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Public Consultation on the revision of the New Legislative Framework

Fields marked with * are mandatory.

Introduction

The New Legislative Framework (NLF) consists of two legal acts: Decision No 768/2008/EC and Regulation (EC) No 765/2008, which are key tools for harmonising EU product legislation. Decision No 768/2008/EC lays down a common framework for the placing on the market of products, which includes reference provisions which can be in turn incorporated in sectorial-specific product harmonisation legislation. On the other hand, Regulation (EC) No 765/2008 sets out the requirements for accreditation and CE mark of products.
This initiative concerns a possible revision of the NLF to ensure its fitness for future and alignment with the objectives of the circular economy and digitalisation. The 2022 NLF evaluation identified several shortcomings that have emerged over the past 17 years. These include overly complex product documentation, ambiguity regarding refurbished and substantially modified products, inconsistent and sometimes misleading practices by notified bodies, lack of clarity in conformity assessment modules, and inconsistent practices in trade agreements. These issues risk jeopardising public interest objectives, such as consumer safety, public health, or the protection of the environment and the proper functioning of the Single Market.
We are consulting stakeholders to gather their experiences and views, to guide the development of the initiative. This public consultation offers the opportunity to comment on the proposed solutions and highlight other factors to consider when advancing this initiative.
The public consultation is open to all stakeholders. We welcome contributions from Member State authorities (e.g. those responsible for market surveillance, notifications, accreditation and customs authorities), companies of all sizes (e.g. manufacturers, distributors, importers and other economic operators), industry associations, notified bodies, citizens/consumers and consumer organisations, NGOs, academic institutions and professional users with relevant expertise.

About you

* Language of my contribution

- Bulgarian
- Croatian
- Czech

- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

* I am giving my contribution as

- Academic/research institution
- Business association
- Company/business
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority

- Trade union
- Other

* First name

Marie

* Surname

Poidevin

* Email (this won't be published)

mpoidevin@evolis.org

* Organisation name

255 character(s) maximum

EVOLIS

* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

9869406101755-32

* Country of origin

Please add your country of origin, or that of your organisation.

This list does not represent the official position of the European institutions with regard to the legal status or policy of the entities mentioned. It is a harmonisation of often divergent lists and practices.

- Afghanistan
- Åland Islands
- Djibouti
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- Libya
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- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
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- Mayotte
- Mexico
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- Moldova
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- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden

- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom

- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
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- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
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- Philippines
- Pitcairn Islands
- Poland
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- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- **Anonymous**
  Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.
- **Public**
  Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

☑ I agree with the personal data protection provisions

Participant Profile

*I am providing my contribution as

- Economic operator – Individual companies, including SMEs, which manufacture products falling within the scope of the NLF-aligned legislation
- Economic operator - Distributors, importers, authorised representatives, fulfilment service providers established in the EU according to Article 4 of Regulation (EU) 2019/1020
- Economic operator - Refurbishers /reprocessors and companies engaged in product circularity
- Business association
- Professional end-users, who use products in their professional, commercial or industrial activities and who have an expertise relevant for the use of the product
- Individual citizen
- Consumer organisation
- Public authority - Market surveillance authority
- Public authority - Customs authorities

- Public authority - Accreditation body
- Public authority - Notifying authority
- Public authority, other than market surveillance authorities, customs authorities, notifying authorities or accreditation bodies
- Conformity assessment bodies and notified bodies
- Non-governmental organisation (NGO), civil society
- Academic/ public research institution
- Trade union
- Other

* What is your level of knowledge of the NLF?

For this consultation, there are a set of **'general'** questions for respondents with **no** or **little knowledge** of the NLF, and an additional set of **'expert'** questions for respondents with **good** or **excellent knowledge** of the Framework. Please select which set you want to respond to:

- General
- Expert

Do you agree to the possibility of being contacted for further clarification on your responses if necessary?

Please indicate your consent by selecting the appropriate option below. Without your consent, we will not use your contacts for this purpose.

