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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

(Text with EEA relevance)

{SWD(2025) 130 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

In its Communication on 'Long-term competitiveness of the EU: looking beyond 2030'[1], the Commission stressed the importance of a regulatory system that ensures objectives are reached at minimum costs. To that end it committed to a dedicated effort to rationalise and simplify reporting requirements and administrative burdens, with the ultimate aim of reducing such requirements by 25% without undermining the related policy objectives.

Reporting requirements play a key role in ensuring the correct enforcement and proper monitoring of legislation. The costs of reporting are overall largely offset by the benefits they bring, in particular as regards monitoring and ensuring compliance with key policy measures. However, reporting requirements can also impose a disproportionate burden on stakeholders, particularly SMEs and micro-companies. The accumulation of these requirements over time can result in redundant, duplicate or obsolete obligations, inefficient frequency and timing, or inadequate methods of collection.

The Commission promotes the 'digital by default' principle in its Digital Strategy/ Better regulation to support digital transformations, facilitating digital-ready policies that take into account the fast-evolving world of digitalisation and technology and are digital, interoperable, future-proof and agile by default. However, there are still various pieces of EU legislation that provide for the use of paper format.

The Communication 'A Competitiveness Compass for the EU'[2] highlights that digitalisation goes hand in hand with simplification to reduce reporting burdens. The communication emphasises that reporting should move to digital formats based on standardised data. However, where digital procedures exist today, aspects such as fragmented IT ecosystems, and inefficient data exchanges all make it burdensome for businesses to interact with public authorities digitally.

The upcoming European Business Wallets initiative will address these challenges by establishing digital identity for all economic operators and by providing the framework for interoperable Business Wallets sharing verified data and credentials, enabling seamless digital interactions between economic operators and public administrations across the Union. This way, the European Business Wallets will build on the already existing digital solutions designed to simplify everyday activities for European economic operators, such as the Single Digital Gateway, the Once Only Technical System ('OOTS'), the Digital Product Passport ('DPP'), eInvoice, thus building a cohesive ecosystem of digital solutions that will maximise synergies and foster greater economic integration and innovation throughout Europe

Removing references to paper format would also force public authorities to rethink the ways they process submissions or reporting by companies. Streamlining such submissions and reporting by promoting digital-by-default would create new incentives to invest in data

[1] COM(2023)168.
[2] COM/2025/30 final.

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.

Moreover, while the New Legislative Framework ('NLF') does not impose a particular format for the instructions for use accompanying the products, practice has shown that most market surveillance authorities expect those instructions to be in paper format and therefore impose this format on manufacturers.

The Blue Guide[5] provides detailed explanations on EU product rules.

Taking into account that in 2024 no less than 94% of EU households had access to internet[3], the paper format of instructions for use accompanying products under the scope of the Regulations is outdated and not aligned with current technologies, consumer habits or green objectives.

Consequently, manufacturers should be able to choose digital format for instructions for use. Where manufacturers choose to provide instructions for use in digital format, the 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. Moreover, end-users should be able to obtain a paper copy of the instructions upon request – at the time of purchase and for a certain period of time after their purchase.

Streamlining reporting obligations, reducing administrative burden and promoting digitalisation are priorities. In this context, the present proposal aims to simplify initiatives included in the headline ambition 'An Economy that works for the people', a 'European Green deal' and 'Promoting our European way of life' in the policy area of the Internal Market, Food safety and Health, impacting a multitude of sectors.

Moreover, the Communication 'A Competitiveness Compass for the EU' identified the need to search for alternative options to give businesses legal certainty regarding compliance with EU rules in situations where harmonised standards do not exist, are not available, are not sufficient, or there is an urgent need. Several current legislative acts already contain an alternative option to provide businesses with legal predictability and prove compliance with EU law, to cater for such situations. The present proposal's objective is to align the alternative option in legislative acts which do not provide for any alternative option to harmonised standards. The alternative option is to be implemented in a uniform manner as regards definition, legal effect, the conditions under which that alternative option may be adopted and adoption procedure.

