Questions on the New Legislative Framework

Fields marked with * are mandatory.

About you

* Name

Martina Griffo

* Email

martina.griffo@cece.eu

* Name of organisation

CECE (Committee for European Construction Sector)

* Type of organisation

Micro enterprise (fewer than 10 employees)

* Your business is interested in:

- [ ] Manufacturing

Please define

CECE represents the interests of 1,200 construction equipment manufacturers through national trade associations in Europe.

* EU legislation / products of your interest:

- Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive
- Simple Pressure Vessels Directive
- Electromagnetic Compatibility Directive
- ATEX Directive
- Battery Regulation
- Radio Equipment Directive
- Low Voltage Directive
- Pressure Equipment Directive
- Construction Products Regulation
- Outdoor Noise Equipment Directive
- Gas Appliances Regulation
- Machinery Directive and Regulation
- CRA
- AI Act
- ESPR

I. Conformity assessment modules

1. Products are **modified, refurbished and being placed on the market as new products,** while the existing conformity assessment modules do not include the validation and verification of a product's **compliance taking into account its entire lifecycle**.

a. Do you see this as a problem and if so, how big is it?

Modified products do not mean that the product is to be considered as "new". It is important to note that refurbished products are not placed on the market as new products and that currently there is no regulatory proposal that makes such an assumption or imposes this kind of rule (for example, the ESPR proposal does not consider refurbished products as new). We believe that the NLF, in combination with the Blue Guide, rightly provides the general principles to be followed, while product legislation includes specific criteria based on those principles for a given sector.

So, the answer to this question is no; this is not a problem. Any product that is considered new in principle will be placed on the EU market for the first time and therefore must conform to the applicable laws and the required or allowed conformity assessment procedures. CECE supports the NLF conformity assessment procedures and is satisfied with the modules for conformity assessment. However, we would like to stress the importance of ensuring consistency in the application of modules across different products and sectors and that the choice of the module is proportionate to the risk of the product, its design complexity, and the nature of its production, as stated in the NLF. Especially the use of Module A together with harmonised European Standards has been proven highly effective. Most importantly, sector legislation should avoid imposing modules that would be too burdensome in relation to the risks covered by the legislation concerned. They should be appropriate for the type of product. Consequently, we do not think that additional conformity assessment modules are needed.

b. Which products are affected?

All products are covered by the application of existing modules and can be subject to modification.

c. How much does it cost now to ensure conformity assessment for modified/refurbished products?

Under the legislations currently covering our sector, modified and refurbished products do not need to undergo any conformity assessment module as they are not considered newly placed on the market.

d. What could be the solution to this problem?

As said in Q1a, we don't consider this a problem. However, we believe that the principles defined in the Blue Guide should be further defined in sector legislation to limit the cases where a modification becomes "substantial" and to avoid discretionary implementation. The key point remains that the products placed on the EU market perform as expected and are safe. In this sense, the conformity assessment modules have proven to be adequate.

e. What impact could the solution have, e.g. on costs and cost savings?

None, since the concept of substantial modifications is well-established. If this situation changes (e.g. adding new conformity modules; more definitions included in the NLF), then manufacturers may face higher costs and less flexibility to adapt to the new rules.

2. The horizontal menu of conformity assessment procedures is shaped towards the examination of product compliance and **does not take into account the compatibility of processes against environmental and sustainability criteria.**

a. Do you see this as a problem and if so, how big is it?

No, we don't see this as a problem. CECE believes that the conformity assessment modules in the NLF remain fit for purpose even for products manufactured with new practices taking into consideration environmental and sustainability criteria. In fact, we consider the existing system to be a coherent approach. The objective of the NLF is to ensure the safety and security of products, not to evaluate environmental performance. The first is demonstrated thanks to conformity assessment modules and CE marking. We do not see useful to modify the NLF in this respect.

The focus of the horizontal menu of conformity assessment procedures primarily centers around examining product compliance, without explicitly considering compatibility with environmental and sustainability criteria. This approach can be seen as advantageous, as the New Legislative Framework (NLF) does not necessitate the inclusion of these criteria. By avoiding duplication and potential conflicts of requirements, the NLF streamlines the conformity assessment process.

Already today, we have sustainability legislation under the NLF covering environmental and sustainability criteria such as ErP (including its implementing measures) or RoHS which include modules A and H. The processes that are a base for the product compliance are implicitly included in the NLF modules already. When it is left to the economic operator to establish and implement the process to include sustainability and environmental processes in their products, this translates into greater innovation capacity for companies. Should there be the need for specific requirements to assess and demonstrate certain processes, this can be included in the sector specific legislation without a need to change the overall framework.

b. Which products are affected?

