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COMMISSION STAFF WORKING DOCUMENT
Accompanying the documents

Proposal for a Directive of the European Parliament and of the Council

amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

and

Proposal for a Regulation of the European Parliament and of the Council

amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications

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A. INTRODUCTION

In its Communication on ‘Long-term competitiveness of the EU: looking beyond 2030’¹, the Commission identified the need of having a regulatory system that achieves objectives at minimal costs. It has stipulated the aim to rationalise and simplify reporting requirements for companies and administrations and to reduce administrative burdens by 25%, without undermining the related policy objectives.

In her political guidelines, President von der Leyen emphasised that ‘We need to make business easier and faster in Europe’. To that end, each Commissioner is tasked with focusing on reducing administrative burdens and simplifying implementation and to stress-test the EU acquis. This is operationalised in the mission letters to all Members of the College, asking them to ensure that existing rules are fit-for-purpose and to focus on reducing administrative burdens and simplifying legislation. This includes reducing reporting obligations by at least 25% – and for SMEs at least 35%.

Furthermore, the Communication on “A simpler and faster Europe” set out a vision for an implementation and simplification agenda². The Commission indicated that it would review and adapt the regulatory framework to make it more responsive to the needs of people and businesses. Among the simplification initiatives that are mentioned, it includes a series of Omnibus packages to tackle priority areas identified with stakeholders over the past years. One of these initiatives relates to the removal of inefficient requests for paper format in product legislation. The other relates to faster unblocking of market access for products for which no standard exists, is not available or there is an urgent need.

Digitalisation

The EU should leverage the power of digital tools to deliver better and faster solutions.

The Communication ‘2030 Digital Compass: the European way for the Digital Decade’³ set out a vision for the digital transformation of businesses and for the digitalisation of public services. In line with this, the Commission promotes the ‘digital by default’ principle in the Better regulation toolbox⁴ to propose policies that are digital, interoperable, future-proof and agile by default.

The Digital Product Passport (‘DPP’) has been recognised as an important tool for the digital transition and a key enabler for the supervision of the e-commerce landscape in the recently published EU Toolbox for Safe and Sustainable E-Commerce⁵.

¹ COM(2023) 168 final.

² COM(2025)47 final, Communication on implementation and simplification.

³ COM(2021) 118 final.

⁴ Better Regulation tool #28 (Digital-ready Policymaking)

⁵ COM(2025)37 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions – A comprehensive EU toolbox for safe and sustainable e-commerce.

Both the Letta and the Draghi reports underlined the importance of digitalisation for simplification, the first proposing to use “horizontal instruments such as ‘simplification law’ that reduce and modernise the reporting obligations and [...] accelerate the digitalisation of authorisation and reporting procedures.” and the second indicating “the need to fully digitalise business to authority reporting.”

This initiative is fully in line with the above objectives, as well as the objectives of the Interoperable Europe Act⁶ and intends to simplify the life of businesses having to comply with one or several product-specific Directives and Regulations based on Article 114 TFEU and Article 100(2) TFEU. These contain obligations related to providing, further to a reasoned request, the declaration of conformity, information and documentation necessary to demonstrate the conformity of the product with the applicable legislations. Moreover, these legislations contain an obligation on manufacturers to provide instructions for use to consumers and other users of products across most sectors. Whether the obligations imposed by product legislation relate to business to government reporting or instructions for use, they are often interpreted by Member State authorities or other authorities as requiring the provision of paper documents. Clarifying that businesses are entitled to provide such documents in digital format not only allows them to save the costs related to paper-based processes but also encourages them to use digital technologies when exchanging information with public administrations and business partners.

Nevertheless, when it comes to instructions for use, it is necessary to safeguard the safety of consumers and other users. As such, it is important that manufacturers still provide safety information and other information related to the health and safety of consumers and other non-professional users in paper format. Providing instruction of use digitally will also offer users the possibility of easier access to information related to the product, including in different languages , and make it easier for information to be updated etc. In addition, it will be more inclusive for some categories of consumers with the possibility to include audio-visual material.

Common specifications

The EU’s Single Market rests upon more than 3600 harmonised European standards, which support the application of numerous EU legal acts. The importance and strategic role of standards for EU policy making was underlined in the Commission’s EU Strategy on Standardisation on setting global standards in support of a resilient, green and digital EU Single Market⁷.

Harmonised standards have proven to be a well-established tool for manufacturers to benefit from a presumption of conformity with the requirements of EU harmonisation legislation across the

⁶ Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act)

⁷ COM(2022) 31, Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions - An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU single market .

Single Market and at the same time to benefit from an easy way to access the market, also at reduced costs.

The Communication ‘A Competitiveness Compass for the EU’ identified the need to search for alternative options to give businesses legal security on compliance with the EU rules, in situations where harmonised standards do not exist, are not available or there is an urgent need⁸. Several legislative acts already contain an alternative option to provide businesses with legal predictability and ensure compliance with the EU acquis to cater for such situations. The present proposal’s objective is to align the alternative option in legislative acts that do not provide for any option to harmonised standards. The alternative option is to be done in a uniform manner as regards definition, legal effect, conditions under which that alternative option may be adopted as well as adoption procedure.

The initiative on common specifications is fully in line with the above referred objective and intends to simplify the life of businesses having to comply with one or several product-specific health and safety requirements, as enshrined in Directives and Regulations that make use of harmonised standards. The alternative option would thus provide legal predictability and certainty regarding compliance with the EU rules in situations where no standard exists, is not available or there is an urgent need.

B. ADMINISTRATIVE BURDEN ASSOCIATED WITH OBLIGATIONS TO PROVIDE PAPER DOCUMENTATION

Most EU Directives and Regulations under the New Legislative Framework (‘NLF’) do not impose any specific format through which economic operators have to provide information to national competent authorities and users. Nevertheless national competent authorities and other economic operators often require paper format. For example, certain Member States accept digital instructions to some extent in certain legislations, e.g. in Directive 2006/42/EC on machinery. This Directive will soon be repealed and replaced by Regulation (EU) 2023/1230 which provides for the possibility to provide instructions in digital form. However, other legislations, for example, the Regulation (EU) 2016/425 on personal protective equipment does not spell this out.