- Yes, on the following email address
- No

Simplification of product information obligations through digitalisation

a) Digital product compliance information

The 2022 NLF evaluation highlighted that for 83% of economic operators, providing printed product information, such as compliance and safety documentation and instruction manuals, was burdensome. It suggested that digitalisation of the declaration of conformity and conformity assessment procedures could simplify processes and reduce administrative burdens for economic operators.

The Ecodesign for Sustainable Products Regulation (ESPR) was the first Union legal framework to introduce the mechanism of the Digital Product Passport (DPP) for data linked to a given product, providing key information about a product's environmental sustainability. The DPP is required for demonstrating product

compliance not only with Ecodesign, but also with the Batteries Regulation, the Construction Product Regulation, in the politically agreed and soon-to-be published Toys Safety Regulation and Detergents Regulation.

If a digital compliance tool is to be set up as part of the revision of the NLF (which may be based on the DPP), in your opinion, which of the following information should be included in that digital compliance tool?

	Strongly agree	Partly agree	Neutral	Partly disagree	Strongly disagree	I don't know
* Compliance information: the type of information included now in the declaration of conformity or declaration of performance, such as the name and address of the manufacturer, the references to the relevant harmonised standards, information related to the conformity assessment etc.	◉	○	○	○	○	○
* Compliance information: notification added by market surveillance and/or customs authority about product's non-compliance	○	○	◉	○	○	○
* Instructions for use	◉	○	○	○	○	○
* Safety information (e.g. safety warnings, instructions relevant for product safety)	○	◉	○	○	○	○
* Refurbishment/repair history information (e.g. replaced components, previous use cycles)	○	◉	○	○	○	○
* Certificates of conformity of third-party conformity assessment bodies, where relevant for products in the scope of sectorial legislation aligned to the NLF (with possibility to limit the access only to the relevant authorities)	◉	○	○	○	○	○
* Technical documentation (with possibility to limit the access only to the relevant actors)	○	○	○	○	◉	○

Other	◉	○	○	○	○	○

* Please indicate which one

Concerning notification from Market Surveillance Authorities, they should only be issued once non-compliance has been conclusively established, at which point the product should be removed from the market.
Manufacturers should be able to include in the digital compliance tool any other information that they wish to add on a voluntary basis.
When digital information is required via the digital compliance tool, the manufacturer should not be required to provide paper copies as well. If there is no specific requirement in the legislations regarding the format in which information should be provided, the manufacturer should always have the choice between paper or digital format.
Technical documentation shall not form part of the digital compliance tool, as this information shall only be made available to market surveillance authorities upon request. The risk of leakage could be significant and detrimental to manufacturers.
That said, it is important that the tool remain practical : If a DPP for a finished product is intended to identify the DPPs of the components or even the raw materials used, at a level of detail that is too precise in relation to business practices, the addition of new information may result in an unusable tool.

If a digital compliance tool is to be set up as part of the revision of the NLF (which may be based on the DPP), in your opinion, which of the following information should be included in that digital compliance tool? **Expected benefits for me/my organisation (e.g. cost saving, time savings, process automation etc.)**

	Very high	High	Moderate	Low	Very low	I don't know
* Compliance information: the type of information included now in the declaration of conformity or declaration of performance, such as the name and address of the manufacturer, the references to the relevant harmonised standards, information related to the conformity assessment etc.	○	◉	○	○	○	○
* Compliance information: notification added by market surveillance and/or customs authority about product's non-compliance	○	○	○	◉	○	○
* Instructions for use	○	◉	○	○	○	○
* Safety information (e.g. safety warnings, instructions relevant for product safety)	○	◉	○	○	○	○
* Refurbishment/repair history information (e.g. replaced components, previous use cycles)	○	○	○	◉	○	○

* Certificates of conformity of third-party conformity assessment bodies, where relevant for products in the scope of sectorial legislation aligned to the NLF (with possibility to limit the access only to the relevant authorities)	○	○	◉	○	○	○
* Technical documentation (with possibility to limit the access only to the relevant actors)	○	○	○	○	◉	○
Other	○	○	○	○	○	○

Could you provide additional quantitative data on expected benefits?