All products are affected, as they can be subject to environmental and sustainability criteria.

c. How is the fulfilment of such those criteria currently ensured and how much does it cost now to demonstrate the fulfilment?

The costs for fulfillment of such criteria depend on the product and the criteria themselves. The processes that are a base for the product compliance are already implicitly included in the NLF modules.

d. What could be the solution to this problem?

We don't consider this as a problem. In fact, the processes that are the basis of the product compliance even when it comes to environmental and sustainability are already implicitly included in the NLF modules. As mentioned above, if specific environmental or sustainability legislation requires the assessment and demonstration of specific processes, these pieces of legislation have to provide the respective requirements. The NLF already explicitly allows for such flexibility.

e. What impact could the solution have, e.g. on costs and cost savings?

Since this approach is already part of the NLF, there would be no impact on costs. However, costs would be higher, and manufacturers could be confronted with a less flexible environment if this situation changes (e.g., adding new conformity modules; stricter definitions included in the NLF).

3. The design phase of **software products** tends to be more voluminous than the "production" phase.

a. Do you agree with this and if so, what does it mean?

We do not agree with this statement, and we believe that the question is misleading: there are different ways to "design" and develop software products and often the "design" and "production" phases may not be able to be clearly separated. Oftentimes the development is an iterative process, in which feedback and user demands are considered in subsequent versions.

However, these observations are not exclusively relevant for software and could also be made for some physical products, which may also be developed further and again be placed on the market. For every iteration (i.e., upgraded version) of such product a risk assessment and a conformity assessment would be needed, if the change is significant enough to constitute a substantial modification. This principle doesn't change with the development of software, but the speed at which these developments take place may be faster.

We would like to underline that the concept of "more voluminous" is too vague. The design phase of physical products can be extremely voluminous, whereas some software (e.g., simple apps), could have a very short design phase.

b. Do the current conformity assessment modules allow an adequate assessment of software products?

Yes, they do allow for an adequate assessment of software, because there are sufficient modules to cover software products:
1) Module A allows for the use of standards with which the manufacturer can address changes to the software in an agile way without the need to involve a notified body in a lengthy and burdensome way. It is up to standardisers to create the hENs in a way that the relevant criteria can be checked and the procedures on how to address security issues are in place.
2) Module B can also be used (because Module B exists in 3 different set-ups: Notified body checks either the Production type, or the design type or the combination of production and design type). The design-type can be used for assessing software. How that is done in practice has to be decided by notified bodies (they have to prove that they have the competency to do so).
3) Module H involves the setup of a Quality Management system and doesn't require tests on the product itself. Therefore, changes to a products/software can be addressed by the manufacturer in an agile way. This is often used for Medical Devices and for that directive, Standalone Software (or Apps) is included already today.

4. In most of the cases, software products are based on a prototype. **Does module B suffice to address the design phase of software products?**

a. Do you see this as a problem and if so, how big is it?

We believe that the use of the word "prototype" in this context is not correct and suggest that to be replaced by "type" or "sample".
We don't see a problem with the use of module B, although we don't see the need to have a third party involved for conformity assessment. A type is needed when addressing the design phase of software products, but this doesn't necessarily require the use of Module B, as Module A is better fit to address the fast paced development cycle of software. In cases where it is necessary to involve a third party for the conformity assessment, Module B is sufficient, as it offers the option to refer to the Production type, the Design type and the combination of Production and Design type. The Design type allows for software to be assessed, in cases where a third-party conformity is absolutely necessary.

If a software product is ready for release, the version which should be released will undergo a type examination like it is also done with physical products. How the software is then assessed and tested is the responsibility of the notified body or, if module A is used, subject to the requirements in a standard, including the use of harmonised standards to benefit from the presumption of conformity. Regarding the design process of the software, the same can be said, as done above in regard to processes for environmental and sustainability criteria: The adherence to proven processes in the development of (software) products e.g., developing along a secure development lifecycle (SDL) can be read off the final product and its documentation, there is no direct need to also assess the process. Especially since there is broad range of development processes.

b. How much does it cost now?

The costs for fulfillment of such criteria depends on the product and the criteria itself.

c. Which software products are impacted?