The initiative on common specifications is fully in line with the need referred to above and aims to simplify the life of businesses that have to comply with one or several product-specific health and safety requirements, as enshrined in sectoral regulations that make use of harmonised standards.

The proposal aims to rationalise and digitalise economic operators' obligations for Regulation (EU) 2016/424 on cableway installations[4], Regulation (EU) 2016/425 on personal protective

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3 Source: Digital economy and society statistics - households and individuals - Statistics Explained

4 Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/424/oj).

equipment[5], Regulation (EU) 2016/426 on appliances burning gaseous fuels[6], Regulation (EU) 2023/1230 on machinery[7], Regulation (EU) 2023/1542 concerning batteries and waste batteries[8] and Regulation (EU) 2024/1781 establishing a framework for the setting of ecodesign requirements for sustainable products[9] by a combination of measures.

Additionally, the proposal aims to align the existing fall-back option to harmonised standards uniformly in Regulation (EU) 2016/424 on cableway installations, Regulation (EU) 2016/425 on personal protective equipment, and Regulation (EU) 2016/426 on gas appliances.

To avoid inconsistencies and an additional burden on 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 use of the DPP's data carrier when such DPP is made mandatory by another piece of legislation that covers the same product.

- **Consistency with existing policy provisions in the policy area**

The proposal is part of a package of measures concerning simplification. It represents a significant step in a continuous process of comprehensively reviewing existing reporting requirements. The aim is to assess their continued relevance and make them more efficient, ultimately streamlining regulatory procedures and reducing administrative burdens.

The rationalisation introduced by these measures will not affect achievement of the objectives in the policy area, for the following reasons:

- The essential information required to ensure compliance with EU legislation will continue to be made available to the relevant authorities and to end-users.

- The increased efficiency of reporting procedures will facilitate the digitalisation of business-to-authority reporting, reduce the administrative burden on businesses and enhancing the overall effectiveness of the regulatory framework.

- The measures will also promote a more consistent and harmonised approach to economic operators' obligations across different EU laws, reducing confusion and facilitating compliance for businesses operating in multiple policy areas.

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5 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 5, ELI: http://data.europa.eu/eli/reg/2016/425/oj).

6 Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99, ELI: http://data.europa.eu/eli/reg/2016/426/oj).

7 Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1, http://data.europa.eu/eli/reg/2023/1230/oj).

8 Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: http://data.europa.eu/eli/reg/2023/1542/oj).

9 Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1781/oj).

- Furthermore, in cases where harmonised standards are not available, common specifications will be accepted, ensuring consistency with existing legislative provisions in certain sectoral policy areas and providing flexibility for businesses to demonstrate compliance.

- **Consistency with other Union policies**

Under the Regulatory Fitness and Performance Programme (REFIT), the Commission ensures that its legislation is fit for purpose, is, tailored to the needs of stakeholders and minimises burdens while achieving its objectives. This proposal is therefore part of the REFIT programme, aimed at reducing reporting burdens arising from Union legislation.

While certain obligations regarding requirements are essential, they need to be as efficient as possible, avoiding overlaps, removing unnecessary burden and using digital and interoperable solutions as much as possible.

The current proposals rationalise reporting requirements and thus make the achievement of the objectives of legislations more efficient and less burdensome for companies and public authorities.

In situations where harmonised standards are not available, alternative solutions are necessary to ensure compliance with Union legislation. These alternatives should be as effective as possible, minimising unnecessary complexity and available within short deadlines.

The introduction of these alternative solutions will streamline compliance with Union legislation, making it more efficient and less burdensome for companies and public authorities.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union, in line with the original legal bases for the adoption of the sectoral frameworks, which this proposal aims to amend. These sectoral frameworks are Regulation (EU) 2016/424 on cableway installations, Regulation (EU) 2016/425 on personal protective equipment, Regulation (EU) 2016/426 on appliances burning gaseous fuels, Regulation (EU) 2023/1230 on machinery, Regulation (EU) 2023/1542 concerning batteries and waste batteries, and Regulation (EU) 2024/1781 establishing a framework for the setting of ecodesign requirements for sustainable products and Regulation (EU) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products.