Because Member States and their various market surveillance authorities have divergent views, notified bodies also tend to refuse to certify the conformity of products in case instructions are provided in digital format. This means that quite often, manufacturers will prefer to stick to paper instructions for use to avoid compliance issues. This can lead to situations where for the same obligations, some Member States require the paper format while others accept a digital format. In addition, the language used in some EU legal texts may raise doubts about whether a digital format is acceptable for exchanging documents.

⁸ COM(2025)30 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions - A Competitiveness Compass for the EU

Obligations related to providing declaration of conformity

All the product legislations aligned with the NLF impose an obligation on the manufacturer to draw up an EU declaration of conformity before placing a product on the market.

Background: Declaration of Conformity

The EU declaration of conformity (DoC) is a mandatory document that a manufacturer or authorised representative needs to sign to declare that the products comply with the EU requirements. By signing the DoC they take full responsibility for the product's compliance with the applicable EU law.

A DoC must contain the following information:

- name and full business address of manufacturer or of authorised representative
- the product's serial number, model or type identification
- a statement, stating to take full responsibility
- means of identification of product allowing traceability – this can include an image
- the details of the notified body which carried out the conformity assessment procedure (if applicable)
- the relevant legislation with which the product complies, as well as any harmonised standards or other means used to prove compliance
- name and signature of the manufacturer
- the date the declaration was issued
- supplementary information (if applicable)

The DoC needs to be translated into the language or languages required by the EU country in which the product is sold.

Besides this obligation, some pieces of product legislation that are covered by this initiative require that a copy of the declaration of conformity accompany the product. These include:

- Regulation (EU) 2016/424 on cableway installations;
- Regulation (EU) 2016/425 on personal protective equipment;
- Regulation (EU) 2016/426 on appliances burning gaseous fuels;
- Directive 2000/14/EC on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors;
- Directive 2014/32/EU on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments;
- Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts;
- Directive 2014/34/EU on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres;

- Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment.

It would therefore be necessary to introduce the possibility for manufacturers to make the DoC available electronically. The DoC must be signed by the manufacturer and often needs to accompany the product. In some cases, it must be provided to market surveillance authorities upon request. Allowing this document to be made available electronically eases the manufacturer's obligations, eliminating the need for it to accompany each product by a paper-based DoC and enabling the provision of a link to the authorities when requested.

Where several pieces of Union harmonisation legislation apply to a product, the manufacturer or the authorised representative has to provide a single declaration of conformity in respect of all such Union acts. However, some recent pieces of EU product legislation, such as Regulation (EU) 2023/1542 concerning batteries and waste batteries ('Batteries Regulation'), foresee the use of a digital product passport (DPP) and the declaration of conformity for batteries is to be included in the digital passport – battery passport. It may happen that a battery for light means of transport is, in addition to the Batteries Regulation also subject to Regulation (EU) 2023/1230 on machinery ('Machinery Regulation'). In such cases, the manufacturer would need to include the declaration of conformity in the DPP under the Batteries Regulation, while the Machinery Regulation does not yet foresee the DPP.

This would mean that the manufacturer should create a DPP under the Batteries Regulation where the DoC drawn up according to the Batteries Regulation should be uploaded, as well as ensure another digitally accessible storage location for the DoC drawn up under the Machinery Regulation. First, this approach would not align with the principle of the single EU declaration of conformity, which aims to simplify and streamline the demonstration of the compliance of the product. Second, this would increase complexity, administrative burden and cost for manufacturers. Moreover, the product would need to bear another code or internet address, besides the QR code for the DPP, where the machinery-related DoC would be available.

This would not only increase the burden on manufacturers but also on authorities, who would need to verify compliance with multiple DoCs. Overall, this approach would result in increasing the burden for both economic operators and authorities, leading to greater complexity, costs, and administrative hurdles.

To avoid inconsistencies and an additional burden for manufacturers and to create an overall coherence between harmonised product laws under the NLF, it is necessary to introduce a provision that allows for the re-use of the DPP and its data carrier when such a DPP is made mandatory by another legal act that covers the same product.

Background: Digital Product Passport

Digital Product Passport (DPP) is a digital record that contains detailed information about a product. Introduced by the Ecodesign for Sustainable Products Regulation (ESPR) to store information about sustainability, environmental impact and regulatory compliance, it has evolved beyond its initial scope into a general container of digitalized product information. Commission proposals, like the Toys Safety Regulation, Detergents and Surfactants Regulation or the Green Claims Directive foresee to use the DPP to store regulatory compliance information like the EU declaration of conformity or conformity certificates.

The data points in the DPP will become mandatory gradually over time based on the adoption of Commission proposals mandating the use of the DPP and the implementation periods set in those proposals. For example, ecodesign data points will only become mandatory in the DPP once the delegated acts for products mentioned in the published ESPR Work Program will be adopted, irrespective if the DPP was introduced for a specific product by a different Commission proposal before.

Main aspects for DPP:

- User-friendly access
- Data integrity
- Differentiated Access
- Comprehensive Data Storage
- Longevity and availability
- Machine-readable, structured and transferable
- Based on open standards to prevent vendor lock-in

Obligations related to providing technical file/documentation

On a reasoned request from a competent national authority, businesses need to provide documentation that is necessary to demonstrate the conformity of the product⁹. This documentation may include certificates from notified bodies or technical documentation. The different pieces of legislation covered by this initiative either foresee that this documentation can be submitted in paper or electronic format, or do not specify any particular format. However, in practice, national authorities are not always ready to receive electronic files.

Regarding correspondence between businesses and conformity assessment bodies, there is no explicit reference to whether this should be electronic or paper-based. However, the language used in the annexes to the legislative acts may raise doubts about whether an electronic format is

⁹ The IA accompanying the revision of the Toys Safety Directive, estimated the annual number of inspections by MSAs in Europe to be around 25,000 (and may rise to 30,000 in case of implementation of the DPP).

acceptable for exchanging documents. Again, some notified bodies request paper format. This is due to the fact that the NLF was adopted in 2008 and the terminology used in it, in the spirit of that law, has been understood as a paper format.

