying obligations it imposes are concerned. Orgalime therefore calls on the Commission to clarify that the proportionate approach to conformity assessment, as required in these Articles, does not imply any compromise on the level of safety. In particular,

1) Regarding Article 4.4, the expression "technical and administrative conditions relating to conformity assessment procedures" only relates to the *application* of conformity assessment and does not mean that a less stringent conformity assessment module should be foreseen for products covered by a piece of legislation just because they are custom-made or produced in small series.
2) Regarding Article R17.6(c), a distinction is necessary:
   - as far as the modules using quality assurance are concerned (modules D, E, H, and their variants), their application needs to be adapted to the size of the undertaking, as is already required by the relevant standard EN ISO 9001;
   - as far as modules B (EC-type examination), F and G are concerned, these are product-related conformity assessment procedures, and therefore their application (i.e. the examination of a product type/batch) must not be made dependent on the size of the manufacturer's organisation.

Nevertheless articles 4.4 and 4.5 of the Decision should facilitate the demonstration of conformity for manufacturers of measuring instruments that typically assemble sub-components. As is already current practice, such manufacturers should be allowed, to continue placing their assembled products (instruments) on the market without resorting to a re-certification (TEC) of the assembled

Orgalime aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@Orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

product, since they already have the type examination certificates issued for the sub-components by a third party. If this interpretation is not made by enforcement authorities, it would impose disproportionate requirements for some engineering sectors (such as the weighing instruments industry) where the final manufacturer is often an SME assembler.

Conformity assessment modules: content of the technical documentation

The conformity assessment modules contained in Annex II to Decision 768/2008/EC require the manufacturer to establish the technical documentation with a list of elements of "minimum content". In order to avoid that authorities impose disproportionate bureaucratic burdens on manufacturers, we ask the Commission to clarify:

1) the term "*wherever applicable*", which leaves too much room for interpretation. This term should mean “as far as relevant for assessment” as formulated in the repealed Modules Decision 93/465, as the purpose of the technical documentation is to allow proper assessment by Notified Bodies and/or market surveillance;
2) that the new explicit requirement for inclusion of an "*adequate analysis and assessment of the risk(s)*" does not require manufacturers to make an additional risk assessment or to draw up additional documentation, if they have applied harmonised standards the development of which is based on a risk assessment. Where the applicable directive (i.e. machinery, medical devices, ATEX, PED) requires an additional risk assessment, this has to be conducted and documented accordingly. Manufacturers may base their assessment on harmonised standards which already include the risk analysis.

Conformity assessment modules: EC declaration of conformity (DoC) model

Concerning the standard model for the EC DoC, it should be clarified that the number mentioned in the first point of Annex 3 to Decision 768/2008/EC corresponds to the filing number of the DoC and **not** to the identification number of the product itself. It might be helpful to also identify the product as required by article R2.5 of the Decision.

3. Specific comments: request for changes in the text of the recast

During the LVD and EMC working party meetings, article 5 of Decision 768/2008 was discussed and industry was invited to give reasons why it should not be implemented as such. Orgalime submitted two requests for significant changes. Nevertheless, our general opinion that the directives should be aligned with the NLF in a consistent way remains unchanged.

Re: Article R34 of Decision 768/2008/EC – Formal non compliance

1. Without prejudice to Article R31, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the conformity marking has been affixed in violation of Article R11 or of Article R12;
(b) the conformity marking has not been affixed;
(c) the EC declaration of conformity has not been drawn up;
(d) the EC declaration of conformity has not been drawn up correctly;
(e) technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market.

This article obliges market surveillance authorities to take specific action in cases of formal non-conformity. In the New Legislative Framework, market surveillance is greatly facilitated thanks to requirements that improve the traceability of a product back to its manufacturer. This is reflected in

Orgalime aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@Orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

the obligations of manufacturers and importers (articles R2.6 and R4.6) to apply their name and address on the product. However, this formal requirement, which will be implemented in the Directives, is not reflected in the list of formal non-conformities.

In order to strengthen the ability of market surveillance authorities to ensure a level playing field, **Orgalime suggests adding a case of formal non-compliance to the list:**

"(e) the name and address of the economic operator has not been affixed."

Article 5, Decision 768/2008/EC – EC declaration of conformity

Where Community harmonisation legislation requires a statement by the manufacturer that fulfilment of the requirements relating to a product has been demonstrated (EC declaration of conformity), the legislation shall provide that a ***single*** *declaration shall be drawn up in respect of all Community acts applicable to the product containing all information required for the identification for Community harmonisation legislation to which the declaration relates, and giving the publication references of the acts concerned.*

This is a requirement that has now been introduced into the draft documents of the aligned EMC and LV directives. During the LVD working party discussions, this issue was addressed by industry with a request to change this requirement. One representative from the market surveillance authorities noted that the meaning of this paragraph is not clear and that the requirement would restrict the possibilities of manufacturers without providing additional benefits for market surveillance. Following this discussion the Commission invited industry to provide a good rationale for changing the original text.