The products impacted are the products falling under respective EU product regulation and covering both standalone software and embedded software products. Looking at the current proposal of the Cyber Resilience Act (CRA), both standalone software products and software components are addressed explicitly.

d. What could be the solution?

The mandatory involvement of a third-party conformity assessment body has to be limited to those software products where this is proportionate to the risk. For most products, Module A will sufficiently cover the requirements. Especially for software with short development cycles, Module A provides for the flexibility needed. If third party involvement is necessary, Module B or H could be used. In the case of Module H, Quality Management provides for better addressing the rapid changes in the product development cycles by addressing the process and not the product.
The processes that are a base for the product compliance of software are included in the NLF modules already. If specific legislation requires the assessment and demonstration of specific processes, those pieces of legislation may provide the additional requirements. The NLF explicitly allows for such flexibility, as it is currently already used for the CRA. In the CRA proposal, the Commission assessed that there was no need to introduce new conformity assessment modules, meaning that the existing ones are fit for purpose including for software.

e. What impact could the solution have, e.g. on costs and cost savings?

Overall, the use of third-party conformity assessment (Module B/H) over self-certification (Module A) leads to additional costs and a longer time to market which also results in additional costs.

However, our solution doesn't involve a change in the existing framework, so from this perspective there would be no impact. However, there would be additional costs stemming from specific legislation, if the scope is extended to regulate on software or hardware which weren't regulated at all before, like we see it with standalone software under the CRA.

5. Substantial modification of a product – common definitions

The NLF has been identified as a decisive cohesion tool in EU product legislation. Thanks to it, the highest possible level of coherence has been achieved in the EU's product legislation. However, some of the revised pieces of NLF-legislation and recent legislative proposals contain different definitions as to what constitutes a substantial modification or a full refurbishment.

a. Have you identified this as a possible difficulty?

There seems to be a confusion made between "refurbishment" and "remanufacturing". As indicated for question n°1, recent legislative proposals do not treat refurbishment as substantial modification and the notion of "full refurbishment" does not exist.

The Blue Guide already identifies the key principles applicable to substantial modifications. Product legislation, such as the new Machinery Regulation, includes specific definitions and criteria for substantial modifications applicable to those products which are in line with the general principles included in the Blue Guide. We believe this is the best approach to deal with new definitions, as it is in line with the NLF approach which provides for possibilities to deviate in specific details and allows for product specificities to be addressed in product legislation.

However, further specification of what can be considered a substantial modification should only be included in product legislation and not in other horizontal frameworks, to avoid duplication and legal uncertainty. For example, the current draft CRA includes a definition of substantial modification which has a much broader scope as compared to the definition provided in the Machinery Regulation. Consequently, when a machinery product with a digital element undergoes substantial modification, and if the CRA text remains as is, it will be unclear which definition should apply.

b. If so, please explain which pieces of legislation and products would be impacted.

The concept of substantial modification is included in several legal text as well as guidelines (e.g., Blue Guide, Machinery Regulation, GPSR, ATEX). The concepts in GPSR, Machinery Regulation and ATEX follow the same approach as the Blue Guide. All these legislation are potentially impacted.

c. Which of these pieces of EU legislation contain the definitions that are most understandable and easily applicable?

We consider the relatively flexible concept in the Blue Guide the best and most broadly applicable, as it can be easily adjusted for sectoral legislation. The Machinery Regulation and the General Product Safety Regulation include definitions of substantial modifications that are in line with the principles outlined in the Blue Guide.

d. Do you think that the absence of common definitions may lead to incoherence of practices under various pieces of legislation?

As long as the different definitions included in product legislation follow the principles outlined in the Blue Guide, we don't think that the absence of a common definition is a problem. On the contrary, we question how a common definition could ever adapt to the specificity of sectoral legislation. A common definition may lead to incoherence of practices under various pieces of legislation. In fact, practical criteria for a substantial modification cannot be the same for all products.
However, all definitions need to be clearer to limit the cases where a modification becomes "substantial" and to avoid discretionary implementation. We consider that a broad definition would deter owners from making modifications to products which would otherwise improve performance or would extend the lifespan of the product. Clarity is linked to product specificity;, thus sectorial legislation is best suited to provide the definition.

e. If so, may the diversity in terminology/definitions related to a substantial modification of products covered with different pieces of legislation (or sometimes more pieces of legislation) lead to additional costs (please provide an estimation).

No response.

f. Which common definitions are in your opinion missing from the NLF framework?