Amending digital information will be easier than amending paper-based information. This flexibility is a significant benefit for manufacturers and end-users alike. It would reduce printing costs, too.

If a digital compliance tool is to be set up as part of the revision of the NLF (which may be based on the DPP), in your opinion, which of the following information should be included in that digital compliance tool? **Expected costs for me/my organisation**

	Very high	High	Moderate	Low	Very low	I don't know
* Compliance information: the type of information included now in the declaration of conformity or declaration of performance, such as the name and address of the manufacturer, the references to the relevant harmonised standards, information related to the conformity assessment etc.	○	○	○	○	○	◉
* Compliance information: notification added by market surveillance and/or customs authority about product's non-compliance	○	○	○	○	○	◉
* Instructions for use	○	○	○	○	○	◉
* Safety information (e.g. safety warnings, instructions relevant for product safety)	○	○	○	○	○	◉
* Refurbishment/repair history information (e.g. replaced components, previous use cycles)	○	○	○	○	○	◉

* Certificates of conformity of third-party conformity assessment bodies, where relevant for products in the scope of sectorial legislation aligned to the NLF (with possibility to limit the access only to the relevant authorities)	○	○	○	○	○	◉
* Technical documentation (with possibility to limit the access only to the relevant actors)	◉	○	○	○	○	○
Other	○	○	○	○	○	◉

* Please indicate which one

The DPP is not implemented in our sectors which makes it difficult to establish a cost as the major costs might come from the implementation of the tool itself .
However we can already assume that the cost would be very high if the Technical Documentation is included because this represents a diversity of document types and high amount of data. In addition, we will need to check all content vs IP content to make sure we only disclose necessary information.
In any case , if a digital tool is implemented , it will be crucial to allow sufficient time to manufacturers to integrate this new tool in all sectors and as long as the DPP is not fully established, its mandatory content should be limited to a minimum, while potentially allowing to store extra information later on.
Finally, the question of granularity on whether or not digital information of components shall be integrated in the DPP of the final product, could also raise additional cost that is impossible to quantify at the moment.

Could you provide additional quantitative data on expected costs?

* In your view, how **instructions for use** (instructions other than those relevant for product safety) should be provided with a product to the end-user. Digital access in this context should be ensured without the need for providing any personal data, downloading additional applications specific to the economic operator or the obligation to register solely to access the instructions and safety information.

- ○ Digitally and in paper, with the product
- ○ Digitally with the product, in paper only on request addressed to the manufacturer, at the time of purchase or up to six months after that purchase
- ○ Digitally only
- ○ Paper only
- ◉ Other

Please specify

In principle we support the freedom of choice offered to the manufacturer, however, on the question itself, considering that current access to the instructions is limited to customers and market surveillance on request, some personal information may be needed to precisely allow the access.
Concerning the possibility to give a paper version at the time of the purchase, ensuring a printable format of the instructions seems to be sufficient and more rationale in terms of cost and environment, so again, it should belong to the manufacturer to offer or not a paper version, as long a the digital format is itself printable.

* In your view, how **safety information** (e.g. safety warnings, instructions relevant for product safety) should be provided with a product. Digital access in this context should be ensured without the need for providing any personal data, downloading additional applications specific to the economic operator or the obligation to register solely to access the instructions and safety information.

- ○ Digitally and in paper, with the product
- ○ Digitally with the product, in paper only on request addressed to the manufacturer, at the time of purchase or up to six months after that purchase
- ○ Digitally only
- ○ Paper only
- ◉ Other

Please specify

See response above

Comments/examples about possible advantages, shortcomings, risks and best practices related to the possible provision of compliance information by digital means:

In your opinion, which **data carrier** would be most suitable to reach the digitalised product information, contained, for instance, in the DPP?