A common feature of these frameworks is that they are more or less closely aligned to the general principles and reference provision laid down in the NLF. The NLF for EU product legislation consists of two legal acts adopted in 2008, which are Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products[10] laying down reference provisions for the drawing up of Union legislation harmonising the conditions for the marketing of products, and Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation

[10] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13/08/2008, p. 82, ELI: http://data.europa.eu/eli/dec/2008/768(1)/oj).

and market surveillance relating to the marketing of products[11], which sets out the principles of the CE marking and accreditations of conformity assessment bodies.

The Union sectoral frameworks laid down by the above-mentioned Regulations are so-called "product harmonisation legislation". They lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of products. Essentially, these sectoral frameworks introduce for each respective sector/product category the essential requirements of public interest which the products should meet and the procedures on how to assess compliance with these requirements.

Thanks to the NLF, most of the above-mentioned pieces of legislation affected by this proposal contain provisions of a similar type. The legislative acts in question, which are aligned with the NLF, share a common structure and contain provisions based on the same model. Hence, the obligations of economic operators, provisions concerning notified conformity assessment bodies, accreditation, and CE marking are identical or very similar in all these legislative acts. This uniformity facilitates familiarity with the various legislative instruments, particularly for businesses that manufacture or distribute products subject to multiple EU legislative acts. The consistency of these elements enables economic operators to more easily navigate the regulatory landscape, thereby reducing complexity and promoting compliance. However, given that the model provisions were established in 2008, certain aspects of the obligations have become redundant or obsolete over time, necessitating a review and update to ensure their continued relevance and effectiveness.

Amending the above-mentioned Regulations in the proposed manner, i.e. removing of paper-based obligations and transitioning to digital equivalents will contribute to the digitalisation of business-to-authority reporting, facilitate the digitalisation of economic operators' obligations, and enhance the overall efficiency and effectiveness of the regulatory framework.

- **Subsidiarity (for non-exclusive competence)**

The reporting requirements and economic operators' obligations concerned are imposed by Union law and can therefore only be amended at Union level. Member States, companies and consumers will benefit from the removal of references to paper format and the digitalisation of the EU declaration of conformity for economic operators that is the subject of this proposal.

- **Proportionality**

The rationalisation and digitalisation of reporting requirements for economic operators' obligations simplifies the legal framework by introducing minimum changes to existing requirements that do not affect the substance of the wider policy objective. The proposal is therefore limited to those changes that are necessary to ensure efficiency without changing any of the substantial elements of the legislation concerned.

The amendments introduce minimal changes to existing requirements, focusing solely on the removal of paper-based references and the digitalisation of the EU declaration of conformity and instructions. By limiting the proposal to these necessary changes, the Commission ensures that the amendments are proportionate to the objectives pursued and do not compromise achievement of the policy goals.

[11] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30, ELI: http://data.europa.eu/eli/reg/2008/765/oj).

Common specifications as a fall-back option to harmonised standards simplify the legal framework by ensuring consistency in the internal market in the absence of available harmonised standards. The proposal is therefore limited to those changes that are necessary to ensure efficiency without changing any of the substantial elements of the legislation concerned.

The amendments introduce minimal changes to existing legislation, focusing solely on aligning common specifications in internal market legislation. By limiting the proposal to these necessary changes, the Commission ensures that the amendments are proportionate to the objectives pursued and do not compromise achievement of the policy goals.

- **Choice of the instrument**

All the regulations to be amended by this Regulation are sectoral pieces of harmonised product legislation under the single market rules and are aligned with the NLF. They all contain paper format references and references to the concept of harmonised standards and presumption of conformity.

The Evaluation of the NLF, published in November 2022, revealed that the NLF has successfully harmonised EU product legislation, resulting in a more coherent framework that has reduced burdens and generated cost savings for both businesses and authorities since 2008. However, the evaluation also highlighted that the NLF's outdated requirements, such as paper-based documentation and correspondence, hinder its ability to keep pace with digitalisation and meet modern expectations.