Given that the proposal for Ecodesign for Sustainable Products Regulation is still under discussion and that it will provide for certain new definitions (e.g., refurbishing, remanufacturing, etc.) we suggest that the Commission waits until this legislation is finalised to assess whether the definitions are fit to be applied in the NLF as well. This will ensure alignment of definitions across legislation.

g. Which areas are not, or not sufficiently, covered (either by rules or definitions) in the NLF? What rules /definitions should be introduced to better support circular economy, foster remanufacturing and high-quality recycling of products but at the same time ensure that only safe products can be placed on the market?

ESPR and other current proposals in the environmental and sustainability area are currently being drafted. These final definitions should be awaited. See answer to question f.

h. Is it clear who is responsible for substantially modified products?

The party responsible for performing substantial modifications bears the responsibility of ensuring that the modified product complies with the specific legal requirements outlined in the relevant product legislation. It is important to note that legal requirements can vary across different legislations. The Blue Guide provides further information and specific guidance for different cases. It is worth mentioning that the concept of "all applicable legal requirements at the time of placing on the market" may not align with the requirements specified in certain regulations, such as the Machinery Regulation (MR), for instance.

II. Digitalisation and CE marking

The CE marking and traceability information have to be affixed on the product.

a. Do you think that **digitalisation** would serve **simplification and environmental protection**? Please explain and estimate the benefits of digitalisation (e.g. digital CE marking, digital traceability requirements, digital DoC, digital technical documentation, digital instructions, etc).

Digitalisation can serve simplification and environmental protection if done right. CECE welcomes and supports technological advances that can facilitate information obligations when these satisfy the needs of the stakeholders. We believe it is important to investigate how compliance can be facilitated and made faster to make it easier for manufacturers to meet information obligations. Digitalisation could apply to CE marking, traceability information, conformity assessment, etc.

However, this should be an “either/or” option, not an additional requirement. Furthermore, information should be stored in the manufacturer database, and not in an EU, centralised platform. The development of common standards and specifications for the contents and the format of the required product information could be helpful to further align and ensure adequate information to the consumer. The revision of the machinery directive shows that legislators are already going in that direction. The digitalisation of relevant documentation will have huge environmental benefits.

Finally, while some may have reservations about the introduction of another centralized database similar to SCIP, it offers practical advantages such as efficient management of access rights, seamless data sharing within a supply chain, and improved harmonization. Furthermore, from a sustainability perspective, a centralized database can be a preferred solution compared to alternatives like blockchain technology, which consumes a significant amount of energy and may not be environmentally sustainable.

Additionally, the centralized database still requires a supervisor to grant and control access, ensuring the necessary oversight is in place.

b. Does this obligation represent a burden, and if so to what extent, for new products that are placed on the EU market?

No, we do not perceive digitalization, and digital CE marking and traceability information, a digital DoC, or digital instructions as a burden but as an opportunity, if digitalisation is introduced as a fully equivalent alternative. This would serve environmental aspects and provide for user-friendliness if the information could be accessed from everywhere.

c. If so, why and what are the costs of this obligation?

No response.

d. Does this obligation represent a burden, and if so to what extent, for substantially modified or used products which are placed on the EU market for the first time? If so, why and what are the costs of this obligation?

No, as long as it is an either/or requirement and does not have to be provided additionally in digital format.

e. Do you think that introducing the digital product passport (which would include CE marking and traceability requirements) would facilitate information obligations related to substantially modified products? If so, to what extent could the cost of modification of a product be reduced?

We recognise that DPP may provide benefits to the industry. While it is challenging to provide an opinion ahead of consolidated text and a clear implementation of the tool, CECE believes that economic actors and the competent national authorities could easily have access to the product lifecycle information. Introducing a digital product passport can indeed facilitate the fulfillment of information obligations concerning substantially modified products. This approach enables seamless linking of modified products to their original counterparts while incorporating essential data associated with the modifications. Consequently, market surveillance authorities would find it more straightforward to assess whether the modifier has fulfilled their responsibilities. This would also further reduce the environmental footprint of re-manufactured and refurbished products.

f. Do you think that the digital product passport should eliminate paper-based (or affixed) product information obligations and that all information about the product (safety instructions, CE marking, traceability information, DoC, technical documentation, certificates of the notified body, test reports) should only be available digitally, on the passport? If you think that certain information should be stored with the products on paper, what would that be and who should be able to access that information.