	Very suitable	Suitable	Neutral	Not very suitable	Not suitable at all	I don't know
* QR code	◉	○	○	○	○	○
* Other barcodes	◉	○	○	○	○	○
* Contactless technologies such as NFC (Near Field Communication) or RFID (Radio Frequency Identification) tags . Contactless technologies like NFC and RFID use radio signals to exchange data wirelessly between a tag and a reader without physical contact. They are commonly used for payments, access cards, product tracking, and smart packaging.	◉	○	○	○	○	○
* Other	◉	○	○	○	○	○

* Please specify

All of the data carriers listed are viable. The NLF should be technology neutral, and the decision on which data carriers are used depends on standardisation. If QR codes are used, the code should direct to a web page to avoid reaching the limit of information that can be directly stored in the QR code. The possibility to access the information stored on the DPP should be limite dto certain stakeholders to avoid any

To what extent do you agree that digitalisation of product compliance information through, for instance, the DPP would facilitate market surveillance checks?

	Strongly agree	Partly agree	Neutral	Partly disagree	Strongly disagree	I don't know
* Compliance information in digital format would facilitate market surveillance	◉	○	○	○	○	○

* Compliance information in digital format would facilitate market surveillance especially for e-commerce	◉	○	○	○	○	○

To what extent do you agree that digitalisation of product compliance information through, for instance, the DPP would facilitate market surveillance checks? **Expected benefits for me/my organisation (e.g. cost saving, time savings, process automation etc.)**

	Very high	High	Moderate	Low	Very low	I don't know
* Compliance information in digital format would facilitate market surveillance	○	◉	○	○	○	○
* Compliance information in digital format would facilitate market surveillance especially for e-commerce	○	◉	○	○	○	○

Could you provide additional quantitative data on expected benefits?

To what extent do you agree that digitalisation of product compliance information through, for instance, the DPP would facilitate market surveillance checks? **Expected costs for me/my organisation**

	Very high	High	Moderate	Low	Very low	I don't know
* Compliance information in digital format would facilitate market surveillance	○	○	○	○	○	◉
* Compliance information in digital format would facilitate market surveillance especially for e-commerce	○	○	○	○	○	◉

Could you provide additional quantitative data on expected costs?

* Products may still be available to consumers after the market surveillance authorities find them non-compliant or dangerous. The information about this is not necessarily available to the end users. With this in mind, to what extent do you agree that market surveillance authorities should be able to upload comments or notes regarding the measures they have taken in the digital compliance tool, to ensure that such information is available to the end users immediately when they scan the data carrier leading, for instance, to the DPP?

- ○ Strongly agree
- ○ Partly agree
- ○ Neutral
- ○ Partly disagree
- ○ Strongly disagree
- ◉ I don't know

b) Digital product compliance information and e-commerce

The European Commission is considering expanding the use of digital compliance tools, for instance the DPP, as part of the revision of the NLF, thus laying down a general principle on the digital provision of compliance information which is to be further complemented and adjusted in the sector-specific product legislations.
Today many non-compliant or dangerous products reach the Single Market through online purchases or distance sales. Many of those products are imported from third countries.
The DPP has been identified as one of the key enablers for the supervision of the e-commerce landscape in the recently published EU Toolbox for Safe and Sustainable E-Commerce, which aims to tackle the large number of non-compliant goods sold via e-commerce.

* To what extent do you agree that market surveillance and customs authorities should have access to digital product compliance information, for instance through the DPP, for the products offered online, so that they can carry out product checks assessing the compliance with the applicable legal requirements (e.g. e.g. confirming that the product was subject to the relevant third-party conformity assessment)?

- ◉ Strongly agree

- Partly agree
- Neutral
- Partly disagree
- Strongly disagree
- I don’t know

* Please explain your answer

Products manufactured outside of the EU and sold online often lack an EU representative, despite this being an obligation under the Market Surveillance Regulation. This makes it very challenging for market surveillance authorities to access a product’s compliance information. Granting market surveillance and customs authorities access to the digital product compliance information would be an important step forward however technical documentation with confidentiality and sensitive data (e.g. risk assessments, construction plans, test reports) shouldn’t be included in this compliance tool, this data should still only be handed over upon request of the responsible authorities.