In conclusion, this omnibus is the best choice as legal instrument due to its ability to efficiently adapt to future needs and remain relevant by allowing for the removal of outdated references, such as to paper formats.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

N/A

- **Stakeholder consultations**

On 14 April 2025, the Commission organised an outreach event in the context of the Industrial Forum Task Force 1.

Members States, industry associations, manufacturers and consumer associations were invited to attend and to give their opinions on the digitalisation of reporting and manufacturer’s obligations. In particular, they were asked whether they believe providing the declaration of conformity and the instructions in electronic form would be seen as a burden reduction.

Answers received during the outreach event show that stakeholders are largely in favour of digitalisation as a form of burden reduction, with the vast majority of respondents indicating they consider digitalisation an effective way of reducing burden. Moreover, the majority of respondents indicated that they consider the digital declaration of conformity and the option to provide for digital instructions for use as burden reduction tool. As regards digital instructions, the majority of respondents expressed a preference for voluntary digital instructions (only if the manufacturer decides on this option).

In parallel, a written consultation was conducted via the same forum to gather stakeholders' opinions and any data on cost saving that this initiative could bring. The majority of respondents indicated they were in favour of digitalisation, including the digital declaration of conformity and digital instructions.

- **Collection and use of expertise**

The proposed simplification measures were identified following a process of internal scrutiny of existing reporting obligations and based on the experience gained from implementation of the related legislation. Since this is a step in the process of continuous assessment of reporting requirements arising from Union legislation, the scrutiny of such burden and of its impact on stakeholders will continue.

- **Impact assessment**

The proposal concerns limited and targeted changes of legislation with a view to simplify reporting requirements and digitalisation and alignment of common specifications. They are based on experience gained from implementing legislation. The changes do not have a significant impact on the policy, but ensure more efficient and effective implementation, also through aligning common specifications with standing legislation.

- **Regulatory fitness and simplification**

This is a REFIT proposal, aiming to simplify legislation and cut burdens for stakeholders.

- **Fundamental rights**

N/A

4. BUDGETARY IMPLICATIONS

N/A

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

N/A

- **Explanatory documents (for directives)**

N/A

- **Detailed explanation of the specific provisions of the proposal**

This proposal includes:

– 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. Once the European Business Wallet is available, the digital address it provides to economic operators could constitute the "digital contact";

– Specifying that the instructions accompanying products may be provided in electronic form, with the exception of safety information which should be provided on paper or marked on the product for consumers;

– The amendment of reporting obligations to national authorities that require 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;

– The introduction of a provision on common specifications as an alternative to harmonised standards;

– 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 other Union legislation that requires the use of such a digital product passport.

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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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Reporting requirements play a key role in ensuring proper monitoring and correct enforcement of legislation. However, in order to ensure that they fulfil their intended purpose and to limit the administrative burden, it is important to streamline those requirements.

(2) In its Communication on 'Long-term competitiveness of the EU: looking beyond 2030'[6], the Commission has committed to rationalise and simplify reporting requirements, with the aim to reduce such burdens by 25%, without undermining the related policy objectives.

(3) In its Better regulation Guidelines [2], the Commission promotes the 'digital by default' principle to support digital transformations, by facilitating digital-ready policies which consider the fast-evolving world of digitalisation and technology, and which are digital, interoperable, future-proof and agile by default.

(4) The increasing importance of digitalisation in simplifying regulatory frameworks necessitates the reduction and modernisation of reporting requirements and economic operators' obligations. In line with the efforts to accelerate digitalisation, it is essential to fully digitalise business-to-authority reporting and economic operators' obligations when they do not affect protection and safety of consumers. Embracing digitalisation

[1] OJ C , , p. .

[2] https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en.

will not only simplify compliance procedures but also enhance the overall efficiency of the regulatory framework, ultimately benefiting both businesses and authorities alike.