As far as possible, Orgalime prefers to address non-specific issues in a horizontal manner, instead of modifying each individual directive during the alignment exercise. However, as industry has now been given this possibility, we would support a change allowing the possibility to make several declarations of conformity for the 10 directives to be aligned for the following reasons:

- Currently, depending on the product and the internal processes, it is the manufacturer's choice whether to mention all directives and related harmonised standards in one DoC or to have individual DoCs for each directive. Since some products are within the scope of a relatively large number of directives, for example LVD, EMC, EUP and RoHS, mentioning all these directives and the related harmonised standards in a single DoC can result in a relatively complex document which is difficult to read.
- Market surveillance is organised differently in the various Member States. In some countries different authorities are responsible for the market surveillance of different directives whilst in others the same authority is responsible for a number of directives. In the first case a single DoC would provide no added value to the market surveillance authorities as they focus on a single directive and require only information related to the scope of that directive, for example product safety.
- Some Directives (e.g. Machinery Directive and ATEX Directives) require that the DoC accompanies the product. For series products these DoCs are printed in large numbers and packed with each product in stock. If a single DoC has to be issued this could add significant problems for products that are covered by several directives. Given that with a change of harmonised standards the DoC has to be aligned, the requirement would significantly increase the frequency of changes to the DoC and, hence, the documentation accompanying the product. This would imply an additional burden for manufacturers.

For these reasons **Orgalime requests that the requirement for a single DoC in the alignment of the 10 product harmonisation directives with the New Legislative Framework should be removed** and that the present choice of the manufacturer for one or several DoCs should be maintained.

--- ~ + ~ + ~ ---

Adviser in charge: Philippe Portalier (firstname.lastname@orgalime.org)

4. Detailed answers to the online Questionnaire for Economic Operators -

IPM reference number is: 128213519251728410

A. Preliminary questions

Preliminary questions concerning the respondent.

A1. Your details (name, job title, organisation) (compulsory)

Orgalime, the European engineering industries association.
Interest register N° 20210641335-88
Adrian Harris, Director General.

A.2 Contact details (address, e-mail, telephone, fax) (optional)

Diamant Building, Bd Reyers 80, B-1030 Brussels. Contact Email: philippe.portalier@Orgalime.org. Tél.: +32-2-706 82 35. .....

A3. Your country (compulsory)

Orgalime represents the European engineering industry throughout its 22 national trade association members across 33 European countries: .....

A4. Sector for which you answer this consultation (compulsory)

- ☒ **Electrical and electronic**
- ☒ **Lifts Pressure equipment**
- ☒ **Measuring instruments**
- ❑ Civil explosives
- ❑ Pyrotechnic articles
- ☒ **Equipment and protective systems for use in potentially explosive atmospheres**

A5. Primary activity in relation to the sector selected above (compulsory)

- ❑ Business organization representing the interest of several companies in this sector

The primary activity of Orgalime member companies is that of “manufacturer”, according to the definition in Regulation 765/2008/EC. They manufacture products in full or in part within the EU single market. Some are also importers of OEM or even of completed machines and equipment that they have designed but have had manufactured by subcontractors outside the EU.

A6. Size of your organisation (optional)

- ❑ 1 to 9 employees
- ❑ 10 to 49 employees
- ❑ 50 to 249 employees
- ❑ 250 to 1000 employees
- ❑ more than 1000 employees
- ❑ self-employed
- ☒ **not applicable**

B. Addressing the problem of non-compliance with existing product requirements

A significant number of products on the market do not fulfil the requirements set out by the directives. Some actors simply affix the CE marking to their products although these products do not fulfil the conditions for being CE marked. Importers and distributors do not all carry out the necessary verifications to ensure that they are only supplying compliant products. Market surveillance authorities often find it difficult to trace the economic operators supplying non compliant products, in particular when the products originate in third countries. Member States are also imposing different obligations on importers and distributors when it comes to ensuring that products meet the applicable requirements. Furthermore, the actions that national authorities are taking vis-à vis non-compliant products (e.g. prohibitions of marketing, withdrawals, etc) sometimes differ from one Member State to another.