We think that whatever the solution, this should be an “either/or” option, not an additional requirement. The choice of either paper- or digital product information depends very much on the product, the user and the environment in which it is used. Furthermore, information should be stored in the manufacturer database, and not in an EU, centralised platform. The development of common standards and specifications for the contents and the format of the required product information could be helpful to further align and ensure adequate information to the consumer. The provision of product information (such as postal address) in digital format does not infringe on the consumer’s (or the professional user’s) right to access this information.

g. If you think that all product related information should be provided only digitally, please explain how it could be ensured that users always access and read safety instructions before using a product? Do you think that certain types of products should always be accompanied by safety instructions? Which products?

Even with product related information available on paper, the manufacturer cannot guarantee that the user reads the instruction or

that – once he/she has read the instruction – he/she follows them. Providing the information digitally would not change this. However, having information available in a digital format could improve the clarity of instructions, as instruction movies/gifs could provide for a faster and easier understanding of the product and how to use it safely.

h. Who should have the right to update the product passport (manufacturer, person who carries out substantial modifications, repairer…)?

Ideally, the modifier should have the ability to update the information specific to the modifications performed. This modified product passport would then serve as the official document for the modified product. However, it is crucial that the product passport created by the manufacturer for the original product remains unaltered and intact, ensuring the accuracy and consistency of the information it contains. By following this approach, both the manufacturer and the modifier can maintain their respective responsibilities and ensure the transparency and traceability of the product's history.

We would also like to bring to your attention the fact that there is a potential practical issue linked to DPP updates which should be considered. Anyone performing work on the machine should bear some responsibility to ensure that the DPP is properly updated and maintained. We also suggest the EC clarifying who will be responsible for hosting the DPP. The end-user/User has access to a copy (via a QR code to access it). For professional products, if the end user decides to modify the product, not in a substantial way, but in a way that needs the instructions to be updated, how will this be done? More generally, the repairer or other persons intervening on the product will need to update the DPP.

We believe the Commission should assess all these practical questions and implications before setting up the DPP.

i. Which information stored on the product passport should the market surveillance authorities be able to access?

What information should be made available to market surveillance authorities without request must be clarified and these measures must respect confidentiality related to protectable trade secrets, IPRs, security laws and for export control legislations (including dual use). Confidentiality related Information trade secrets, IPRs, export control information (e.g., dual use) including the technical documentation should not be a mandatory element of the DPP. The market surveillance authorities should be able to access the same data as they would have access to if the information would be provided offline as required by EU product legislation. It is up for the manufacturer to provide additional data on a voluntary basis.

j. In your opinion, what percentage of economic operators or consumers would be negatively impacted by digitalisation and how could it be ensured that less digitally adept users are duly informed about the product?

The provision of product information (such as postal address) in digital format does not infringe on the customers right to access this information. Looking at current trends and future outlooks, the digitalisation of documents is an inevitable development that legislators should embrace.

k. Should consumers/users have the possibility to receive instructions on paper upon request? How often would consumers/users request paper-based instructions and would the burden be reduced with this option (comparing to mandatory paper-based instructions obligations)?

In the B2C area, it could be allowed for consumers to receive a paper version upon request. Consumers/users should have the option to request paper-based instructions at no cost for their initial copy. However, for subsequent requests, it may be reasonable to charge a fee. It is crucial to prevent distributors from developing a habit of requesting hardcopies unnecessarily, without an actual request from the customer, as this can result in unnecessary burdens. By offering the possibility of paper-based instructions upon request, while discouraging frivolous or unwarranted requests, the overall burden can be minimized, ensuring a more efficient and balanced approach for both consumers and distributors.

l. Could the digital product passport, and if so to what extent, ease administrative burdens of the economic operators and reduce costs?

Yes, as product can be delivered to the user without concern of language documents with the products, as the user can choose its preferred language online. Economic operators can easily supply updated information (additional accessories/software) online and

notify the user when registered. This, however, would only be the case, if the product passport is implemented instead of paper documentation to be provided with the product or on the packaging. Moreover, it is important that for compliance with NLF-requirements, mandatory data to be provided should not exceed the requirements set by the EU product legislation.
Nevertheless, the implementation of a digital product passport may not necessarily alleviate administrative burdens and reduce costs for economic operators. The process of collecting, maintaining, and sharing data in a digital format can be complex and may introduce additional challenges. Clear benefits can be identified for market surveillance authorities. By utilizing software tools, these authorities can efficiently identify discrepancies and enforce compliance, leading to improved monitoring and enforcement capabilities.

m. Do you encounter any problems in practice concerning the CE marking of software product?

No response.