(5) A number of sectoral Union legal acts lay down harmonised rules regarding the obligations of economic operators when placing a product on the market or putting it into service. Such legal acts include Regulations (EU) 2016/424[3], (EU) 2016/425[4], (EU) 2016/426[5], (EU) 2023/1230[6], (EU) 2023/1542[7] and (EU) 2024/1781[8] of the European Parliament and of the Council (the 'Regulations concerned'). The Regulations concerned are based on the principles of the 'new approach' to technical harmonisation and are aligned with the reference provisions laid down in Decision No 768/2008/EC of the European Parliament and of the Council[9].

(6) In accordance with the Regulations concerned, manufacturers are to draw up an EU declaration of conformity stating that the fulfilment of essential requirements set out in the applicable Regulations has been demonstrated. In order to enable seamless electronic processes, the EU declaration of conformity should be drawn up only in electronic form.

(7) Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, and (EU) 2023/1230 require that a copy of the declaration of conformity accompanies the product. Considering the evolution of digitalisation, it is essential to modernise this obligation by requiring that such EU declaration of conformity electronically accompany the product. The manufacturer will make sure that the EU declaration of conformity is accessible through an internet address or a machine-readable code.

(8) Taking into account that in 2024 no less than 94% of EU households had access to internet[10], the paper format of the instructions accompanying the products under the scope of the Regulations concerned is outdated and not aligned with the current technologies, the practice of consumers nor with green objectives. Consequently, the possibility for a digital format of the instructions should be introduced in the

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3 Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/424/oj).

4 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51, ELI: http://data.europa.eu/eli/reg/2016/425/oj).

5 Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99, ELI: http://data.europa.eu/eli/reg/2016/426/oj).

6 Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and amending Directive (EU) 2021/647 (OJ L 165, 29.6.2023, p. 1, ELI: http://data.europa.eu/eli/reg/2023/1230/oj).

7 Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: http://data.europa.eu/eli/reg/2023/1542/oj).

8 Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L 281, 28.6.2024, p. 1, ELI: http://data.europa.eu/eli/reg/2024/1781/oj).

9 Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82, ELI: http://data.europa.eu/eli/dec/2008/768(1)/oj).

10 Source: Digital economy and society statistics - households and individuals - Statistics Explained.

Regulations concerned. This will allow manufacturers to provide instructions in digital format, if they wish to do so. Where manufacturers choose to provide instructions in digital format, in order to still protect the safety of consumers, the safety information, including instructions having impact on product safety, should be provided in paper format or marked on the product. Moreover, end-users should be able to obtain a paper copy of the instructions for use or safety information, upon request – at the time of the purchase and for a certain period of time after their purchase.

(9) In order to facilitate communication between economic operators and national competent authorities and end-users, the indication of a digital contact of the manufacturer on the product and in the EU declaration of conformity is necessary to enhance the effectiveness of market surveillance and to expedite the process of tracing non-compliant products. Currently, economic operators are required to indicate their postal address on the product, but this is not always sufficient to ensure that competent authorities can establish rapid contact. It is therefore necessary to require economic operators to provide both a postal address and a digital contact on the product and in the EU declaration of conformity. Such digital contact should be defined in the Regulations concerned.

(10) The Regulations concerned require that economic operators provide, on a reasoned request from a competent national authority, all information and documentation necessary to demonstrate the conformity of the concerned products with the respective Regulations, in paper or electronic form. The paper-based form is an outdated requirement, while electronic communication enhances interaction between authorities and businesses, streamlining processes and reducing administrative burdens. In order to achieve the digitalisation of reporting requirements and to reduce administrative burden for economic operators and competent authorities, the economic operators should be required to provide the necessary information and documentation in electronic form only. Documentation provided in electronic form could be made available, for example, in a digital printable format, which allows the possibility to print, download and save the documentation on an electronic device.