This problem could be addressed by aligning the legislation to the provisions in Decision 768/2008 designed to tackle this problem. For the purpose of this questionnaire these provisions are regrouped under **“Action 1”** and consist of the following measures:

- **Introduction of obligations for importers and distributors:** Both actors must check that products bear the CE marking, are accompanied by the required documents and carry the name of the manufacturer and the importer (if relevant). Importers must furthermore check that the manufacturer outside the EU has applied the correct conformity assessment procedure and establish a link to the manufacturer that allows him to obtain the technical documentation, when it is requested by authorities. They must carry out sample tests on products which they have supplied, when this is appropriate in the light of the risks presented by a product to the health and safety of consumers. If necessary, they must also keep a register of complaints, non- conforming products and product recalls and keep distributors informed about such monitoring (Articles R4 and R5 in Annex 1 of Decision 768/2008).
- **Additional manufacturer obligations:** In addition to the obligations that the current legislation already foresees for manufacturers they must provide instructions and safety information in the language easily understood by consumers and end-users. Furthermore they are subject to the same obligations on sample testing and product monitoring as importers (Article R3 in Annex 1 of Decision 768/2008).
- **Introduction of traceability requirements:** New obligations are introduced for all economic operators to ensure traceability of products throughout the whole distribution chain. Manufacturers and importers must put their name and address on the product or, where this is not possible, on the packaging or an accompanying document. Furthermore every economic operator must be able to inform the authorities from whom he purchased a product and to whom he supplied it. This obligation does not include sales to end-users (Article R7 in Annex 1 of Decision 768/2008).
- **Reorganisation of safeguard clause procedure (market surveillance):** The safeguard clause procedure has been reorganised and streamlined. The new procedure ensures that the relevant enforcement authorities are informed about dangerous products and that equivalent action is taken against that product in all Member States (Articles R31-33 in Annex 1 of Decision 768/2008).

B1. Do you think that this sector is affected by non-compliance? (compulsory)

☒ **Yes**

❍ No

B2.1. Please provide an estimate of the proportion of non-compliant products for the product categories in this sector that you know best. Please specify product category in the open field below and choose your estimation among those indicated in B2.2. (compulsory) (maximum 150 characters)

It is impossible to provide an estimate. Non-compliant engineering products could vary from just a few to 40% of the whole market in some sub sectors.

B2.2. Proportion of non-compliant products for: (compulsory)

☒ **Between 0 and 10%**

❑ Between 11 and 20%

❑ Between 21 and 30%

❑ Between 31 and 50%

❑ Greater than 50%

❑ Unable to provide indicative estimates

B3. Please provide examples of non-compliance experienced by you and any other information available to you on the size of the problem for the product categories you know. (optional) (between 1 and 500 characters)

LVD sector (mostly imported with questionable compliance marks or certificates. Many are counterfeits):

- Installation equipment, multi-meters, cord sets
- Cables, switches, switchgear, household appliances, generator sets
- Lamps, lamp holders, ballasts, luminaires, lighting chains,

ATEX sector: luminaires for which there are no compliance certificates

PED and SPVD: valves for industrial applications and valves and fittings for potable water; water heaters, small cookers.

B4. Competitive disadvantage suffered by economic operators due to competitors non-compliance with product requirements as laid down in legislation

B4.1 Do you think that your business is exposed to unfair competition by non-compliant products ? (compulsory)

☒ **Yes**

B4.2 Do you consider that the competitive disadvantaged suffered by your business is of such importance to affect your sales and/or your market shares? (compulsory)

- ❑ Yes, to a significant extent
- ☒ **Yes, to a moderate extent**
- ❑ No
- ❑ I don't know

B4.3.a) How do you evaluate approximately the drop in sale due to unfair competition for your products? Please specify product category in the open field below and choose your evaluation among those indicated in B4.3.b): (optional) (between 1 and 150 characters)

According to the products and the countries, the impact is variable from a few to 10% of the turnover of one lawful manufacturer.

B4.3.b) Please evaluate: (optional)

- ❑ Between 0 and 5% of the turnover
- ❑ Between 6 and 10% of the turnover
- ❑ Between 11 and 15% of the turnover
- ❑ Between 16 and 20% of the turnover
- ❑ Between 21 and 30% of the turnover
- ❑ Greater than 30% of the turnover
- ☒ **Unable to provide indicative estimates**

B4.4.a) How do you evaluate approximately the drop in market share due to unfair competition for your products? Please specify product category in the open field below and choose your evaluation among those indicated in B4.4.b): (optional) (between 1 and 150 characters)

Depending on products and countries, the drop in market share for engineering products due to unfair competition varies between a few and 20%.

