

# Response statistics for 'New Legislative Framework for the marketing of products: proposal to align 10 product harmonisation directives to Decision 768/2008.'

▶ Current search:

## Query definition

All data requested

## Result pages

▶ There are 76 responses matching your criteria of a total of 76 records in the current set of data.

▶ Expand all - Collapse all


Sorted answers  Original order

## A. Preliminary questions

Preliminary questions concerning the respondent.

A3. Your country -single choice reply- (compulsory)

	Number of requested records	Requested records (76)	% of total number records (76)
Austria	3	(3.9%)	(3.9%)
Belgium	5	(6.6%)	(6.6%)
Bulgaria	0	(0%)	(0%)
Cyprus	0	(0%)	(0%)
Czech Republic	3	(3.9%)	(3.9%)
Denmark	5	(6.6%)	(6.6%)
Estonia	1	(1.3%)	(1.3%)
Finland	1	(1.3%)	(1.3%)
France	7	(9.2%)	(9.2%)
Germany	11	(14.5%)	(14.5%)
Greece	0	(0%)	(0%)
Hungary	1	(1.3%)	(1.3%)
Ireland	0	(0%)	(0%)
Italy	4	(5.3%)	(5.3%)
Latvia	0	(0%)	(0%)
Lithuania	1	(1.3%)	(1.3%)
Luxembourg	0	(0%)	(0%)
Malta	0	(0%)	(0%)
Netherlands	3	(3.9%)	(3.9%)
Poland	4	(5.3%)	(5.3%)
Portugal	0	(0%)	(0%)

Romania	5	(6.6%)	(6.6%)
Slovakia	1	(1.3%)	(1.3%)
Slovenia	0	(0%)	(0%)
Spain	1	(1.3%)	(1.3%)
Sweden	4	(5.3%)	(5.3%)
United Kingdom	8	(10.5%)	(10.5%)
EEA country	2	(2.6%)	(2.6%)
USA	0	(0%)	(0%)
Canada	0	(0%)	(0%)
China	0	(0%)	(0%)
India	0	(0%)	(0%)
 Other (please specify)	6	(7.9%)	(7.9%)

#### A4. Sector for which you answer this consultation -single choice reply- (compulsory)

	Number of requested records	Requested records (76)	% of total number records (76)
Electrical and electronic products	16	(21.1%)	(21.1%)
Lifts	9	(11.8%)	(11.8%)
Pressure equipment	23	(30.3%)	(30.3%)
Measuring instruments	13	(17.1%)	(17.1%)
Civil explosives	4	(5.3%)	(5.3%)
Pyrotechnic articles	2	(2.6%)	(2.6%)
Equipment and protective systems for use in potentially explosive atmospheres	9	(11.8%)	(11.8%)

## 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? -single choice reply- (compulsory)**

	Number of requested records	Requested records (76)	% of total number records (76)
Yes	44	(57.9%)	(57.9%)
No	16	(21.1%)	(21.1%)
I don't know	16	(21.1%)	(21.1%)


**B2.1. Proportion of non-compliant products for: -single choice reply- (compulsory)**

These figures relate to specific product categories identified separately by each respondent under previous questions


	Number of requested records	Requested records (44)	% of total number records (76)	% of total number records (44)
Between 0 and 10%	10	(22.7%)	(13.2%)	(22.7%)
Between 11 and 20%	10	(22.7%)	(13.2%)	(22.7%)
Between 21 and 30%	6	(13.6%)	(7.9%)	(13.6%)
Between 31 and 50%	11	(25%)	(14.5%)	(25%)
Greater than 50%	2	(4.5%)	(2.6%)	(4.5%)
Unable to provide indicative estimates	5	(11.4%)	(6.6%)	(11.4%)
N/A	32	(42.1%)	(42.1%)	-


**B8. Are you aware of any market surveillance activities carried out in relation to products in this sector? -single choice reply- (compulsory)**

	Number of requested records	Requested records (76)	% of total number records (76)
Yes	49	(64.5%)	(64.5%)
No	27	(35.5%)	(35.5%)

 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)? - single choice reply- (optional)