It therefore seems necessary to introduce the obligation for such information exchange to take place electronically. Both businesses and notified bodies should be equipped to utilise digital tools. This transition can eliminate paper-based information, thereby reducing paper waste and supporting sustainability goals, which are often priorities in professional settings. Digital formats also help manage limited space in professional environments by reducing clutter and making it easier to organise and store essential safety information.

Obligations related to instructions

Under the NLF, manufacturers have the obligation to ensure that products are accompanied by instructions for use and other information, such as safety information, in a language that can be easily understood by consumers and other end-users, as determined by the Member State concerned. While the NLF does not impose a particular format for the instructions for use, practice has shown that practical experience indicates that most market surveillance authorities expect these instructions to be in paper format and consequently enforce this expectation on end users. This stems from the terminology used in the NLF, which has been interpreted within the context of the legal framework adopted in 2008. For instance, the NLF specifies that products should be accompanied by instructions and safety information, which, at the time of adoption, implied a paper format.

This interpretation cannot be easily altered because safety information still requires a paper format. Changing the long-standing interpretation of certain terms might disadvantage end users when a paper format is genuinely needed. Therefore, it is essential to explicitly clarify whether a digital format for certain documents is permissible or acceptable.

This leads to products being accompanied by paper booklets, which include the instructions in multiple languages (based on the Member States where the product is sold), with significant costs for manufacturers. While evidence on the actual use of paper instructions by EU consumers is not available¹⁰, some industry stakeholders consulted for this proposal signalled that this use is limited.

Considering that in 2024 no less than 94% of EU households had access to the internet¹¹, obliging the instructions for use accompanying the products in scope of the proposals to be in paper format is outdated and is not aligned with the current technologies, the practice of consumers nor with sustainability objectives. Consumers often report that they frequently find paper instructions burdensome, as they can easily be misplaced over time. When these instructions are needed, users often resort to searching for them online. Digital instructions provide a more convenient solution, as they are easily accessible, can be stored indefinitely without the risk of loss, and allow for quick searches of specific information. Additionally, digital formats can be updated more readily, ensuring users always have access to the most current information. This shift not only enhances

¹⁰ There is general research on the use of manuals by consumers, e.g. a research article from 2014 concluded that most people did not read manuals.

¹¹ Source: [Digital economy and society statistics - households and individuals - Statistics Explained](#)

user experience but also aligns with modern consumer habits and preferences. Yet, consumers who prefer having paper-based instruction will still be able to request one, free of charge, at the time of purchase, or up to six months after that purchase.

Consequently, manufacturers should be able to choose a digital format for the instructions for use. Where manufacturers choose to provide instructions for use in digital format, the essential safety information (including any parts of the instructions for use deemed imperative for safety) should still be provided in paper format to protect the safety of consumers or non-professional users. Moreover, users should be able to obtain a paper copy of the instructions for use upon request – at the time of the purchase and for a certain period after their purchase.

The reason a mandatory paper-based quick user guide has not been foreseen is that it could be an additional burden and at the same time such an obligation could give the impression that instructions for the safe use of the product are not necessarily required to be provided in paper form. It is challenging to distinctly separate safety information from instructions. Since safety information should always be provided in paper form with consumer products, it inherently includes the essential details necessary for safe and efficient use.

Other obligations related to paper format

Directive 2014/90/EU on marine equipment has a specific rule that a paper copy of the declaration of conformity needs to be kept on board an EU ship until the marine equipment is removed.

C. BURDENS FOR BUSINESSES ASSOCIATED WITH ABSENCE OF HARMONISED STANDARDS

The Commission is committed to a fair and effective functioning of the Single Market. The NLF and the inherent role of the European standardisation system play an important part in this.

This is why in recently revised product harmonisation legislation and Commission proposals; legal provisions refer to harmonised European standards that are elaborated in line with Article 10 of Regulation (EU) 1025/2012 on European standardisation.

By using harmonised standards, businesses benefit from a presumption of conformity with the essential requirements in a wide range of legislation. Depending on the sectoral legislation, this can enable simplified conformity assessment procedures, often without third-party conformity assessment (except for certain high-risk products). If harmonised standards are not available (in a timely manner or at all), businesses cannot benefit from the presumption of conformity. Consequently, they are obliged to resort to other methods to demonstrate conformity and to conduct a third-party conformity assessment, thereby incurring additional costs and complexity.

The non-availability or late availability of harmonised standards is common, as demonstrated by the forthcoming evaluation of the Standardisation Regulation. The evaluation concludes that current average timelines for standard-development do not meet market and policy needs. Stakeholders are critical about whether the current timelines (1) allow timely implementation in

relevant industries, (2) provide ample time for clear communication and preparation for implementation, and (3) are reasonable for industry stakeholders¹².

The issue has become increasingly pressing, as there have been situations in recent years when the European standardisation organisations (ESOs) did not provide the Commission with the requested harmonised standards. This leaves a gap in the application of EU legislation.

Following the recent European Court of Justice (ECJ) ruling on access to standards, ISO/IEC standards, which underpin the functioning of sectoral legislation, have not been offered to the Commission since March 2024. It is not expected that the situation will improve soon as ISO/IEC have initiated a litigation at the ECJ against the Commission. This lack of standards is now blocking – and seriously disrupting – the functioning of the Single Market. This situation will only exacerbate today there are 117 ISO/IEC harmonised standards that should have been offered to the Commission as a draft for referencing in the OJEU in the past 142 months but have not. The role of ISO and IEC standards in the EU is significant: 28% of CEN's harmonised European standards are based on ISO standards and 67% of CENELEC's harmonised standards are based on IEC standards.

The absence of ISO/IEC-based standards is undermining the functioning of the Single Market. Specifically, this means that businesses are facing the burden of having to find alternative methods to demonstrate conformity with EU regulatory requirements, leading to more paperwork, significantly higher costs, and disruptions to the Single Market's efficiency. This situation is already seriously disrupting the opening of biobanks, market entry of certain medical devices, and soon of heat pumps. Without these standards, businesses must find alternative ways to comply with EU laws.