B4.4.b) Please evaluate: (optional)

- ❑ Between 0 and 5% of my market shares over the past 5 years
- ❑ Between 6 and 10% of my market shares over the past 5 years
- ❑ Between 11 and 15% of my market shares over the past 5 years
- ❑ Between 16 and 20% of my market shares over the past 5 years
- ❑ Between 21 and 30% of my market shares over the past 5 years
- ❑ Greater than 30% of my market shares over the past 5 years
- ☒ **Unable to provide indicative estimates**

B6. Please provide, on the basis of your knowledge or understanding, the following information on the product categories you indicated in the previous answers.

B6.1 Origin:

Indicative % of products with origin in a third country (optional)

- ❑ Up to 1/4
- ❑ Between 1/4 and 1/2
- ☒ **Between 1/2 and 3/4**
- ❑ More than 3/4

Indicative % of products with EU origin (optional)

- ☒ **Up to 1/4**
- ❑ Between 1/4 and 1/2
- ❑ Between 1/2 and 3/4
- ❑ More than 3/4

Indicative % of products for which you do not know the origin (optional)

- ☒ **Up to 1/4**
- ❑ Between 1/4 and 1/2
- ❑ Between 1/2 and 3/4
- ❑ More than 3/4

B6.2 Organisation of supply chain:

Indicative % of products supplied to end users directly by manufacturer or its commercial representative (optional)

- ❑ Up to 1/4
- ❑ Between 1/4 and 1/2
- ☒ **Between 1/2 and ¾**
- ❑ More than 3/4

Indicative % of products supplied to end users by other economic operators (e.g. importers, distributors) (optional)

- ❑ Up to 1/4
- ☒ **Between 1/4 and 1/2**
- ❑ Between 1/2 and ¾
- ❑ More than 3/4

Indicative % of products for which you do not know the answer (optional)

- ☒ **Up to 1/4**
- ❑ Between 1/4 and 1/2
- ❑ Between 1/2 and ¾
- ❑ More than 3/4

B7. Do you sell or purchase goods in more than one EU country? (compulsory)

- ☒ **Yes**
- ❍ No

B8. Are you aware of any market surveillance activities carried out in relation to products in this sector?

- ☒ **Yes**
- ❍ No

B9. Do you think that there are differences in the way market surveillance authorities (MSA) in different EU countries deal with non-compliant products in this sector (i.e. this is the case if the same case of non-compliance is likely to be treated more strictly in a country than in another)? (compulsory)

- ❑ Yes, remarkable differences
- ☒ **Yes, some differences**
- ❑ Not many differences
- ❑ No differences
- ❑ I don't know

B10. If so, please explain where the differences are (multiple choice possible) (optional)

- ☒ **MSA in different EU countries do not impose the same obligations on importers**
- ☒ **MSA in different EU countries do not impose the same obligations on distributors**
- ☒ **MSA in different EU countries do not impose the same obligations on manufacturers**
- ☒ **MSA in EU countries follow act differently when they deal with products presenting a risk (i.e. when they verify if products comply with legal requirements and when they address any risk found)**
- ☒ **The same product may be withdrawn from market or otherwise restricted in an EU country and supplied freely in another**
- ☒ **When a safeguard clause procedure is launched, not all EU countries follow Commission opinion**
- ❑ Other

B11. How do you evaluate the impact of the four elements of Action 1 recalled below on the level of compliance, safety of products, functioning of the internal market, defense of competitiveness of EU firms, operational costs/administrative burdens for economic operators for the product categories you know?

B11.1 Impact of the following elements of Action 1 on the level of non-compliance

Obligations for importers/distributors (optional)

- ❑ No, or no significant improvement
- ☒ **Moderate improvement**
- ❑ Significant improvement
- ❑ Unable to evaluate impact

Traceability obligations (optional)

- ❑ No, or no significant improvement
- ☒ **Moderate improvement**
- ❑ Significant improvement
- ❑ Unable to evaluate impact

Post marketing obligations on manufacturers (optional)

- ❑ No, or no significant improvement
- ☒ **Moderate improvement**
- ❑ Significant improvement
- ❑ Unable to evaluate impact

Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU

- ❑ No, or no significant improvement
- ❑ Moderate improvement
- ☒ **Significant improvement**
- ❑ Unable to evaluate impact

B11.2 Impact of the following elements of Action 1 on health and safety conditions for consumers and workers dealing with products in this sector [this question does not apply to the measuring instruments sector]

Obligations for importers/distributors (optional)

- ❑ No, or no significant improvement
- ☒ **Moderate improvement**
- ❑ Significant improvement
- ❑ Unable to evaluate impact

Traceability obligations (optional)

☒ **No, or no significant improvement**
❑ Moderate improvement
❑ Significant improvement
❑ Unable to evaluate impact

Post marketing obligations on manufacturers (optional)

☒ **No, or no significant improvement**
❑ Moderate improvement
❑ Significant improvement
❑ Unable to evaluate impact

Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU (optional)

❑ No, or no significant improvement
❑ Moderate improvement
☒ **Significant improvement**
❑ Unable to evaluate impact

B11.3 Impact of the following elements of Action 1 on well-functioning of the internal market (i.e. creation of a level playing field within the EU where economic operators are subject to the same rules and the same market surveillance procedure regardless of the country they are active on)

Obligations for importers/distributors (optional)

☒ **Moderate improvement**
❑ Significant improvement
❑ No, or no significant improvement
❑ Unable to evaluate impact

Traceability obligations (optional)

❑ No, or no significant improvement
☒ **Moderate improvement**
❑ Significant improvement
❑ Unable to evaluate impact

Post marketing obligations on manufacturers (optional)

☒ **No, or no significant improvement**
❑ Moderate improvement
❑ Significant improvement
❑ Unable to evaluate impact

Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU (optional)

❑ No, or no significant improvement
❑ Moderate improvement
☒ **Significant improvement**
❑ Unable to evaluate impact

B11.4 Impact of the following elements of Action 1 on the defence of the competitiveness of EU compliant firms against unfair competition of non-compliant firms

Obligations for importers/distributors (optional)

❑ No, or no significant improvement
☒ **Moderate improvement**
❑ Significant improvement
❑ Unable to evaluate impact

Traceability obligations (optional)

❑ No, or no significant improvement
☒ **Moderate improvement**
❑ Significant improvement
❑ Unable to evaluate impact

Post marketing obligations on manufacturers (optional)

☒ **No, or no significant improvement**
❑ Moderate improvement
❑ Significant improvement
❑ Unable to evaluate impact

Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU (optional)

❑ No, or no significant improvement
☒ **Moderate improvement**
❑ Significant improvement
❑ Unable to evaluate impact

B11.5 Impact of the following elements of Action 1 on operating costs and/or administrative burdens for economic operators ("administrative burden" designate costs specifically linked to information that businesses would not collect and provide in the absence of a legal obligation)

Obligations for importers/distributors (optional)

❑ Reduction of operating costs and/or administrative burden
❑ No, or no significant increase in operating costs and/or adm. Burden
☒ **Moderate increase in operating costs and/or adm. burden**
❑ Significant increase in operating costs and/or adm. burden
❑ Unable to evaluate impact

Traceability obligations (optional)

❑ Reduction of operating costs and/or administrative burden
❑ No, or no significant increase in operating costs and/or adm. Burden
☒ **Moderate increase in operating costs and/or adm. burden**
❑ Significant increase in operating costs and/or adm. burden
❑ Unable to evaluate impact

Post marketing obligations on manufacturers (optional)

❑ Reduction of operating costs and/or administrative burden
☒ **No, or no significant increase in operating costs and/or adm. Burden**
❑ Moderate increase in operating costs and/or adm. burden
❑ Significant increase in operating costs and/or adm. burden
❑ Unable to evaluate impact

Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU (optional)

❑ Reduction of operating costs and/or administrative burden
❑ No, or no significant increase in operating costs and/or adm. Burden
☒ **Moderate increase in operating costs and/or adm. burden**
❑ Significant increase in operating costs and/or adm. burden
❑ Unable to evaluate impact

B12. If you have any additional comments on the impact of action 1, please indicate them here (optional) (maximum 500 characters)

It may increase costs of testing and physical inspection of electrical and electronic products, especially those operating in explosive atmospheres.
All sectors expect a moderate increase of costs of paperwork (e.g. checks of documentation accompanying the products, filing and storing of information on products).
The costs involved are estimated both as a percentage of current operating costs and in terms of additional time spent (hours/month).

B13. If you answered that one or more of the elements of Action 1 may give rise to a **significant increase in operating costs** and/or administrative burden:

~~B13.1 Please explain why (multiple choices possible): (optional)~~

- ~~It will increase the cost of inputs (raw materials, semi-finished products, components)~~
- ~~It will increase costs of testing and physical inspection of products~~
- ~~It will increase costs of paperwork (e.g. checks of documentation accompanying the products, filing and storing of information on products)~~
- ~~Other (please explain)~~
- ~~Unable to specify~~

~~B13.2 Please provide an indicative estimate of the increase you expect by choosing one of the following options: (optional)~~

- ~~a percentage of current operating costs~~
- ~~in terms additional time spent (hours/month)~~
- ~~unable to provide estimate~~

~~B13.3 Please explain how you regard this increase in operating costs and/or administrative burden in relation to the objective of reducing non-compliance in this sector (optional)~~

- ~~Very reasonable~~
- ~~Quite reasonable~~
- ~~Quite unreasonable~~
- ~~Not reasonable at all~~
- ~~I don't know~~