	Number of requested records	Requested records (49)	% of total number records (76)	% of total number records (46)
Yes, remarkable differences	11	(22.4%)	(14.5%)	(23.9%)
Yes, some differences	20	(40.8%)	(26.3%)	(43.5%)
Not many differences	5	(10.2%)	(6.6%)	(10.9%)
No differences	0	(0%)	(0%)	(0%)
I don't know	10	(20.4%)	(13.2%)	(21.7%)
N/A	30	(39.5%)	(39.5%)	-

 B.10 If so, please explain where the differences are (multiple choices possible): -multiple choices reply- (optional)

	Number of requested records	Requested records (49)	% of total number records (76)
MSA in different EU countries do not impose the same obligations on importers	27	(55.1%)	(35.5%)
MSA in different EU countries do not impose the same obligations on distributors	23	(46.9%)	(30.3%)
MSA in different EU countries do not impose the same obligations on manufacturers	19	(38.8%)	(25%)
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)	18	(36.7%)	(23.7%)
The same product may be withdrawn from market or otherwise restricted in an EU country and supplied freely in another	19	(38.8%)	(25%)
When a safeguard clause procedure is launched, not all EU countries follow Commission opinion	9	(18.4%)	(11.8%)
 Other (please specify)	2	(4.1%)	(2.6%)

## B11. How do you evaluate the impact of the four elements of Action 1 recalled below on the level of compliance, safety of products and functioning of the internal market 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 -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (73)
No, or no significant improvement	10	(13.2%)	(13.2%)	(13.7%)
Moderate improvement	25	(32.9%)	(32.9%)	(34.2%)
Significant improvement	34	(44.7%)	(44.7%)	(46.6%)
Unable to evaluate impact	4	(5.3%)	(5.3%)	(5.5%)
N/A	3	(3.9%)	(3.9%)	-

Traceability obligations -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (73)
No, or no significant improvement	6	(7.9%)	(7.9%)	(8.2%)
Moderate improvement	32	(42.1%)	(42.1%)	(43.8%)
Significant improvement	31	(40.8%)	(40.8%)	(42.5%)
Unable to evaluate impact	4	(5.3%)	(5.3%)	(5.5%)
N/A	3	(3.9%)	(3.9%)	-

#### Post marketing obligations on manufacturers -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (73)
No, or no significant improvement	16	(21.1%)	(21.1%)	(21.9%)
Moderate improvement	21	(27.6%)	(27.6%)	(28.8%)
Significant improvement	29	(38.2%)	(38.2%)	(39.7%)
Unable to evaluate impact	7	(9.2%)	(9.2%)	(9.6%)
N/A	3	(3.9%)	(3.9%)	-

#### Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
No, or no significant improvement	5	(6.6%)	(6.6%)	(6.9%)
Moderate improvement	23	(30.3%)	(30.3%)	(31.9%)
Significant improvement	36	(47.4%)	(47.4%)	(50%)
Unable to evaluate impact	8	(10.5%)	(10.5%)	(11.1%)
N/A	4	(5.3%)	(5.3%)	-

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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 -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (64)
No, or no significant improvement	8	(10.5%)	(10.5%)	(12.5%)
Moderate improvement	23	(30.3%)	(30.3%)	(35.9%)
Significant improvement	27	(35.5%)	(35.5%)	(42.2%)
Unable to evaluate impact	6	(7.9%)	(7.9%)	(9.4%)
N/A	12	(15.8%)	(15.8%)	-

#### Traceability obligations -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (64)
No, or no significant improvement	6	(7.9%)	(7.9%)	(9.4%)

Moderate improvement	27	(35.5%)	(35.5%)	(42.2%)
Significant improvement	25	(32.9%)	(32.9%)	(39.1%)
Unable to evaluate impact	6	(7.9%)	(7.9%)	(9.4%)
N/A	12	(15.8%)	(15.8%)	-

#### Post marketing obligations on manufacturers -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (63)
No, or no significant improvement	10	(13.2%)	(13.2%)	(15.9%)
Moderate improvement	22	(28.9%)	(28.9%)	(34.9%)
Significant improvement	25	(32.9%)	(32.9%)	(39.7%)
Unable to evaluate impact	6	(7.9%)	(7.9%)	(9.5%)
N/A	13	(17.1%)	(17.1%)	-