To what extent do you agree that mandatory inclusion of digital product compliance information, such as warning or safety information, in an online offer would:

	Very high	High	Neutral	Low	Very low	I don't know
* Allow equal access to the same product compliance information for online and brick-and-mortar stores	○	○	○	○	○	◉
* Allow end users (consumers/ professionals) to make more informed product choices	○	◉	○	○	○	○
* Lead to a decrease in offer/supply of products available to consumers	○	○	○	○	○	◉
* Allow market surveillance authorities to check more products offered online	○	◉	○	○	○	○
* Reduce the number of non-compliant products entering the EU from third countries through online sales	○	○	○	○	○	◉
* Decrease the costs of product inspections by the market surveillance authorities	○	◉	○	○	○	○
* Increase product prices for consumers to cover the costs of including this information in the online offer	○	○	○	○	○	◉
Other	○	○	○	○	○	○

* To what extent do you agree that each product listed for online sales must be accompanied by compliance information in digital form, for instance, by the DPP?

- (●) Strongly agree
- ( ) Partly agree
- ( ) Neutral
- ( ) Partly disagree
- ( ) Strongly disagree
- ( ) I don't know

Comments/examples:

same rule should apply for products sold offline or online.

c) Digital product compliance information and CE mark

The CE mark is a self-declaration by the manufacturer that a product complies with European Union legal requirements regarding safety, health, and other essential requirements or essential characteristics. It is mandatory for certain categories of products sold within the European Economic Area (EEA). The 2022 NLF evaluation found that the CE mark holds significant value and functions well but also highlighted some challenges. Consumer associations remain concerned that consumers misunderstand the CE mark as a quality or certification mark, rather than a compliance mark.

The European Commission is considering revising the approach to the CE mark as a conformity self-declaration.

* To what extent do you agree that the CE mark should be displayed only digitally, by including it, for instance, in the DPP?

- ( ) Strongly agree
- ( ) Partly agree
- ( ) Neutral
- ( ) Partly disagree
- (●) Strongly disagree

- ○ I don’t know

* In case you are in favour of keeping the obligation of physically affixing the CE mark, please indicate your reasons and choose all that apply:
  - ☑ It is easier for any type of stakeholder to visually identify products that comply with the EU product rules anywhere in the EU
  - ☐ CE mark gives guarantee that the product is compliant
  - ☑ Consumers trust more in CE-marked products
  - ☐ Other

Comments/examples:

The CE marking is an essential tool that is recognised by all parties as a sign of compliance.
The compliance must consequently be easily and quickly recognisable by all, including those not having access to the DPP or equivalent tool.

* To what extent do you agree that the requirement to physically affix the CE mark should remain and be complemented by a digital display, to be included, for instance, in the DPP?
  - ○ Strongly agree
  - ◉ Partly agree
  - ○ Neutral
  - ○ Partly disagree
  - ○ Strongly disagree
  - ○ I don’t know

Comments/examples:

It does not seem necessary to complement the physically affixed CE mark by a digital display. Choice should be given to the manufacturer.

Enhanced circularity in the NLF

The 2022 NLF evaluation shows that there is a potential need for introducing, updating and clarifying certain definitions within the context of the NLF, as well as clarifying responsibilities based on the type of product modification.

Market surveillance authorities face difficulties distinguishing between substantially modified (new), reused and refurbished products, partly because the NLF does not define key terms like refurbisher, refurbishment, repairer, reuse or repair.

The Ecodesign for Sustainable Products Regulation (ESPR) defines 'refurbishment' as *"actions carried out to prepare, clean, test, service and, where necessary, repair a product or a discarded product in order to restore its performance or functionality within the intended use and range of performance originally conceived at the design stage at the time of the placing of the product on the market"*. On the other hand, the concept of 'repair' is defined as *"one or more actions carried out to return a defective product or waste to a condition where it fulfils its intended purpose"*. Finally, the concept of 'remanufacturing' is defined as *"actions through which a new product is produced from objects that are waste, products or components and through which at least one change is made that substantially affects the safety, performance, purpose or type of the product"*.

While some of these concepts may have been defined in certain sectorial legal frameworks aligned to the NLF, the NLF itself currently does not lay down a comprehensive and exhaustive list of definitions, which capture the modifications that a product may sustain after it has been placed on the market. The Machinery Regulation, for example, defines 'substantial modification' as a modification of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not planned by the manufacturer. As a result, the compliance of the machinery product with the relevant essential health and safety requirements may be affected. In contrast, refurbishment does not affect the risks and performance of the product.