B14. If you answered that one or more of the elements of Action 1 may result in a **reduction in operating costs** and/or administrative burden:

~~B14.1 Please explain why (multiple choices possible) (optional)~~

- ~~It will reduce the cost of inputs (raw materials, semi-finished products, components)~~
- ~~It will reduce the costs of testing and physical inspection of~~
- ~~It will reduce costs of paperwork (e.g. costs to gather information on reliability of products supplied to me by importers or distributors)~~
- ~~Reduction in costs of insurance to cover the risk due non-compliant products~~
- ~~Other (please specify)~~
- ~~Unable to specify~~

~~B14.2 Please provide an indicative estimate of the reduction you expect by choosing one of the following options: (optional)~~

- ~~percentage of costs~~
- ~~in terms of time saved~~
- ❑ unable to provide estimate

B15. How would you evaluate the following options in terms of their effectiveness to address the problem of non compliance in this sector?

Obligations on economic operators and market surveillance procedures will be included in legal texts (e.g. EU directives) and will be binding on economic operators and market surveillance authorities (optional)

- ❑ Very effective
- ☒ **Quite effective**
- ❑ Quite ineffective
- ❑ Not effective at all
- ❑ I don't know

Obligations on economic operators and market surveillance procedures will be included in informal guidance text (e.g. the Blue Guide on the implementation of New Approach Directives) and will become non-binding reference for economic operators and market surveillance authorities (optional)

❑ Very effective ❑ Quite effective ❑ Not effective at all

☒ **Quite ineffective** ❑ I don't know

C. Addressing problems with the performance of certain Notified Bodies

Eight of the ten directives concerned require the certification of products by "notified bodies" (bodies testing, inspecting and certifying products).

While most notified bodies carry out their tasks in a thorough and responsible manner, there have been some cases raising doubts on the competence of certain bodies and the credibility of certificates issued by them. There are differences in the approach and the level of rigor in the way how Member States evaluate and monitor the competence of notified bodies. Particular concerns exist about the competence of subsidiaries or subcontractors located outside the EU.

This problem could be addressed by aligning the legislation to the provisions in Decision 768/2008 designed to tackle this problem. For the purpose of this questionnaire they are regrouped under "Action 2" and consist of the following measures:

- **Reinforcement of the notification requirements for notified bodies:** To be authorised to carry out conformity assessment activities under the directives, notified bodies must satisfy certain requirements. These requirements have been reinforced and clarified. All notified bodies must follow the work of notified body coordination groups and apply the guidance developed by them. Subcontractors and subsidiaries, who are carrying out parts of the conformity assessment activities must also fulfil the notification criteria(Article R17 and R20 in Annex 1 of Decision 768/2008).
- **Revised notification process:** Member States notifying a body must include information on the evaluation of competence of that body. Other Member States have the possibility to object to the notification within a certain period. Where the competence is demonstrated by an accreditation certificate, a facilitated procedure applies. Where Member States have not used accreditation to evaluate the body's competence, documentary evidence will have to be sent and the objection period is longer (2 months) (Articles R22 and R23 in Annex 1 of Decision 768/2008).
- **Requirements for notifying authorities** (i.e. the national authorities in charge with the assessment, notification and monitoring of notified bodies): Specific requirements and obligations for notifying authorities are introduced (Articles R14, R15 in Annex 1 of Decision 768/2008), according to which they should be organised and operated in such a way to safeguard objectivity, impartiality and competence in carrying out their activity.
- **Information obligations**: Notified bodies must inform notifying authorities on refusals, restrictions, suspensions and withdrawals of certificates and other notified bodies on negative conformity assessment results (Article R28 in Annex 1 of Decision 768/2008).

C16. Do you make use of services provided by Notified Bodies? (compulsory)

☒ **Yes** ❍ No

C17. Are you aware of problems with the quality of services provided by Notified Bodies (NB) in this sector? (compulsory)

☒ **Yes**

❍ No

❍ I don't know

C18. If so, please explain what the problem is (multiple choice possible) (optional)

☒ **Lack of competence of NB**

☒ **Mistakes in assessment carried out by NB**

❑ Professional secrecy not respected

❑ NB did not apply generally agreed guidelines by notified bodies groups

❑ NB had conflict of interest

❑ Lower quality of service performed by subcontractor or subsidiary of NB

☒ **Other (please specify) - bureaucratic problems**

C19. Do you think that your business is exposed to the unfair competition of products whose conformity to legal requirements has not been assessed correctly by Notified Bodies? (compulsory)

❑ Yes, to a significant extent ❑ No

☒ **Yes, to a moderate extent** ❑ I don't know

C21. Do you think that there are differences in the way notifying authorities (NA) in different EU countries apply, verify and monitor the requirements for Notified Bodies (NB)? (compulsory)