#### Common safeguard (market surveillance) procedures to deal with products presenting a risk across the EU -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (64)
No, or no significant improvement	2	(2.6%)	(2.6%)	(3.1%)
Moderate improvement	22	(28.9%)	(28.9%)	(34.4%)
Significant improvement	31	(40.8%)	(40.8%)	(48.4%)
Unable to evaluate impact	9	(11.8%)	(11.8%)	(14.1%)
N/A	12	(15.8%)	(15.8%)	-

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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 -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (70)
No, or no significant improvement	5	(6.6%)	(6.6%)	(7.1%)
Moderate improvement	24	(31.6%)	(31.6%)	(34.3%)
Significant improvement	34	(44.7%)	(44.7%)	(48.6%)
Unable to evaluate impact	7	(9.2%)	(9.2%)	(10%)
N/A	6	(7.9%)	(7.9%)	-

#### Traceability obligations -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (70)
No, or no significant improvement	3	(3.9%)	(3.9%)	(4.3%)
Moderate improvement	28	(36.8%)	(36.8%)	(40%)
Significant improvement	31	(40.8%)	(40.8%)	(44.3%)
Unable to evaluate impact	8	(10.5%)	(10.5%)	(11.4%)

N/A	6	(7.9%)	(7.9%)	-
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Post marketing obligations on manufacturers -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (70)
No, or no significant improvement	7	(9.2%)	(9.2%)	(10%)
Moderate improvement	30	(39.5%)	(39.5%)	(42.9%)
Significant improvement	24	(31.6%)	(31.6%)	(34.3%)
Unable to evaluate impact	9	(11.8%)	(11.8%)	(12.9%)
N/A	6	(7.9%)	(7.9%)	-

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

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (69)
No, or no significant improvement	2	(2.6%)	(2.6%)	(2.9%)
Moderate improvement	22	(28.9%)	(28.9%)	(31.9%)
Significant improvement	35	(46.1%)	(46.1%)	(50.7%)
Unable to evaluate impact	10	(13.2%)	(13.2%)	(14.5%)
N/A	7	(9.2%)	(9.2%)	-

## 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 -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (74)
Very effective	17	(22.4%)	(22.4%)	(23%)
Quite effective	52	(68.4%)	(68.4%)	(70.3%)
Quite ineffective	1	(1.3%)	(1.3%)	(1.4%)
Not effective at all	1	(1.3%)	(1.3%)	(1.4%)
I don't know	3	(3.9%)	(3.9%)	(4.1%)
N/A	2	(2.6%)	(2.6%)	-

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 -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (74)
Very effective	4	(5.3%)	(5.3%)	(5.4%)
Quite effective	8	(10.5%)	(10.5%)	(10.8%)
Quite ineffective	32	(42.1%)	(42.1%)	(43.2%)

Not effective at all	26	(34.2%)	(34.2%)	(35.1%)
I don't know	4	(5.3%)	(5.3%)	(5.4%)
N/A	2	(2.6%)	(2.6%)	-

## 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).

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

	Number of requested records	Requested records (76)	% of total number records (76)
Yes	52	(68.4%)	(68.4%)
No	18	(23.7%)	(23.7%)
I don't know	6	(7.9%)	(7.9%)

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

	Number of requested records	Requested records (76)	% of total number records (76)
Lack of competence of NB	28	(36.8%)	(36.8%)
Mistakes in assessment carried out by NB	29	(38.2%)	(38.2%)
Professional secrecy not respected	2	(2.6%)	(2.6%)
NB did not apply generally agreed guidelines by notified bodies groups	33	(43.4%)	(43.4%)
NB had conflict of interest	12	(15.8%)	(15.8%)
Lower quality of service performed by subcontractor or subsidiary of NB	16	(21.1%)	(21.1%)
 Other (please specify)	9	(11.8%)	(11.8%)


C20. Do you think that your business is exposed to the unfair competition of other Notified Bodies who do not assess correctly conformity of products to legal requirements? -single choice reply- (compulsory)

	Number of requested records	Requested records (76)	% of total number records (76)
Yes, to a significant extent	13	(17.1%)	(17.1%)
Yes, to a moderate extent	36	(47.4%)	(47.4%)
No	15	(19.7%)	(19.7%)
I don't know	12	(15.8%)	(15.8%)

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)? -single choice reply- (compulsory)