(11) The current Union standardisation framework, which is based on Regulation (EU) No 1025/2012 of the European Parliament and of the Council[11], represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety or other requirements. However, where no harmonised standards exist or where they are insufficient, the Commission should be able to adopt implementing acts establishing common specifications for the essential health and safety or other requirements, as an exceptional fall-back solution to facilitate the manufacturer's obligation to comply with those health and safety or other requirements.

(12) As the digital product passport is foreseen in certain EU legislation, such as Regulation (EU) 2023/1542, it is essential to require economic operators to store the information contained in the EU declaration of conformity and instructions in the digital product passport where a product is covered by multiple pieces of legislation.

[11] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12, ELI: http://data.europa.eu/eli/reg/2012/1025/oj).

This approach would reduce the administrative burden on manufacturers, as they would no longer need to maintain separate storage locations for compliance documents. By storing the documentation in one place, all necessary documents demonstrating product compliance would be easily accessible, ensuring transparency and facilitating compliance. This streamlined approach would enhance the overall efficiency of the regulatory framework, and it aligns with the principle that where several pieces of Union harmonisation legislation apply to a product, the manufacturer or other economic operator, where appropriate, should provide a single EU declaration of conformity.

(13) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as this Regulation amends Regulations which are harmonising products legislations but can rather by reason of better harmonisation of EU applicable rules to products, be achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(14) To ensure a smooth and effective transition, to minimize disruptions, and to provide a reasonable timeframe for industries to adjust to the new requirements amendments to Regulations (EU) 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation should be deferred. Amendments to Regulation (EU) 2023/1230 should apply from the date of application of that Regulation.

(15) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of amendments to Regulations (EU) 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the market in accordance with those Regulations in their version applicable before that date.

(16) Regulations (EU) 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 765/2008

Regulation (EU) 765/2008 is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (9a) is inserted:

‘(9a) ‘a common specification’ means a set of technical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a product, device, service, process or system;’;

(b) paragraph 10 is replaced by the following:

‘10. ‘accreditation’ shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards or common specifications and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;’;

(2) in Article 10, paragraph 5 is replaced by the following:

‘5. Peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 8, taking into account the relevant harmonised standards or common specifications referred to in Article 11.’;

(3) in Article 11, paragraph 1 is replaced by the following:

‘1. National accreditation bodies that demonstrate conformity with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the Official Journal of the European Union, or with the criteria laid down in common specifications , by having successfully undergone peer evaluation under Article 10 shall be presumed to fulfil the requirements laid down in Article 8.’.

Article 2

Amendments to Regulation (EU) 2016/424

Regulation (EU) 2016/424 is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (17a) is inserted:

‘(17a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(b) the following point (19a) is inserted:

‘(19a) ‘common specifications’ means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 11 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of a subsystem or a safety component with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’;

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in subsystem or safety component design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the subsystem or the safety component is declared shall be adequately taken into account.’;

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the subsystem or the safety component their name, registered trade name or registered trademark as well as their postal address and digital contact or, where

that is not possible, on the packaging or in a document accompanying the subsystem or safety component. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.';

(d) paragraph 7 is replaced by the following:

'7. Manufacturers shall ensure that the subsystem or the safety component is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the instructions and safety information, in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and safety information. When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

However, where a large number of subsystems or safety components are delivered to a single economic operator or end-user, the batch or consignment concerned may be accompanied by a single internet address or machine-readable code through which the EU declaration of conformity can be accessed.

When the instructions, referred to in the first subparagraph, are provided in electronic form the manufacturer shall:

(a) mark on the subsystem or the safety component, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the subsystem or the safety component; this requirement also applies where the instructions are embedded in the software of the subsystem or the safety component;

(c) make them accessible online during the expected lifetime of the subsystem or the safety component and for at least 30 years after the placing on the market of the subsystem or the safety component.

