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European Commission

EVALUATION ROADMAP

Roadmaps aim to inform citizens and stakeholders about the Commission's work to allow them to provide feedback and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to share any relevant information that they may have.

TITLE OF THE INITIATIVE	*Evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)*
LEAD DG (RESPONSIBLE UNIT)	GROW B1
INDICATIVE PLANNING	
ADDITIONAL INFORMATION	*https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en*

The Roadmap is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the document, including its timing, are subject to change.

A. Context, purpose and scope of the evaluation

Context

The New Legislative Framework (hereafter NLF) for EU product legislation consisted of Decision No 768/2008/EC and Regulation (EC) No 765/2008 aiming to improve the Internal Market for goods and boost the quality of conformity assessment of products. Decision No 768/2008/EC was a template for future Union product legislation and more than 20 pieces of legislation are today aligned to the Decision[1]. Since its adoption, industry and products have undergone a digital and green transformation. The NLF ensures the compliance of products with the applicable legislation at the time they are placed on the market. Products are increasingly digital and being frequently updated or upgraded after they have been put into service. They may also incorporate artificial intelligence that will lead to further changes of the product. Remanufacturing of products is an ever-growing business where the objectives of promoting the circular economy and ensuring product safety need to be adequately tackled. It needs to be reassessed whether the NLF continues to be fit for purpose in the current economic reality and changing digital environment. In addition, the conformity assessment procedures ensuring that products placed on the Union market are compliant with the applicable legislation must still be fit for purpose in this changing environment. Where an independent third party (the so called “notified bodies”) intervenes in the conformity assessment procedure, the competence of such a body needs to be guaranteed. To that end, the NLF defines the accreditation of notified bodies as the preferred means to demonstrate the competence of such bodies, and thus may play an important role, but its use is not compulsory in the EU[2].

In addition, the recent COVID-19 crisis has put to test the resilience of Union product legislation based in the provisions of the NLF, in particular as to whether they could adequately cope with a crisis. When certain products which were instrumental in the fight against COVID-19 (in particular personal protective equipment and medical devices) became scarce, the fast entrance of new products into the market appeared challenging, in particular as regards getting acquainted with the legislation and standards, and completing the conformity assessment procedures.

Purpose and scope

The Evaluation of the NLF shall assess the effectiveness, efficiency, its relevance in particular given the

[1] See https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

[2] EU product legislation is based on the fact that the manufacturer is responsible for the compliance of the product with the applicable legislation and must carry out the relevant conformity assessment procedure to demonstrate such compliance. Certain pieces of EU product legislation require a third-party conformity assessment body to intervene in the conformity assessment procedure and carry out certain tests on the product. Where this is the case, only those conformity assessment bodies designated by Member States authorities to that effect can perform the conformity assessment tasks required in that legislation. These are the so-called **notified bodies**. They must be notified to the Commission and other Member States by public authorities in the Member State where these bodies are established. These **notifying authorities** are responsible for the competence and monitoring of the notified bodies. In order to demonstrate their competence, notified bodies may provide an accreditation certificate, delivered by the **national accreditation body** and attesting their competence to perform the conformity assessment tasks specific required by EU product legislation, in accordance with Regulation (EC) No 765/2008.

technological development, the coherence with similar initiatives and the overall EU added value. The main purpose is to bring forward an informed analysis of the current performance of the NLF, with the exception of the provisions of the Regulation (EC) No 765/2008 relating to market surveillance, which were already subject to an evaluation and review[3]. The present evaluation will cover 27 EU Member States and 3 EFTA Members (Norway, Iceland and Liechtenstein) and the period from 2014 to 2020[4]. In particular, the assessment should focus on whether: 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; 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; iii) the rules for notified bodies are robust enough to ensure the competence of those bodies; iv) the accreditation system functions well and ensures that the competence of the notified bodies intervening in the conformity assessment procedures is sufficiently guaranteed; v) affixing the CE marking and other product information to the product itself continues to be appropriate; and vi) whether the lack of a crisis instrument for urgency situations renders the NLF less effective or efficient.

B. Better Regulation

Consultation of citizens and stakeholders

The consultation strategy will aim to ensure the highest possible representativeness across the different product sectors, type of stakeholders and Member States. The following categories of stakeholders will be consulted: 1) Member states relevant authorities including market surveillance authorities and notifying authorities) as well as accreditation bodies, 2) individual companies which are manufacturers, including SMEs and industry associations, 3) other economic operators (such as distributors and importers), 4) notified bodies, 5) consumer organisations.

The following consultation activities will be carried out:

- Public consultation aiming at gathering general evidence for the evaluation and lasting 16 weeks;
- Online targeted survey to collect quantitative and qualitative data from the different categories of stakeholders listed above;
- Interviews to gather information on the evaluation questions, including on the different type of compliance and administrative costs (mainly linked to the conformity assessment procedure) and benefits and to validate/test the evidence collected as well as filling the gaps to have a robust and credible basis to substantiate the evaluation's findings;
- A validation workshop will be organised with the main actors involved in the evaluation.

The Commission will inform stakeholders about the launch of the open public consultation.

Data collection and methodology

The methodology for the evaluation will include:

- Desk research and literature review, which include the previous evaluation for the Internal market legislation on Industrial products (SWD(2014)23), as well as existing evaluations of specific product legislation based on the NLF. It will also include the REFIT evaluation accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and annexes (SWD(2017)469), where relevant.
- The data analysis methodology will include at least the intervention logic analysis, indicators to measure the direct and indirect impacts of the NLF, triangulation of the information, relevant statistics to support the analysis to map regulatory and administrative costs and benefits stemming from the NLF. Data on cost-benefits of the NLF will be gathered through targeted surveys and interviews to the stakeholders that intervene in the process; economic operators (manufacturers, importers, distributors), notified bodies involved in the conformity assessment procedure, market surveillance authorities and consumer organisations.
- Case studies based on specific product categories based on the availability of data and the peculiarity of the product.

[3] The market surveillance provisions of Regulation (EC) No 765/2008 were already subject to a REFIT evaluation (SWD(2017) 469 final). Since then, a new Regulation (EU) 2019/1020 will replace those provisions as of July 2021.

[4] This evaluation will build upon, and complement the evaluation SWD(2014)23 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52014SC0023&qid=1604000100861) accompanying the Commission Communication COM(2014)25 on 'A vision for the internal market for industrial products' (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52014DC0025&qid=1603999880951).