	Number of requested records	Requested records (76)	% of total number records (76)
Yes, remarkable differences	26	(34.2%)	(34.2%)
Yes, some differences	27	(35.5%)	(35.5%)
Not many differences	8	(10.5%)	(10.5%)
No differences	0	(0%)	(0%)
I don't know	15	(19.7%)	(19.7%)

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

	Number of requested records	Requested records (76)	% of total number records (76)
NA in different EU countries do not impose the same requirements on NB	44	(57.9%)	(57.9%)
NA in different EU countries do not have the same capacity (resources and/or skills) to verify that NB requirements are fulfilled before notification	35	(46.1%)	(46.1%)
NA in different EU countries do not put the same efforts in monitoring performance of NB after notification	48	(63.2%)	(63.2%)
 Other (please specify)	5	(6.6%)	(6.6%)

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? -single choice reply- (compulsory)

	Number of requested records	Requested records (76)	% of total number records (76)
Yes, sometimes	34	(44.7%)	(44.7%)
Yes, often	8	(10.5%)	(10.5%)
No	7	(9.2%)	(9.2%)
I don't know	27	(35.5%)	(35.5%)

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

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (43)
Mainly in another EU country	17	(22.4%)	(22.4%)	(39.5%)
Mainly outside the EU	4	(5.3%)	(5.3%)	(9.3%)
Both in another EU country and outside the EU in approximately same proportion	19	(25%)	(25%)	(44.2%)
Unable to specify location	3	(3.9%)	(3.9%)	(7%)
N/A	33	(43.4%)	(43.4%)	-

## 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 operational costs/administrative burdens for Notified Bodies?

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

Reinforcement of notification requirements for NB -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
No or no significant improvement	7	(9.2%)	(9.2%)	(9.7%)
Moderate improvement	36	(47.4%)	(47.4%)	(50%)
Significant improvement	28	(36.8%)	(36.8%)	(38.9%)
Unable to evaluate impact	1	(1.3%)	(1.3%)	(1.4%)
N/A	4	(5.3%)	(5.3%)	-

Revised procedures for notification -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
No or no significant improvement	11	(14.5%)	(14.5%)	(15.3%)
Moderate improvement	34	(44.7%)	(44.7%)	(47.2%)
Significant improvement	24	(31.6%)	(31.6%)	(33.3%)
Unable to evaluate impact	3	(3.9%)	(3.9%)	(4.2%)
N/A	4	(5.3%)	(5.3%)	-

Information obligations on NB -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
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No or no significant improvement	24	(31.6%)	(31.6%)	(33.3%)
Moderate improvement	36	(47.4%)	(47.4%)	(50%)
Significant improvement	10	(13.2%)	(13.2%)	(13.9%)
Unable to evaluate impact	2	(2.6%)	(2.6%)	(2.8%)
N/A	4	(5.3%)	(5.3%)	-

C25.2 Impact of the following elements of Action 2 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]

Reinforcement of notification requirements for NB -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (66)
No or no significant improvement	9	(11.8%)	(11.8%)	(13.6%)
Moderate improvement	35	(46.1%)	(46.1%)	(53%)
Significant improvement	18	(23.7%)	(23.7%)	(27.3%)
Unable to evaluate impact	4	(5.3%)	(5.3%)	(6.1%)
N/A	10	(13.2%)	(13.2%)	-

Revised procedures for notification -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (66)
No or no significant improvement	13	(17.1%)	(17.1%)	(19.7%)
Moderate improvement	30	(39.5%)	(39.5%)	(45.5%)
Significant improvement	17	(22.4%)	(22.4%)	(25.8%)
Unable to evaluate impact	6	(7.9%)	(7.9%)	(9.1%)
N/A	10	(13.2%)	(13.2%)	-

Information obligations on NB -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (66)
No or no significant improvement	15	(19.7%)	(19.7%)	(22.7%)
Moderate improvement	32	(42.1%)	(42.1%)	(48.5%)
Significant improvement	15	(19.7%)	(19.7%)	(22.7%)
Unable to evaluate impact	4	(5.3%)	(5.3%)	(6.1%)
N/A	10	(13.2%)	(13.2%)	-