The Construction Products Regulation defines 'used product' which is placed on the market again or 'remanufactured product' which has been subject to a transformative process going beyond checking, cleaning and repairing recovery operations and then placed on the market again. The Medical Devices Regulation defines 'reprocessing' as a "process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device".

With increasing policy focus on circular economy objectives, and in the absence of a clear legal framework, market surveillance authorities may face difficulties in assessing the compliance of such products, and economic operators may lack clarity on their obligations. Hence, the question, whether the NLF should extend its focus towards any modifications that may be brought to products after they are placed on the market, which is also related to product circularity.

To what extent do you consider the requirements below as necessary to ensure the safety of refurbished products? Please choose all that apply:

	Absolutely necessary	Very necessary	Moderately necessary	Slightly necessary	Not necessary at all	I don't know
* Clear distinction of refurbished/ remanufactured products from new ones, e. g. through labelling or marking	○	○	◉	○	○	○
* Mandatory safety checks for refurbished products by a third party (e.g. a notified body)	○	○	○	○	◉	○
* Mandatory safety checks for refurbished products by the refurbishers themselves (e.g. performance of internal risk analysis)	○	○	◉	○	○	○
* Obligation for the refurbisher to provide information on the spare parts replaced in the product	○	○	○	◉	○	○
* Obligation for the manufacturer to provide the product information necessary for safe refurbishment	○	○	◉	○	○	○
* Responsibility for the refurbisher for product compliance and safety limited to the refurbished parts	○	○	◉	○	○	○
* Responsibility of the refurbisher for the whole product following the refurbishement	○	○	○	○	◉	○
Other	○	○	○	○	○	○

Comments/Examples regarding the possible impact of these such changes (if known):

The current definition of ‘remanufacturing’ in the ESPR is not appropriate. It is insufficiently precise and severely limits the possibilities for marketing second-hand products for two reasons: it is too broad, and it implies that remanufactured products should be considered as new products, subject to all the regulatory changes that have taken place since the initial product was placed on the market. In practice, this will result in many products that could have been reused becoming non-compliant.
On the requirement to undergo an internal risk analysis for refurbished products, it very much depends on the definition given to the term “refurbished”. A simple cleaning should not trigger burdensome process for the refurbisher. However, there may be cases where an internal risk analysis may be necessary, depending on the importance of the modification for the safety of the product and the degree of deviation from the instructions provided by the original manufacturer.
Generally speaking we do believe that risk analysis are part of a routine for any manufacturers/refurbishers, and no additional requirements should be enforced.

* Do you support the idea of a separate conformity assessment module for substantially modified products?

- ○ Yes
- ◉ No
- ○ Only in case of products subject to third-party conformity assessment
- ○ Other
- ○ I don't know / cannot answer

* Do you support the idea of a separate conformity assessment module for used products?

- ○ Yes
- ◉ No
- ○ Only in case of products subject to third-party conformity assessment
- ○ Other
- ○ I don't know / cannot answer

Comments/examples:

The existing modules are well suited to carry out the conformity assessment of any products and as such no new modules are needed. Should a module be included for substantially modified products only, the limits or scope of such conformity assessment will be difficult to establish making it very difficult for manufacturers, users /consumers and authorities to know how to treat them.
Several legislation already contain a definition of substantial modification and a common definition does not seem applicable in practice, however the NLF should clarify what are the manufacturers obligations, once a product fulfils the condition of a substantial modification, in terms of original CE marking (to be replaced or not), level of compliance required after the substantial modification (only to the parts affected by this

modification? Compliance to all newly applicable legislation or only to the piece of legislation for which the substantial modification is established ?etc) . The concept of substantial modifications should not disproportionately restrict the marketing of second-hand products or path to a circular and sustainable economy.

Enhanced responsibility of conformity assessment bodies

a) Strengthening oversight and accountability of notified bodies

Notified bodies are organisations designated by national authorities to assess the conformity of certain products before they are placed on the market.