The co-legislators have recognised the need to compensate for the non-availability of harmonised standards by introducing a safety net, the so-called fallback option, in various pieces of recently adopted EU product legislation (e.g. in respect of fertiliser products, medical devices, machinery and web-accessibility¹³. This fallback option enables the Commission to adopt common specifications via implementing acts with a comitology procedure). Depending on the product legislation, this option can be used under specific conditions, for instance when there is no harmonised standard available. The option was introduced only in recent legislation and under varying conditions, hence it cannot be applied in a comprehensive and coherent manner across existing product legislation. This adds to the legal complexity and unpredictability.

¹² Only 26% agreed or strongly agreed that standards are developed in a timeframe that allows timely implementation in relevant industries; only 35% agreed that the duration of the development process provides ample time for clear communication and preparation for implementation; only 30% agree that the timelines for standardisation requests are reasonable for industry stakeholders; Evaluation Study of the Regulation (EU) No 1025/2012 on European standardisation, Section 4.1.1.1

¹³ Regulation (EU) 2017/745 (on Medical Devices), Regulation (EU) 2017/746 (on In Vitro Diagnostic Medical Devices), Directive (EU) 2016/1629 (on technical requirements for inland waterway vessels), Directive (EU) 2016/2102 (Web Accessibility Directive), Directive (EU) 2019/882 (European Accessibility Act), Regulation (EU) 2019/1009 (Fertilisers Regulation), Regulation (EU) 2023/1230 (Machinery Regulation), Regulation (EU) 2023/1542 (on batteries and waste batteries), Regulation (EU) 2024/1689 (AI Act), Construction Products Regulation.

Therefore, the Commission now proposes to introduce the option of common specifications in a consistent manner across a wide range of product legislation, building up on the concept already available in several legislative acts. In the absence of harmonised standards, these common specifications provide legal certainty and simplification to businesses by helping them avoid the need to find other methods to demonstrate conformity, thus closing an existing gap in the application of EU legislation. In such situations, they also help businesses avoid the costs of third-party conformity assessment, which is often required by sectoral legislation in the absence of harmonised standards. Such costs can vary significantly between sectors and product categories (see Section E below). Moreover, in the absence of harmonised standards, common specifications can also provide clarity on product safety and thereby preserve consumer trust in products in the Single Market.

D. STAKEHOLDER CONSULTATIONS

1. Consultations carried out in prior impact assessments and evaluations

The issues related to the digitalisation of the DoC have been consulted with stakeholders in the context of past evaluations and impact assessments. This chapter briefly summarises the relevant findings contained in those documents.

(i) NLF evaluation and consultations

In the targeted consultations for the evaluation of the NLF¹⁴, 74.5% of the respondents thought that the efficiency of the conformity assessment procedure would largely improve (35 responses) due to digitalisation of the declaration of conformity / technical product information / technical file, without hindering market surveillance activities, while a further 12.8% (six responses) thought it would improve to a moderate extent.

The NLF evaluation also found (on p. 35) that “The burden of printing out product information to accompany the product (e.g. safety documentation, instruction manuals, guidance on reasonably foreseeable use etc.) was most likely to be rated high or very high (83%, 39 responses).”. In addition, it found (on p.49) that “Industry respondents were in favour of moving towards digital-only CE marking, product compliance and user information as soon as possible. This was seen as potentially reducing costs, but only if hard copy versions were no longer required. However, none of the national competent authorities shared this view.”

The NLF evaluation further found (on p. 50) that “Respondents that viewed digitalisation positively argued that it should always be possible to provide and access information, regarding whether a product carries the CE mark, and in relation to its declaration of conformity or the technical file, in digital format rather than on paper. Triangulating these findings with the views of interviewed stakeholders, a general consensus emerged across all stakeholder groups regarding the potential benefits of digitalising the obligations that require information to be printed. Most stakeholders believe that digitalisation could facilitate and speed up compliance by simplifying the

¹⁴ SWD(2022)364 final/2, p. 34

way in which manufacturers meet information obligations. Digitalisation would serve two objectives: simplification and environmental protection.”

According to the public consultation carried out for the NLF evaluation (p.50), 45,5% of the stakeholders would appreciate a digital CE marking, 63,2% would appraise positively the digital traceability information (e.g. postal address of the manufacturer/importer), while 72% took the view that providing safety documentation and instruction materials in a digital form would be beneficial. Economic operators, industry associations, consumer associations, MSAs and national competent authorities were asked in the targeted consultations about the extent to which the digitalisation of CE marking / traceability / product information would jeopardise the right of consumers to be duly informed. There was some divergence in the responses of the different stakeholder types. Industry associations (71%, 22 responses) and economic operators (43.8%, seven responses) were most likely to answer that digitalisation would ‘not at all’ jeopardise the consumer’s right to be informed. However, none of the national competent authorities shared this view. While some acknowledged that they preferred ‘a digital way forward’, it was also accepted that not all consumers are digitally adept. Stakeholders explained that providing information in a digital format of documents such as the EU declaration of conformity or the instruction accompanying the product, could be an ‘either/or’ option, and not an additional requirement. The development of common standards and specification for the content and format of the required product information would further facilitate the fulfilment of administrative obligations.

The NLF evaluation (on p. 60) also touched upon a relevant Opinion¹⁵ of the Fit for Future Platform (F4F), which suggested that the Commission evaluates carefully and draws lessons relevant to explore whether product information and documentation could be given digitally as a default (digital-by-default), except when the product information is mandatory for consumers. The F4F recommended that the Commission identifies where and when it could be encouraged that information is provided digitally.

(ii) Machinery Regulation Impact Assessment

The Impact Assessment of the Machinery Regulation¹⁶ reported on p. 19 that “Manufacturers state that the requirement to provide printed versions increases costs and administrative burden for economic operators and has a negative impact on the environment. On the other hand, some authorities and users (workers and consumer associations) have concerns about ending this requirement because of: (i) users that are less digitally savvy and that may prefer paper documentation; (ii) a lack of internet access in certain environments; and (iii) changes or updates to an online manual that might not match the version of an already purchased product.”