C25.3 Impact of the following elements of Action 2 on well-functioning of the internal market (i.e. creation of a level playing field within the EU where economic operators are subject to conformity assessment carried out according to the same level of quality regardless of the country in which they are active and of the specific Notified Bodies providing the service)

Reinforcement of notification requirements for NB -single choice reply- (optional)

Number of Requested % of total % of total

	requested records	records (76)	number records (76)	number records (72)
No or no significant improvement	9	(11.8%)	(11.8%)	(12.5%)
Moderate improvement	34	(44.7%)	(44.7%)	(47.2%)
Significant improvement	25	(32.9%)	(32.9%)	(34.7%)
Unable to evaluate impact	4	(5.3%)	(5.3%)	(5.6%)
N/A	4	(5.3%)	(5.3%)	-

#### Revised procedures for notification -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
No or no significant improvement	12	(15.8%)	(15.8%)	(16.7%)
Moderate improvement	32	(42.1%)	(42.1%)	(44.4%)
Significant improvement	21	(27.6%)	(27.6%)	(29.2%)
Unable to evaluate impact	7	(9.2%)	(9.2%)	(9.7%)
N/A	4	(5.3%)	(5.3%)	-

#### Information obligations on NB -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
No or no significant improvement	17	(22.4%)	(22.4%)	(23.6%)
Moderate improvement	33	(43.4%)	(43.4%)	(45.8%)
Significant improvement	17	(22.4%)	(22.4%)	(23.6%)
Unable to evaluate impact	5	(6.6%)	(6.6%)	(6.9%)
N/A	4	(5.3%)	(5.3%)	-

C25.5 Impact of the following elements of Action 2 on operating costs and/or administrative burdens for Notified Bodies ("Administrative burden" designate costs specifically linked to information that businesses would not collect and provide in the absence of a legal obligation)

#### Reinforcement of notification requirements for NB -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
Reduction of operating costs and/or administrative burden	3	(3.9%)	(3.9%)	(4.2%)
No or no significant increase in operating costs and/or adm. burden	23	(30.3%)	(30.3%)	(31.9%)
Moderate increase in operating costs and/or adm. burden	28	(36.8%)	(36.8%)	(38.9%)
Significant increase in operating costs and/or adm. burden	18	(23.7%)	(23.7%)	(25%)
N/A	4	(5.3%)	(5.3%)	-

#### Revised procedures for notification -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
Reduction of operating costs and/or	1	(1.3%)	(1.3%)	(1.4%)


administrative burden				
No or no significant increase in operating costs and/or adm. burden	31	(40.8%)	(40.8%)	(43.1%)
Moderate increase in operating costs and/or adm. burden	24	(31.6%)	(31.6%)	(33.3%)
Significant increase in operating costs and/or adm. burden	16	(21.1%)	(21.1%)	(22.2%)
N/A	4	(5.3%)	(5.3%)	-

#### Information obligations on NB -single choice reply- (optional)



	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (72)
Reduction of operating costs and/or administrative burden	3	(3.9%)	(3.9%)	(4.2%)
No or no significant increase in operating costs and/or adm. burden	32	(42.1%)	(42.1%)	(44.4%)
Moderate increase in operating costs and/or adm. burden	26	(34.2%)	(34.2%)	(36.1%)
Significant increase in operating costs and/or adm. burden	11	(14.5%)	(14.5%)	(15.3%)
N/A	4	(5.3%)	(5.3%)	-

C27. If you answered that Action 2 may result in a significant increase in operating costs and/or administrative burden, please provide the following information:

#### C27.1 Source of costs/administrative burden -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (33)
Accreditation (only for NB not already accredited)	23	(30.3%)	(30.3%)	(69.7%)
 Other (please specify)	10	(13.2%)	(13.2%)	(30.3%)
N/A	43	(56.6%)	(56.6%)	-

C27.2 Please provide an indicative estimate of the increase you expect by choosing one of the following options: -multiple choices reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (51)
 a percentage of current operating costs	16	(21.1%)	(21.1%)	(31.4%)
 additional time spent (hours/month)	15	(19.7%)	(19.7%)	(29.4%)
unable to provide estimate	20	(26.3%)	(26.3%)	(39.2%)
N/A	25	(32.9%)	(32.9%)	-