- ❑ Yes, remarkable differences
- ☒ **Yes, some differences**
- ❑ Not many differences
- ❑ No differences
- ❑ I don't know

C22. If so, please explain where the differences are (multiple choice possible) (optional)

- ☒ **NA in different EU countries do not impose the same requirements on NB**
- ☒ **NA in different EU countries do not have the same capacity (resources and/or skills) to verify that NB requirements are fulfilled before notification**
- ☒ **NA in different EU countries do not put the same efforts in monitoring performance of NB after notification**
- ❑ Other (please specify)

C23. Do Notified Bodies carrying out conformity assessment for products in this sector subcontract any of the relevant conformity assessment activities to other bodies or subsidiaries located in another country? (compulsory)

- ☒ **Yes, sometimes**
- ❑ Yes, often
- ❑ No
- ❑ I don't know

C24. If the answer to the previous question is positive, please specify the location of subcontractors or subsidiaries (optional)

- ❑ Mainly in another EU country
- ❑ Mainly outside the EU
- ❑ Both in another EU country and outside the EU in approximately same proportion
- ☒ **Unable to specify location**

C25. How do you evaluate the impacts of the three elements of Action 2 recalled below on the performance of Notified Bodies, safety of products, functioning of the internal market and defence of competitiveness of EU firms in this sector?

C25.1 Impact on the level of quality of services provided by Notified Bodies

Reinforcement of notification requirements for NB (optional)

- ❑ No, or no significant improvement
- ❑ Moderate improvement
- ☒ **Significant improvement**
- ❑ Unable to evaluate impact

Revised procedures for notification (optional)

- ❑ No, or no significant improvement
- ☒ **Moderate improvement**
- ❑ Significant improvement
- ❑ Unable to evaluate impact

Information obligations on NB (optional)

- ❑ No, or no significant improvement
- ☒ **Moderate improvement**
- ❑ Significant improvement
- ❑ Unable to evaluate impact

C26. If you have any additional comments on the impact of action 2, please indicate them here (optional) (maximum 200 characters)

We have insufficient experience of the enforcement of NLF on NB to judge the efficiency of the new legislation but we are not very positive as the rules given to the NB have not really changed.

C32. How would you evaluate the following options in terms of their effectiveness to ensure the quality of services provided by Notified Bodies in this sector?

The stricter requirements for Notified Bodies and notification procedures will be included in legal texts (e.g. EU directives) and will be binding on notified bodies and notifying authorities (optional)

☒ **Very effective**
❑ Quite effective
❑ Quite ineffective
❑ Not effective at all
❑ I don't know

The stricter requirements for Notified Bodies and notification procedures will be included in informal guidance text (e.g. the Blue Guide on the implementation of New Approach Directives) and will become non-binding reference for notified bodies and notifying authorities (optional)

❑ Very effective
❑ Quite effective
☒ **Quite ineffective**
❑ Not effective at all
❑ I don't know

D. Addressing inconsistencies on specific issues in current legislation

The directives in question often follow a risk based approach and sometimes several directives apply simultaneously to one product.

For example, a considerable number of measuring instruments also have to comply with the Electromagnetic Compatibility Directive. Certain pyrotechnic articles also come under the Low Voltage Directive or the Electromagnetic Compatibility Directive. Another example concerns lifts which also have to comply with requirements set out in the Machinery Directive. For the manufacturer this means that he has to apply all the requirements to the product.

This can prove difficult because the directives do not always use the same terminology. Generally used terms like "manufacturer" or "placing on the market" are defined differently in the directives; sometimes they are not defined at all and leave room for diverging interpretations. Apart from that the simultaneous applicability of several directives to one single product can lead to difficulties in the conformity assessment procedure ("module"), in particular when directives use the same module, but the text of the module differs from one directive to the other.

This problem could be addressed by aligning the definitions and the texts of the modules to those set out in Decision 768/2008. For the purpose of this questionnaire these measures are regrouped under **"Action 3"**:

- **Introduction of harmonised definitions:** The definitions of common terms like "manufacturer", "importer", "placing on the market" set out in Article R2 of Decision 768/2008 are introduced into the directives concerned. Existing conflicting definitions are removed.
- **Alignment of modules:** The existing text of the modules in the directives is aligned to the standard modules set out in Annex II of Decision 768/2008.