Notifying authorities are the national entities responsible for designating and supervising these notified bodies.

The 2022 NLF evaluation has identified shortcomings in the oversight of notified bodies, that may ultimately lead to safety risks

* Should the general principle that the Commission shall have the authority to suspend, restrict or withdraw the notification of a notified body, when necessary to ensure compliance, be included in the NLF?

- ○ Yes, but only when a notifying Member State authority fails to act despite clear non-compliance or misconduct of notified body
- ○ Yes, but Commission should only be able to suspend temporarily the notification (if substantiated/urgent)
- ○ Yes, including investigative powers over the notified bodies
- ◉ No
- ○ Other
- ○ I don't know/cannot answer

* What mechanisms could strengthen the accountability of notified bodies?

reporting, KPIs etc

* Should there be mandatory timelines for notifying authorities to complete the periodic reassessment of notified bodies?

- ○ Yes, and if the timeline for the reassessment is not respected the notified body should be automatically removed from NANDO (New Approach Notified and Designated Organisations database)

- (●) Yes, but with flexibility, the absence of timely reassessment should not result in automatic removal from NANDO
- ( ) No, current practices are appropriate
- ( ) No
- ( ) Other
- ( ) I don't know/cannot answer

b) Enhancing the monitoring of outsourcing the tasks of notified bodies

According to the findings of the 2022 NLF evaluation, notified bodies are increasingly outsourcing tasks, often due to internal staff and facility shortages, or completely relying on subcontractors, without hiring own staff or having own equipment. They often delegate entire activities to subcontractors in third countries. This trend raises concerns about the reliability and oversight of subcontracted work. At the same time, maintaining independence and impartiality is particularly challenging when notified bodies also engage in related services like consultancy or testing.

* What measures do you think could be effective to address the challenges related to subcontracting by notified bodies? Please choose up to **three options** you think would be most effective.

between 1 and 3 choices

- [x] Stricter rules requiring that key certification decisions be made exclusively by permanent, in-house staff of the notified body
- [ ] The subcontractor should be notified or accredited together with the notified body
- [ ] Maintain the current rules regarding subcontracting
- [ ] Remove the possibility for subcontracting outside EU
- [ ] Introduce stricter rules for subcontracting outside EU
- [ ] Other
- [ ] I don't know/cannot answer

* Which additional requirements should the NLF include to ensure the reliability of notified bodies? You may select multiple replies.

- [x] The minimum number of permanent full-time staff
- [x] Stricter requirements for the expertise of the staff, with sufficient technical expertise
- [x] Minimum tasks carried out by the notified body without subcontracting
- [ ] Minimum number of certifications delivered per year in the notified area
- [x]

- [ ] Minimum technical equipment
- [ ] No new requirements
- [x] Other
- [ ] I don't know/cannot answer

* Please specify

The shortage of staff or equipment in notified bodies could lead to significant delays in processing CE certificates. Manufacturers are not always aware of this situation upfront which puts them at a disadvantage compared to competitors.

* Which additional measures should be introduced to ensure the integrity and independence of notified bodies? You may select multiple replies.

- [ ] More restrictive ownership rules
- [x] More precise rules setting out prohibited practices
- [x] Dedicated assessment of the professional integrity during the reassessment of notified bodies
- [x] Breaching the rules related to professional integrity should be an explicit reason for the withdrawal of the notification
- [x] Mandatory accreditation
- [x] Other
- [ ] I don't know/cannot answer

* Please specify

Notified bodies do not all follow the same rules : some are using harmonised standards as the only allowed reference for compliance , even though standards are voluntary leaving no option for the manufacturers to use another reference (ISO standards or other). Besides, the interpretation given to the harmonised standards may vary from one NB to the others, leading to unequal treatment in assessing the compliance of a product.

* If mandatory accreditation is introduced, should the NLF still keep the notifying authorities separately from the national accreditation bodies?

- ( ) Notifying authorities should still exist besides the national accreditation bodies
- ( ) Notifying authorities should be abolished – national accreditation bodies should take over their tasks

- ○ Other
- ◉ I don't know/cannot answer

* Do you think that accreditation could improve if there were an EU-level monitoring, investigative, and decision-making power in the area of accreditation?