C27.3 Please explain how you regard this increase in operating costs and/or administrative burden in relation to the objective of ensuring the quality of services provided by notified bodies in this sector -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (48)
Very reasonable	3	(3.9%)	(3.9%)	(6.2%)
Quite reasonable	25	(32.9%)	(32.9%)	(52.1%)
Quite unreasonable	8	(10.5%)	(10.5%)	(16.7%)

Not reasonable at all	3	(3.9%)	(3.9%)	(6.2%)
I don't know	9	(11.8%)	(11.8%)	(18.8%)
N/A	28	(36.8%)	(36.8%)	-

C28. If you answered that Action 2 may result in a reduction in operating costs and/or administrative burden, please provide an indicative estimate of the reduction you expect by choosing one of the following options: -multiple choices reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (15)
📁 a percentage of current operating costs	4	(5.3%)	(5.3%)	(26.7%)
📁 time saved (hours/month)	2	(2.6%)	(2.6%)	(13.3%)
unable to provide estimate	9	(11.8%)	(11.8%)	(60%)
N/A	61	(80.3%)	(80.3%)	-

### 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 -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (73)
Very effective	19	(25%)	(25%)	(26%)
Quite effective	50	(65.8%)	(65.8%)	(68.5%)
Quite ineffective	4	(5.3%)	(5.3%)	(5.5%)
Not effective at all	0	(0%)	(0%)	(0%)
I don't know	0	(0%)	(0%)	(0%)
N/A	3	(3.9%)	(3.9%)	-

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 -single choice reply- (optional)

	Number of requested records	Requested records (76)	% of total number records (76)	% of total number records (74)
Very effective	3	(3.9%)	(3.9%)	(4.1%)
Quite effective	13	(17.1%)	(17.1%)	(17.6%)
Quite ineffective	36	(47.4%)	(47.4%)	(48.6%)
Not effective at all	21	(27.6%)	(27.6%)	(28.4%)
I don't know	1	(1.3%)	(1.3%)	(1.4%)
N/A	2	(2.6%)	(2.6%)	-

## 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.


D33.1. Are you notified for more than one of the ten directives concerned by this consultation? - single choice reply- (compulsory)

	Number of requested records	Requested records (76)	% of total number records (76)
 Yes	52	(68.4%)	(68.4%)
No	24	(31.6%)	(31.6%)


 D33.2. Please indicate which ones -multiple choices reply- (compulsory)

	Number of requested records	Requested records (52)	% of total number records (76)
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	23	(44.2%)	(30.3%)
Simple Pressure Vessels Directive: Council Directive 2009/105/EC on the harmonisation of the laws of the Member States relating to simple pressure vessels	18	(34.6%)	(23.7%)
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	12	(23.1%)	(15.8%)
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	9	(17.3%)	(11.8%)
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	25	(48.1%)	(32.9%)


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	23	(44.2%)	(30.3%)
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	25	(48.1%)	(32.9%)
Measuring Instruments Directive: Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments	15	(28.8%)	(19.7%)
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	22	(42.3%)	(28.9%)
Pyrotechnic articles Directive 2007/23/EC on the placing on the market of pyrotechnic articles	6	(11.5%)	(7.9%)
 Other product harmonisation directive (please specify)	23	(44.2%)	(30.3%)




 D33.3. Are you aware of cases where you or other NB had to apply different conformity assessment procedures to one and the same product due to the simultaneous applicability of directives? -single choice reply- (compulsory)


	Number of requested records	Requested records (52)	% of total number records (76)	% of total number records (52)
Yes	24	(46.2%)	(31.6%)	(46.2%)
No	12	(23.1%)	(15.8%)	(23.1%)
I don't know	16	(30.8%)	(21.1%)	(30.8%)
N/A	24	(31.6%)	(31.6%)	-


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


	Number of requested records	Requested records (52)	% of total number records (76)	% of total number records (46)
Yes, significant costs/burden	6	(11.5%)	(7.9%)	(13%)
Yes, some extra costs/burden	22	(42.3%)	(28.9%)	(47.8%)
No extra costs/burden	9	(17.3%)	(11.8%)	(19.6%)
I do not know	9	(17.3%)	(11.8%)	(19.6%)
N/A	30	(39.5%)	(39.5%)	-