D33. Simultaneous applicability of several directives

D33.1. Do you have to apply more than one of the ten directives concerned by this consultation simultaneously to your products? (compulsory)

☒ **Yes**
❍ NO

D33.2. Please indicate which ones (compulsory)

☒ **Low Voltage Directive: Directive** 2006/95/EEC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits

☒ **Simple Pressure Vessels Directive**: Council Directive 2009/105/EC on the harmonisation of the laws of the Member States relating to simple pressure vessels

☒ **Non-automatic Weighing Instruments Directive**: Council Directive 90/384/EEC on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments

❑ **Civil Explosives Directive**: Council Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil use

☒ **ATEX Directive**: Directive 94/9/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres

☒ **Lifts Directive** European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts

☒ **Pressure Equipment Directive**: Directive 97/23/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning pressure equipment

☒ **Measuring Instruments Directive**: Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments

☒ **Electromagnetic Compatibility Directive**: Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC

❑ **Pyrotechnic articles Directive** 2007/23/EC on the placing on the market of pyrotechnic articles Other product harmonisation directive (please specify)

D33.3 Do you have to apply different conformity assessment procedures to one and the same product due to the simultaneous applicability of directives? (compulsory)

☒ **Yes** ❍ No ❍ I don't know

D33.4. Does the simultaneous applicability of directives lead economic operators to bear additional costs or administrative burden in relation to conformity assessment procedures? (compulsory)

❑ Yes, significant costs/burden

☒ **Yes, some extra costs/burden**

❑ No extra costs/burden

❑ I do not know

D33.5. If you answered that the simultaneous applicability of directives lead to additional costs or administrative burden, please explain why and, if possible, quantify the additional costs by choosing one of the following options: (optional)
Please explain why a percentage of current operating costs in terms of additional time spent (hours/month) Unable to provide estimate
Between 0.5% and 3.5%.....

D34. If you are applying simultaneously two or more of the ten directives concerned by this consultation, which impacts do you expect from aligning the texts of the conformity assessment procedures to the texts of the corresponding conformity assessment procedures set out in Annex II of Decision 768/2008? (multiple choices possible) (compulsory)

❑ No changes or no significant changes

❑ It will create difficulties as the corresponding version of the relevant conformity assessment procedures set out in the Decision are not adequate for my sector

☒ **It will lead to more coherence with other legislation**

❑ It will certainly reduce costs

❑ It will probably reduce costs

❑ It will probably increase costs

❑ It will certainly increase costs

❑ It will give rise to interpretation difficulties and differences in the application by notified bodies throughout the EU

☒ **It will lead to more coherent conformity assessment carried out by Notified Bodies throughout sectors**

❑ Others (please specify)

~~D35. If you answered that aligning the conformity assessment procedures may result in a significant increase in operating costs and/or administrative burden, (optional)~~

~~Please explain why Provide an estimate of the increase you expect Unable to provide estimate~~

~~D36. If you answered that aligning the conformity assessment procedures may result in a reduction in operating costs and/or administrative burden, (optional)~~

~~Please explain why Provide an estimate of the reduction you expect Unable to provide estimate~~

D37. Since you are applying simultaneously two or more of the ten directives concerned by this consultation, have you experienced different interpretations of generally used notions like “placing on the market”, “manufacturer”, "importer", "distributor", etc.? (compulsory)

☒ **Yes** ❍ No ❍ I don't know

D38. Which effects do you expect from clarifying and harmonising generally used notions like “placing on the market”, “manufacturer”, "importer", "distributor", etc.? (multiple choices possible) (compulsory)

❑ No or no significant changes

☒ **It will make the relevant directives clearer**

☒ **It will avoid different interpretations by national authorities**

❑ It will lead to difficulties as existing definitions in the directive(s) by which I am concerned will be changed

☒ **It makes the whole legal framework clearer**

❑ It makes the whole legal framework more confusing

❑ It will lead to more consistent terminology throughout EU harmonisation legislation on products.

☒ **Others, please specify**

(However there are some differences for the definitions and their consequences with directives or regulations applying to products under one of several of the ten New Approach directives on the one hand and all directives dealing with the environment on the other hand!)

D39. How would you evaluate the following options in terms of their effectiveness to address the problem of inconsistencies in legislation currently applicable to this sector?

Adjustment to definitions and conformity assessment modules will be included in legal texts (e.g. EU directives) and will be binding on economic operators and market surveillance authorities (compulsory)

☒ **Very effective**

❑ Quite effective

❑ Quite ineffective

❑ Not effective at all

❑ I don't know

Adjustment to definitions and conformity assessment modules will be included in informal guidance text (e.g. the Blue Guide on the implementation of New Approach Directives) and will become non-binding reference for economic operators and market surveillance authorities (compulsory)

❑ Very effective

❑ Quite effective

☒ **Quite ineffective**

❑ Not effective at all

❑ I don't know

Your response has been successfully submitted. The IPM reference number is: 128213519251728410