(iii) Digital labelling for fertilising products Impact Assessment

The Impact Assessment of digital labelling for fertilising products¹⁷ found (on p.219) that “Manufacturers are divided on whether digitalisation in general would save them money. 48.4%

¹⁵ Fit for Future Platform Opinion 2021/SBGR1/01 (New Legislative Framework for Products)

¹⁶ SWD(2021) 82 final

¹⁷ SWD(2023) 49 final

think that it would provide financial savings (N=49). The majority of those who thought that digitalisation would save them money were larger enterprises. SMEs were not so supportive of the view that digitalisation would save them money (p. 219)”

(iv) Toys Safety Regulation Impact Assessment

The 2023 Impact Assessment for the Toys Safety Regulation estimates that moving to digital provision of compliance information could save EUR 2.62-3.93 million per year in that sector only. In addition, it would lower the costs of inspections for companies, as relevant documentation would be available online, facilitating document retrieval.

(v) Standardisation Regulation public consultation

In the public consultation underpinning the forthcoming evaluation of the Standardisation Regulation, most respondents (55%) strongly agreed that the availability of harmonised standards facilitates cross-border activities and trade within the Internal Market, with 32% agreeing (sample size N=254). A majority of SMEs participating in the public consultation (N=66) strongly agreed (37%) or agreed (25%) that harmonised standards facilitate their access to the EU market. In the targeted consultation of industry, when asked about the efficiency of the time taken to develop harmonised standards, only a small percentage of industry stakeholders considered the current process efficient (4% strongly agree, 16% agree)¹⁸. Opinions of industry stakeholders were mixed regarding the impact of whether the time of the process does not hinder innovation, with 28 % agreeing, 14% strongly agreeing, but 24% disagreeing and 12% strongly disagreeing. Individual interviews with industry stakeholders underpinning the evaluation suggested that the speed of development and citation is not in line with market needs, which are evolving at a faster rate than harmonised standard development¹⁹.

2. Consultation of stakeholders

On 6 February 2025, the Commission organised an outreach event aiming at gathering the opinions and feedback of the stakeholders on the simplification exercise.

During this event, the Commission asked stakeholders whether a gradual approach to ‘digital by default’ in product legislation is beneficial or whether there are other aspects that need to be fixed. To this question, the stakeholders mainly answered that a gradual ‘digital by default’ initiative is indeed beneficial.

Moreover, when asked what the simplification benefits would from the ‘digital by default’ be and in which specific areas, stakeholders answered that they would benefit the most from a ‘digital by default’ approach regarding instructions for use and product compliance documentation.

In parallel, the Commission reached out directly to stakeholders representing sectorial industries in order to gather data on potential cost savings that a ‘digital by default’ policy could create.

¹⁸ Targeted Survey Industry Q9: To what extent are you satisfied with the time needed to develop harmonised standards? Sample size: N = 50. Results: 4% strongly agree, 16% agree, 30% disagreed, 22% strongly disagreed, 26% neither agreed nor disagreed and 2% doesn’t know.

¹⁹ Evaluation of the Standardisation Regulation (2025, forthcoming), Annex V

In addition, on 14 April 2025, the Commission consulted the members of Task Force 1 of the Industrial Forum and other stakeholders, including representatives of consumer organizations to gather their opinions on (i) the digitalisation of the DoC, digital instructions for use and on the introduction of the DPP and its use as a tool for making compliance related information accessible and (ii) the use of common specifications as a back-up solution where no harmonised standards exist. Digitalisation and voluntary digital instructions received broad support from industry at this event.

All members of the Industrial Forum could share their views on this simplification exercise and highlight their key expectations regarding the digitalisation of the EU product legislation, including answering (and disseminating to their members) and EU survey on aligning EU product legislation with the digital age. Nearly 100 answers were received to the EU survey by 25 April.

All stakeholders welcome and support the digitalisation. This reflected as well as in the written contributions, during the meeting and in the slido:

Declaration of Conformity (DoC)

- Unanimous support in favour of digitalisation. In the slido, a majority considers it as a burden reduction

Instructions for use:

- Support in favour of digitalisation. Industry would prefer to have the instructions only in digital/electronic format. While one consumer association expressed its preference to have the digital format in complement to the paper format, another consumer association supported the digital format of the instructions following the model of the Machinery Regulation in its written answer to the survey (i.e. that essential safety information is provided in paper and a paper copy of the instructions for use could be requested by the consumer).
- During the online consultation, a majority was in favour of voluntary digital instructions (i.e. the manufacturer has the choice, but the administration has to accept the digital format) and only a minority were in favour of mandatory digital instructions. This was underlined by several stakeholders.²⁰
- A majority of participants considers the digitalisation of instructions for use as a burden reduction.

Digital Product Passport (DPP)

- Most stakeholders expressed their support in favour of the DPP, be it in the survey, in the slido or during the meeting.

²⁰ During the meeting, some stakeholder asked to include the digitalisation of the instructions for use foreseen by the General Product Safety Regulation (this is, however, not foreseen in the scope of acts to be covered by the omnibus proposal: only specific product legislation is covered) and a representative from the medical device sector advocated a full digitalisation (medical devices are not in the scope of the omnibus proposal).

- Most stakeholders were in favour of using the DPP as a tool to provide the mandatory compliance documentation such as the DoC and instructions for use.
- The companies shall have the choice of the technical system to generate the DPP file as long as it complies with DPP standards.

Economic impact: costs and savings

- The stakeholders indicated that the digitalisation of the DoC and the instruction of use would imply zero costs or would be negligible.
- Several stakeholders underlined the savings that the digitalisation of instructions for use could bring: paper costs, transport and related environmental benefits. Figures were provided in the answers to the survey.
- Some companies provided estimates on the potential saving in their manufacturing sector of around 50 million euros. The field of activities concerned mainly household appliances, personal protective equipment or products falling under the radio-equipment directive, the ATEX directive or pressure equipment.

Standardisation

In response to the *EU survey* in the remits of the consultations of the Task Force 1 of the Industry Forum and additional stakeholders organised by DG GROW in April 2025, stakeholders showed concern about the burdens associated with the absence of harmonised standards:

- Respondents, including both major industry companies and SMEs, as well as industry representatives, emphasised the challenges arising from the absence of or delayed publication of harmonised standards, namely in terms of costs and administrative burden.
- In view of this, some stakeholders recommended improving legal clarity and mutual recognition of alternatives to harmonised standards.