 D33.5. If you answered that the simultaneous applicability may give rise to additional costs and/or administrative burden, please explain why and, if possible, quantify the additional costs by choosing one of the following options: -multiple choices reply- (optional)


	Number of requested records	Requested records (52)	% of total number records (76)	% of total number records (24)
 Please explain why	4	(7.7%)	(5.3%)	(16.7%)
 A percentage of current operating costs	1	(1.9%)	(1.3%)	(4.2%)
 In terms of additional time spent (hours/month)	3	(5.8%)	(3.9%)	(12.5%)
Unable to provide estimate	16	(30.8%)	(21.1%)	(66.7%)
N/A	52	(68.4%)	(68.4%)	-



 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) -multiple choices reply- (optional)


	Number of requested records	Requested records (52)	% of total number records (76)
No changes or no significant changes	7	(13.5%)	(9.2%)
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	4	(7.7%)	(5.3%)
It will lead to more coherence with other legislation	23	(44.2%)	(30.3%)
It will certainly reduce costs for economic operators	2	(3.8%)	(2.6%)
It will probably reduce costs for economic operators	12	(23.1%)	(15.8%)
It will probably increase costs for economic operators	4	(7.7%)	(5.3%)
It will certainly increase costs for economic operators	1	(1.9%)	(1.3%)
It will give rise to interpretation difficulties and differences in the application by notified bodies throughout the EU	3	(5.8%)	(3.9%)
It will lead to more coherent conformity assessment carried out by Notified Bodies throughout sectors	25	(48.1%)	(32.9%)
 Others (please specify)	3	(5.8%)	(3.9%)

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

	Number of requested records	Requested records (52)	% of total number records (76)	% of total number records (11)
 Please explain why	3	(5.8%)	(3.9%)	(27.3%)
 Provide an estimate of the increase you expect	0	(0%)	(0%)	(0%)
Unable to provide estimate	8	(15.4%)	(10.5%)	(72.7%)
N/A	65	(85.5%)	(85.5%)	-


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


	Number of requested records	Requested records (52)	% of total number records (76)	% of total number records (13)
 Please explain why	2	(3.8%)	(2.6%)	(15.4%)
 Provide an estimate of the reduction you expect	1	(1.9%)	(1.3%)	(7.7%)
Unable to provide estimate	10	(19.2%)	(13.2%)	(76.9%)
N/A	63	(82.9%)	(82.9%)	-

 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.? -single choice reply- (compulsory)

	Number of requested records	Requested records (52)	% of total number records (76)	% of total number records (52)
Yes	27	(51.9%)	(35.5%)	(51.9%)
No	23	(44.2%)	(30.3%)	(44.2%)

I don't know	2	(3.8%)	(2.6%)	(3.8%)
N/A	24	(31.6%)	(31.6%)	-

 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)  
-multiple choices reply- (compulsory)

	Number of requested records	Requested records (52)	% of total number records (76)
No or no significant changes	5	(9.6%)	(6.6%)
It will make the relevant directives clearer	36	(69.2%)	(47.4%)
It will avoid different interpretations by national authorities	32	(61.5%)	(42.1%)
It will lead to difficulties as existing definitions in the directive(s) by which I am concerned will be changed	2	(3.8%)	(2.6%)
It makes the whole legal framework clearer	27	(51.9%)	(35.5%)
It makes the whole legal framework more confusing	2	(3.8%)	(2.6%)
It will lead to more consistent terminology throughout EU harmonisation legislation on products.	34	(65.4%)	(44.7%)
 Others, please specify	0	(0%)	(0%)

### 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 -single choice reply- (compulsory)

	Number of requested records	Requested records (52)	% of total number records (76)
Very effective	15	(28.8%)	(19.7%)
Quite effective	33	(63.5%)	(43.4%)
Quite ineffective	2	(3.8%)	(2.6%)
Not effective at all	0	(0%)	(0%)
I don't know	2	(3.8%)	(2.6%)

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 -single choice reply- (compulsory)

	Number of requested records	Requested records (52)	% of total number records (76)
Very effective	0	(0%)	(0%)
Quite effective	14	(26.9%)	(18.4%)
Quite ineffective	24	(46.2%)	(31.6%)
Not effective at all	12	(23.1%)	(15.8%)
I don't know	2	(3.8%)	(2.6%)