- ○ Strongly agree
- ○ Partly agree
- ○ Neutral
- ○ Partly disagree
- ○ Strongly disagree
- ◉ I don’t know

Please elaborate on main reasons:

Please choose all that apply: To what extent do you agree that integrating third-party conformity assessment certificates into the digital compliance tool, for instance, the DPP, would….

	Strongly agree	Partly agree	Neutral	Partly disagree	Strongly disagree	I don't know
* … enhance reliability of the certificate as it could not be falsified	○	○	◉	○	○	○
* … facilitate the checks of the product by the market surveillance authorities	○	◉	○	○	○	○
* … would facilitate the monitoring of the notified bodies	○	◉	○	○	○	○
* … not make a significant difference	○	○	○	◉	○	○

* Other	○	○	○	○	○	◉

c) Levelling the competence of notified bodies

The NLF currently treats accreditation of notified bodies as voluntary, though most rely on it. Making accreditation mandatory could ensure consistent quality across the EU but concerns about cost and process length may impact smaller conformity assessment bodies and new entrants, particularly in small sectors where there are few notified bodies.

Accreditation has the potential to to demonstrate the competence of notified bodies. According to the 2022 NLF evaluation, some stakeholders see mandatory accreditation as the only way to ensure the appropriate and equal high level of competence of notified bodies, while others point to the significant amount of time and costs needed for accreditation comparing to its benefits.

* What measures do you think could help ensure a more aligned level of competence among notified bodies? Please choose all that apply.

- ☑ Strengthening the supervision of notified bodies by Member States authorities
- ☑ Strengthening the Commission's oversight of notified bodies, including through investigative and decision-making powers
- ☑ Introducing mandatory accreditation for all notified bodies
- ☑ Improved peer reviews of the national accreditation bodies, ensuring coherent practices in all Member States
- ☑ Other
- ☐ I don't know/cannot answer

* Please specify

Better checks of competence upon accreditation

* Should non-harmonised standards or other rules be allowed as a basis for accreditation of conformity assessment bodies?

- ◉ Yes
- ○ No
- ○ I don't know/No opinion

* If so, what should be used as a basis for accreditation of conformity assessment bodies, as an alternative to harmonised standards? Please choose all that apply.

- [ ] Harmonised European standards only, without alternatives
- [ ] Harmonised European standards based on ISO standards, without alternatives
- [x] Harmonised European standards + requirements of the specific legislation in question
- [x] Specific requirements in the NLF related to the notified bodies + requirements of the specific legislation
- [x] Other requirements in line with NLF and specific legislation (no presumption of conformity, hence the need to demonstrate)
- [ ] The non-harmonised area should be treated separately, with more flexibility, applying different rules

* Would you agree that the current peer assessment system for national accreditation bodies ensures coherent practices?

- ( ) Strongly agree
- ( ) Partly agree
- ( ) Neutral
- (•) Partly disagree
- ( ) Strongly disagree
- ( ) I don't know

Comments/examples:

* What measures would ensure a greater coherence of practices by national accreditation bodies?

- (•)

Clear and detailed schemes for sectoral legislation

- ○ Strengthened EU level oversight of peer reviews
- ○ Permanent team of peer evaluators
- ○ A common pool of peer evaluators for different sectorial legislation
- ○ Other
- ○ No need for improvement

* The revision of the NLF is carried out in parallel with the revision of the Market Surveillance Regulation and the Standardisation Regulation. Do you think the three legal acts should be merged into one **European Product Act** to ensure legislative coherence?

- ○ Strongly agree
- ◉ Partly agree
- ○ Neutral
- ○ Partly disagree
- ○ Strongly disagree
- ○ I don't know

* Please elaborate on main reasons:

The Standardisation Regulation could remain a stand-alone as the it goes beyond products and includes services.
However, the three regulations are highly interrelated. It is consequently crucial that sufficient time is given to co legislators to be able to address the different revisions in parallel to ensure coherence between them.

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