In exchanges with National Standardisation Bodies, the acute problems resulting from the absence of harmonised standards and the value of uniform, consistent conditions for the use of common specifications were recognised.

The *Evaluation Study of the Regulation (EU) 1025/2012 on European Standardisation*, and the related public consultation and targeted consultations carried out in 2024, showed that:

- Industry strongly relies on a well-functioning standardisation system. Majority of industry respondents indicated strong agreement that harmonised standards support EU cross-border activities and trade. Without harmonised standards, businesses are faced with unnecessary complexity and costs.
- Industry expressed concern about the duration of the standard-development process, with a majority of industry stakeholders considering the current process inefficient.
- Some industry stakeholders cautioned against reducing the reliance on harmonised standards and consider that technical or common specifications should be used only as a last resort in case it is not possible to develop a harmonised standard within a reasonable amount of time.

E. OBJECTIVES TO BE ACHIEVED

1. Reducing administrative burden

The objective of this initiative is two-fold: (i) to reduce the burdens related to the provision of information in paper format as described above and (ii) to prevent future situations in which legal obligations enter into force without there being a reliable way to demonstrate compliance with such obligations due to the absence of relevant standards.

To achieve the digitalisation objective, it is necessary to amend the majority of directives and regulations under the NLF in order to clarify that the obligations of economic operators to provide information to national competent authorities (specifically those relating to the declarations of conformity) shall be fulfilled through digital means and that instructions for use may be provided digitally.

In order to achieve the burden reduction objective, the following changes are foreseen:

- Specifying that the EU declaration of conformity, or a similar document, must be drawn up in electronic form and made accessible through an internet address or machine-readable code when that declaration needs to accompany a product;
- The addition of a “digital contact” as information to be indicated by manufacturers on the products which are placed on the market in order to facilitate communication between economic operators and national authorities;
- Specifying that the instructions accompanying products may be provided in electronic form with the exception of the safety information which should be provided in paper for non-professional users while professional users may request paper-based safety information when there is a need for it. Digital safety information is more practical and beneficial for professional users, for several reasons. Professionals typically use products regularly and are well-versed in their safety requirements, reducing the need for constant reference to paper-based information. Eliminating paper-based information reduces paper waste and supports sustainability goals, which is often a priority for professional settings. Professional users also have the skills and tools to access digital formats of safety information, which can be more convenient and up-to-date than printed materials. The amendment of reporting obligations to national authorities that foresee a “paper or electronic format” to “electronic form” only;
- The insertion of an obligation for exchanges by electronic means between the economic operators and competent authorities;
- An obligation to provide the information contained in the EU declaration of conformity and instructions on the digital product passport when the product is subject to another Union legislation that requires the use of such digital product passport.

To achieve the objective of preventing future situations in which legal obligations enter into force without there being a reliable way to demonstrate compliance with such obligations due to the

absence of relevant standards, it is necessary to amend the majority of directives and regulations under the NLF in a coherent manner. The following changes are foreseen:

- The introduction of provisions empowering the Commission to adopt common specifications as an alternative to harmonised standards where no standards exist, are unavailable or there is an urgency.

The use of common specifications as a means of establishing technical requirements in EU legislation is a significant development that can have far-reaching implications for the implementation and enforcement of regulatory measures. The concept of common specifications already exists in EU legislation, to cater for situations where harmonised standards are needed but unavailable. Common specifications offer a flexible and efficient way to establish technical requirements, allowing for quicker adaptation to changing market conditions and technological advancements in situations where harmonised standards' development is insufficient. The process of developing common specifications is less cumbersome compared to harmonized standards, which are often delayed, as evident from the current unavailability of 117 harmonised standards based on ISO/IEC for over a year. The high dependency on ISO/IEC standards, with 28% of CEN harmonised standards based on ISO and 67% of CENELEC harmonised standards based on IEC, underscores the need for alternative solutions. Common specifications, which already exist in over 10 legislative acts and are proposed to be introduced in 16 further directives and regulations, have the same legal effect as harmonized standards, providing a viable alternative.

When considering the measure to address the legal certainty gap in situations where harmonised standards are not available, other measures than common specifications were considered, such as soft-law measures. A possible measure could have been guidelines which would provide necessary elements for economic operators to comply with essential requirements or a non-binding Commission communication on transitional methods that could be used temporarily to overcome absence of an applicable harmonised standard. However, soft law measures cannot produce any binding legal effects in the Single Market. Therefore, a legislative measure which would put common specifications on equal legal footing with harmonised standards was chosen as the most appropriate measure.

A potential drawback of the proposed solution is that the common specifications will not be developed by European standardisation organisation who according to standing rules laid down in Regulation No 1025/2012 retain exclusivity in standards development. However, the measure is aimed to precisely address the situation where the exclusive standard developers are not delivering harmonised standards which are necessary to support sectoral legislation.

The benefits of common specifications, including their ability to promote public safety, environmental protection, and economic growth, outweigh the drawbacks, making them a measure that ensures a smooth and effective solution in case of disruptions in availability of harmonised standards. Ultimately, the use of common specifications can help mitigate the urgent need for harmonized standards, providing a temporary solution to the current shortage.

this change does not affect the use and relevance of the traditional procedures for the development and delivery of harmonised standards yet creates a single coherent and reliable alternative with

uniform conditions of application in the EU acquis in case the three European Standardisation Organisations are not able to deliver draft harmonised standards in a timely manner.

This simplification measure is fully complementary with the planned revision of the Standardisation Regulation (Regulation (EU) 1025/2012), due for adoption in 2026. The revision will involve a comprehensive review and adaptation of the EU standardisation framework. As announced in the 2025 EU Competitiveness Compass, it will aim to accelerate standard-setting processes, make them more inclusive and introduce more agility and flexibility in the system.

