

JBCE feedback on the Evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)

Japan Business Council in Europe (JBCE) thanks the European Commission for the opportunity to provide feedback on the Roadmap for the evaluation of the New Legislative Framework (NLF). Indeed, legal, technical and commercial developments are changing the way a product is assessed, placed on the market, updated, as well as the way information is shared, including with the end user of the product and market surveillance authorities. Therefore, an assessment of the NLF is welcome.

The NLF, based on the “New Approach” principle, allows a balance between the objectives of safety and other public interests forming the essential requirements of the directives and regulations with the flexibility offered to the manufacturers for the conformity assessment of the products, based on voluntary standards, harmonized at European level which are for the most part aligned at global level. However, we note that the referencing of harmonized standards has become very problematic, affecting the effectiveness of the NLF, and that this point appears to be missing in the program of the evaluation. We encourage to link to this evaluation, an assessment of European regulation 1025/2012 on standardization, particularly on the importance of a clear communication of normative references in line with the state of the art as provided by the standardisation offices, onto which technical compliance may be assumed by all the players.

On top, some inconsistencies in the scope and applications of harmonized standards of NLF directives (EMC and LVD) that may apply to vehicles needs to be considered.

Also, NLF directives are affected by the Regulation (EU) 2019/1020, and more particularly by its article 4. Nevertheless, the NLF decision and consequent directives and regulations haven’t been properly amended by that regulation. This fact shall be also part of the program of the evaluation as a way for improving the clarity of the regulation to the players, and more particularly economic operators, including Japanese Manufacturers.

Our detailed views on the six identified assessment focus points are in summary:

- i) [The NLF is fit to address the way products may be changing during their lifetime to both support the take-up of smart connected or remanufactured products and to ensure safety;](#)
For products whose characteristics may be changed through their lifetime, any new roles and obligations shall be attached to the operator who brings those changes to the product, and shall apply only where new or extended risk is introduced or the intended use of the product is changed. The existing NLF provisions are sufficient for remanufactured product outside the above category.
- ii) [The conformity assessment procedures remain fit for purpose and ensure the safety and compliance with the applicable requirements of the products placed on the Union market;](#)

The toolbox of conformity assessment procedures is adequate for addressing the categories of products presenting various levels of risk. The harmonisation legislator does have the choice of which should be available and the circumstances under which these are applicable. The NLF should not be adjusted to solve problems not directly attributable to it (e.g. inefficient citation of harmonised standards).

iii) **The rules for notified bodies are robust enough to ensure the competence of those bodies;**

JBCE doesn't represent any Notified body. Nevertheless, we noted that Notified body's opinions are usually based on available harmonised standards (cited in the official journal or not), in such situation the added value of the Notified body is limited to the identification of the proper standard. Where harmonised standard is not available, alignment of opinions based on common approach from different Notified bodies might be a subject of interest. Also, the information from Notified body to the manufacturer about the evaluation of the state of the art applicable to the approved product is rarely practiced despite the requirement according to the NLF. These 3 points shall be subject to the evaluation.

iv) **The accreditation system functions well and ensures that the competence of the notified bodies intervening in the conformity assessment procedures is sufficiently guaranteed;**
Same as iii)

v) **Affixing the CE marking and other product information to the product itself continues to be appropriate;**

Thanks to the generalisation of communicating technologies and digitalization over the last decade, affixing by hardware markings and contact details on product, and providing systematically paper instruction manual, can be avoided and replaced by e-labelling solution. JBCE believes this would seriously contribute to the reduction of the environmental footprint in line with the Circular Economy principles. This proposal shall be part of the evaluation.

The CE marking shall remain the reference mark to indicate full compliance with the essential requirements and additional markings or indications requested by individual member states to demonstrate compliance shall be avoided at all times.

vi) **Whether the lack of a crisis instrument for urgency situations renders the NLF less effective or efficient.**

The NLF together with Regulation (EU) 2019/1020 address such crises situations.

About JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of about 90 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, textiles and glass products. For more information:

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