However, the end-user may, at time of the purchase of the product, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(e) paragraph 9 is replaced by the following:

'9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.';

(3) in Article 12(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component;’;

(4) Article 13 is amended as follows:

(a) in paragraph 2, first subparagraph, the second sentence is replaced by the following:

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the subsystem or the safety component bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the instructions and safety information and, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 11(5) and (6).’;

(b) in paragraph 3, first subparagraph, the first sentence is replaced by the following:

‘Importers shall indicate on the subsystem or the safety component their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the subsystem or safety component.’;

(c) paragraph 9 is replaced by the following:

‘9. Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.’;

(5) Article 14 is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

‘Before making a subsystem or a safety component available on the market, distributors shall verify that the subsystem or the safety component bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the instructions and safety information and, where appropriate, by other required documents, in a language which can be easily understood by end-users as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 11(5) and (6) and Article 13(3) respectively.’;

(b) paragraph 5 is replaced by the following:

‘5. Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have made available on the market.’;

(6) the following Article 17a is inserted:

‘*Article 17a*

Common Specifications

1. The Commission may by means of implementing acts adopt common specifications that enable compliance with the essential requirements set out in Annex II in any of the following cases:

(a) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;

(b) requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of a product with the essential requirements set out in Annex II; or

(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

2. Subsystems and safety components that are in conformity with common specifications or parts thereof shall be presumed to be in conformity with essential requirements covered by those specifications or parts thereof, set out in Annex II.';

(7) in Article 18, paragraph 3 is replaced by the following:

'3. Records and correspondence relating to the conformity assessment procedures shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures referred to in paragraph 2 is established or in a language accepted by that body. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.';

(8) in Article 19, the following paragraph 5 is added:

'5. Where other Union legislation applicable to subsystem or a safety component requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in in Annex IX to be included in the EU declaration of conformity and referred to in Article 11(7) shall be provided only in that digital product passport.';

(9) in Article 26, paragraph 7, point (c) is replaced by the following:

'(c) appropriate knowledge and understanding of the essential requirements set out in Annex II, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;';

(10) in Article 34, paragraph 3 is replaced by the following:

'3. Where a notified body finds that the essential requirements set out in Annex II or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.';

(11) in Article 43(1), point (d) is replaced by the following:

'(d) the subsystem or safety component is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;'.

(12) Annexes III to IX are amended in accordance with Annex I to this Regulation.

Article 3

Amendments to Regulation (EU) 2016/425

Regulation (EU) No 2016/425 is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (8a) is inserted:

‘(8a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(b) the following point (10a) is inserted:

‘(10a) ‘common specifications’ means a set of technical requirements, other than a standard, that provides a means of complying with the essential requirements applicable to a product, device, service, process or system;’;

(2) Article 8 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15, in electronic form, and affix the CE marking referred to in Article 16.’;

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in the design or characteristics of the PPE and changes in the harmonised standards, or in the common specifications, or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.’;

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the PPE. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;

(d) paragraphs 7 and 8 are replaced by the following:

‘7. Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and information may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the PPE when deciding the specific format for the instructions and information set out in point 1.4 of Annex II.

In the case of PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or make them visible on the packaging, the instructions and information set out in point 1.4 of Annex II.. Such information shall be easily visible and legible for consumers.

When drafting the instructions and information set out in point 1.4 of Annex II, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the PPE, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the PPE; this requirement also applies where the instructions are embedded in the software of the PPE;

(c) make them accessible online during the expected lifetime of the PPE and for at least 10 years after the placing on the market of the PPE.

However, the end-user may, at time of the purchase of the PPE, or up to six months after that purchase, request the instructions and information set out in point 1.4 of Annex II in paper format. Where the end-user requests those instructions and information set out in point 1.4 of Annex II, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.