The planned revision of the Standardisation Regulation does not remove the need to introduce a simpler and more coherent way to obtain common specifications across all sectoral/product legislation as a fall-back solution. As it concerns a comprehensive revision due in 2026, it also does not tackle the urgency related to the regulatory burden on businesses resulting from the refusal of certain standardisation organisations to submit draft harmonised standards, hence the need for this dedicated simplification measure.

a) Burden reduction for businesses

Digitalisation

As far as economic operators are concerned, the digitalisation of their obligations would simplify and facilitate as well as speed up the transmission of documents to national competent authorities. Cost savings would mainly derive from simpler document management (no handling of paper copies, and no update costs of existing documents) and paper and postage costs (replaced by electronic transmission).

As regards the obligation to provide the certificate of conformity and the technical file upon request of an authority, the related costs would be reduced to a one-off cost of uploading the relevant information to a digital storage. No information is available regarding the costs associated today to those actions, but they can be assumed to be relatively small at the level of an individual business. They may be more significant for EU businesses producing or importing a wide range of products falling under obligations related to the provision of DoCs or technical files to public authorities. On the other hand, businesses that are already making use of the possibility to provide the relevant information digitally and who only have to deal with public administrations that do not request paper documents will not see any savings. It is estimated that there are approximately 250 000 businesses active in the manufacturing sectors related to the products in scope of the omnibus. At the same time, this number may include EU manufacturing companies that only produce intermediate goods, which do not fall under the obligations related to the DoC and technical file and would therefore not realise any savings. There is no information about the numbers of products concerned, nor is there any data on how often manufacturers have to provide the DoC or technical file to an authority in paper format or what the related costs are. Assuming that this might happen on average once per year per company and for one product, and that the related cost for paper, printing and postage is about €4, this would mean that the expected annual cost savings could be in the magnitude of about €1 million.

The possibility to provide instructions for use only in digital format is likely to generate considerably larger savings for businesses. These savings relate to the avoided costs of procuring the paper, printing and handling costs. The personal protective equipment sector has estimated that digital instructions could help save between €100 million and €150 million for their industry per year. Similarly, for the home appliances sector, it estimated a potential of €170 million savings, noting that several manufacturers already have digital manuals available. The medical devices sector estimated yearly savings for the sector to be at least €13 million, whereas for producers of equipment for potentially explosive atmospheres the savings could amount to 2-3 € per device. No information is available regarding other sectors. The protective equipment and home appliances sectors are likely to cover a large part of the number of products concerned by the omnibus. On this basis, a conservative estimate of the savings related to the digital provision of instructions for use is that this will save businesses up to €300 million annually (the range of cost savings based on the three sectors for which estimates are available is between €283 million and €333 million per year).

Some industrial stakeholders noted that a possible requirement to print the instructions at consumer/end-user request might generate significant costs, however these cannot be estimated. Other industrial stakeholders did not consider it as a problem.

Common specifications

When harmonised standards are not available on time, manufacturers and businesses face significant uncertainty, leading to increased costs. A part of these costs concerns the need to resort to alternative methods to demonstrate compliance and to conduct more costly third-party conformity assessment. These third-party conformity assessment fees can vary greatly depending on the sector, the type of product and the legal requirements. According to the 2017 impact assessment on the New Legislative Framework²¹, they are estimated to amount to an average annual budget of firms for services of Notified Bodies is in the range of EUR 30 000 – 80 000 and around EUR 4 000 for certification of a single product. In the field of toys, in terms of certification costs (excluding costs for technical documentation and labelling), the 2023 impact assessment of the revision of the Toy Safety Directive reports²² an estimated average of EUR 500 per new toy model in case of self-certification and EUR 1 000 in case of third-party conformity assessment plus the costs of the internal production controls²³. Third-party conformity assessment fees for more complex products may be significantly higher. For example, the impact assessment of the Machinery Regulation (2023/1230) estimated the costs of the conformity assessment to be between

²¹ Impact Assessment 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, SWD(2017) 466 final

²² Staff Working Document, Impact assessment report accompanying the document proposal for a Regulation on the safety of toys and repealing Directive 2009/48/EC Toy Safety Regulation, SWD(2023) 269 final

²³ Internal production controls are part of Module C of a conformity assessment, as outlined in Decision 768/2008/EC. In the absence of a presumption of conformity from a harmonised standard, such internal production controls must be undertaken in addition to the third-party certification.

€105,000 and €275,000.²⁴ A full quantification is not possible in the absence of comprehensive granular data on the third-party assessment fees and products placed on the market but given the prevalence of self-assessments based on a presumption of conformity through the use of harmonised standards, the total costs can be significant.

Beyond these direct costs, the unpredictability related to the search for alternative methods to demonstrate compliance, their application and the uncertainty whether these alternative methods are accepted by the third-party conformity assessment can also carry significant burden. More resources are needed to identify and implement these alternative methods, although these cost implications are difficult to quantify. Furthermore, the potential costs of non-compliance, such as product recalls, fines and reputational damage can be substantial. These costs can be a significant obstacle for businesses, particularly small and medium-sized enterprises, which may not have the resources to absorb them.

By providing common specifications, the industry can reduce these costs and avoid the financial implications of non-compliance. Common specifications can help businesses avoid the costs of third-party conformity assessment and -in certain cases- product redesign, retesting, and recertification, which can be a significant expense. Furthermore, common specifications can reduce the costs associated with regulatory uncertainty, such as the costs of consulting with experts, conducting risk assessments, and developing contingency plans. By providing a mirror of the legal requirements, common specifications can help businesses save resources and allocate their budget more efficiently. This, in turn, can lead to increased competitiveness, improved profitability, and enhanced innovation, ultimately benefiting both businesses and consumers. The total cost savings will depend on the future prevalence of unavailable harmonised standards, which cannot be quantified. However, as presented in Section C above, the risk of non-availability of harmonised standards has significantly increased in light of the non-submission of recent ISO and IEC standards, which play an important role in the EU Single Market.

b) Burden reductions for public administrations

Abolishing the provision of paper documents in relation to the products covered by this initiative would also allow public administrations (e.g. market surveillance authorities) to realise savings related to paper handling (opening letters, registering the document, filing/storing the physical document). On the other hand, the public authorities need to ensure that their staff is trained to work with electronic documents/relevant IT systems. In the medium- to long-term, paperless processes are however likely to increase the efficiency of the relevant public bodies by paving the way for the adoption of modern IT tools that will automate relevant tasks. The savings for public administrations could not be quantified.

24 Commission Staff Working Document, Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council on machinery products, 21.4.2021, SWD (2021) 82 final

2. Supporting the digital transition

In 2024, the vast majority (95.36%) of EU enterprises with at least 10 employees and self-employed persons used a fixed broadband connection to access the internet. The share was even higher for medium and large enterprises, where almost all enterprises connect to the internet via fixed broadband. As far as household are concerned, 94% of EU Households had access to internet in 2024 (Source Eurostat).

The proposed amendments will contribute to reflect in the EU legislation the evolution observed among European citizens and economic operators. At the same time, they contribute to the digital transition and encourage technological innovation in businesses and public administrations.

In this context, clarifying that economic operators should only fulfil their obligations via digital means will encourage national competent authorities to rethink the ways they process submissions or reporting. A digital-by-default approach would create new incentives to invest in data collection and processing with eGovernment solutions that could pave the way to a document-free Single Market based on interoperable structured data and the once-only principle.

For national competent authorities, this would also pave the way for automation of market surveillance activities and digital enforcement and their associated benefits in terms of costs and efficiency.

3. Environmental benefits

There are environmental costs associated with paper documentation, from sourcing of raw materials, the paper manufacturing and printing process to disposal. Virgin paper is made from wood, which is important for terrestrial carbon-dioxide storage. In addition, paper production is an energy-intensive process. It is estimated that roughly one ton of CO₂ emissions are associated to the production of one ton of paper²⁵, with lower values for recycled paper and higher values for virgin paper. Using the above estimate of approximately €300 million savings related to paper documentation, and using an assumed 3 cents per page of A4 paper (stakeholder estimate), this would translate into 10 billion A4 pages saved per year. At an average paper weight of 5 g per A4 page, this would translate into savings of 50 000 tons of paper (and a similar amount of CO₂ emissions). CO₂ emissions could also be reduced due to decreased weight of products being transported and shipped, thanks to a possible elimination of paper instruction booklets.

On the other hand, there are environmental impacts related to the use of digital infrastructure (e.g. electricity use) and impacts related to the lifecycle costs of the digital infrastructure (e.g. where additional servers and storage need to be put in operation). At the same time, it can be argued that there is large technological progress in digital devices, continuously reducing energy use for the same functionality, which is unlikely to be the same for the lifecycle costs related to using paper. It can therefore be expected that the environmental balance in the medium to long run is favourable for replacing paper with digital technology.

²⁵ <https://bioresources.cnr.ncsu.edu/resources/life-cycle-carbon-footprint-analysis-of-pulp-and-paper-grades-in-the-united-states-using-production-line-based-data-and-integration/>

Conclusion on expected savings

The digitalisation of obligations related the provision of DoCs and the technical file will simplify and speed up the transmission of documents to national competent authorities. No significant costs are expected for manufacturers due to the foreseen flexibility regarding the digital means. Cost savings for manufacturers of the concerned products due to simpler document management and avoided paper and postage costs are estimated to be of a magnitude of approximately €1 million per year. The possibility to provide instructions for use in digital format could allow the manufacturers to save up to €300 million per year. As this depends on the (voluntary) uptake of this possibility by manufacturers, this estimate can only be seen as indicative. **The overall savings for companies related to digitalisation are thus estimated at around €300 million per year.** Public authorities may have to invest in training staff to work with digital tools but in the longer term, the digitalisation of DoCs and the technical file could allow for increased automation and efficiency gains. None of this could, however, be estimated.

The common specifications will provide a reliable and cost saving way for demonstrating conformity with EU requirements, in cases where harmonised standards are missing or insufficient. By mirroring the presumption of conformity for harmonised standards, common specifications provide an opportunity for businesses to avoid other more costly methods to demonstrate conformity. A full quantification of the overall savings is not possible in the absence of comprehensive granular data on the third-party assessment fees and the number of products placed on the market, but given the prevalence of self-assessments based on a presumption of conformity, the total costs can be significant.

The digitalisation is also expected to lead to environmental benefits related to saving paper. It is expected that this could save approximately 50 000 tons of CO₂ emissions per year.

Annex:

Application of the 'one in, one out' approach			
[M€]	One-off (annualised total net present value over the relevant period)	Recurrent (nominal values per year)	Total
Businesses			
New administrative burdens (INs)	n/a	n/a	n/a
Removed administrative burdens (OUTs)	n/a	An estimated EUR 1 million savings related to the provision of DoCs and technical file digitally EUR 300 million savings related to the possibility to provide instructions for use in digital format	EUR 301 million

<i>Net administrative burdens*</i>	n/a	EUR -301 million	EUR -301 million
Adjustment costs**	Not quantifiable but likely to be very limited	n/a	
Citizens			
New administrative burdens (INs)	n/a	n/a	n/a
Removed administrative burdens (OUTs)	n/a	n/a	n/a
<i>Net administrative burdens*</i>	n/a	n/a	n/a
Adjustment costs**	n/a	n/a	
Total administrative burdens***	n/a	EUR -301 million	EUR -301 million

(*) *Net administrative burdens* = *INs* – *OUTs*;

(**) *Adjustment costs* falling under the scope of the OIOO approach are the same as reported in Table 2 above. Non-annualised values;

(***) *Total administrative burdens* = *Net administrative burdens* for businesses + *net administrative burdens* for citizens.

I. Overview of Benefits (total for standardisation) – Preferred Option		
Description	Amount	Comments
Direct benefits		
Compliance cost reduction resulting from the availability of common specifications	On average 4 000 EUR per product, which would have required certification in the absence of a harmonised standard.	The figure given is not an aggregated one. It represents the amount for a single conformity assessment of one individual product (placed on the market) in the absence of harmonised standards and when no alternative option exists for using the presumption of conformity (i.e. common specifications) under one of the legislative acts covered by the proposal. On top of this, the business would avoid costs related to legal uncertainty and finding alternative methods to demonstrate compliance, which cannot be quantified.