8. The manufacturer shall provide the internet address or machine-readable code through which the EU declaration of conformity can be accessed with the PPE.';

(e) in paragraph 10, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority.';

(3) in Article 9(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the PPE;';

(4) Article 10 is amended as follows:

(a) in paragraph 3, the first sentence is replaced by the following:

'Importers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact through which they can be reached or, where that is not possible, on its packaging or in a document accompanying the PPE.';

(b) in paragraph 9, the first sentence is replaced by the following:

'Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority.';

(5) in Article 11(5) the first sentence is replaced by the following:

'Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the PPE.';

(6) the following Article 14a is inserted:

‘Article 14a

Common Specifications

1. The Commission may by means of implementing acts adopt common specifications that enable compliance with essential requirements set out in Annex II in any of the following cases:

   (a) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;

   (b) requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of PPE with the requirements set out in Annex II, or

   (c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant PPE.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

2. PPE that is in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II.’;

(7) in Article 15, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to the PPE requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IX to be included in the EU declaration of conformity and the instructions referred to in Article 8(7) shall be provided only in that digital product passport.’;

(8) in Article 19, the following paragraph is added:

‘Where applicable, the manufacturer shall provide to the notified body carrying out the conformity assessment procedure all the information and documentation relating to conformity assessment procedures in electronic form.’;

(9) in Article 24(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards or common specifications, and of the relevant provisions of Union harmonisation legislation and of national legislation’;

(10) Article 25 is replaced by the following:

‘Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or common specifications or parts thereof the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.’;

(11) In Article 32, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential health and safety requirements set out in Annex II or the corresponding harmonised standards, or common specifications, or other

technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.'

(12) Annexes II, III, V, VII, VIII, and IX are amended in accordance with Annex II to this Regulation.

Article 4

Amendments to Regulation (EU) 2016/426

Regulation (EU) No 2016/426 is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (21a) is inserted:

'(21a) digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;'

(b) the following point (23a) is inserted:

'(23a) 'common specifications' means a set of technical requirements, other than a standard, that provides a means of complying with the essential requirements applicable to a product, device, service, process or system;';

(2) Article 7 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

'Where compliance of an appliance or a fitting with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.';

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

'Changes in appliance or fitting design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the appliance or the fitting is declared shall be adequately taken into account.';

(c) paragraphs 6 and 7 are replaced by the following:

'6. Manufacturers shall indicate on the appliance their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the appliance. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.

Manufacturers shall indicate on the fitting their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the fitting. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities.7. Manufacturers shall ensure that the appliance is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, in a language which can be easily understood by consumers and other end-users, as

determined by the Member State concerned. The instructions and safety information may be provided in an electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

Manufacturers shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and safety information.

In the case of appliance or fitting intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the equipment, the safety information. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

Manufacturers shall ensure that the fitting is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned. The instructions may be provided in electronic form.

However, where a large number of fittings are delivered to a single end-user, the batch or consignment concerned may be accompanied by a single internet address or machine-readable code through which the EU declaration of conformity can be accessed.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

(a) mark on the appliance or fitting, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;

(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the appliance or fitting;

(c) make them accessible online during the expected lifetime of the appliance or fitting and for at least 10 years after the placing on the market of the appliance or fitting.

However, the end-user may, at time of the purchase of the appliance or fitting, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';';

(d) in paragraph 9, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the appliance or the fitting with this Regulation, in a language which can be easily understood by that authority.';

(3) in Article 8(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the appliance or the fitting;';

(4) Article 9 is amended as follows:

(a) in paragraph 2, second subparagraph, the second sentence is replaced by the following:

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the fitting bears the CE marking and is accompanied by the internet address and machine-readable code through which the EU declaration of conformity can be accessed and by, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).’;

(b) paragraph 3 is replaced by the following:

‘3. Importers shall indicate on the appliance their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the appliance. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.

Importers shall indicate on the fitting their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the fitting. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities.’;

(c) in paragraph 4, the second subparagraph is replaced by the following:

‘Importers shall ensure that the fitting is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned.’;

(d) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an appliance or a fitting in a language which can be easily understood by that authority.’;

(5) Article 10 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Before making a fitting available on the market, distributors shall verify that the fitting bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed, and by, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.’;

(6) in paragraph 5, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an appliance or a fitting.’;

(7) the following Article 13a is inserted:

‘*Article 13a*

Common Specifications

1. The Commission may by means of implementing acts adopt common specifications that enable compliance with essential requirements set out in Annex I in any of the following cases:

   (a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;

   (b) requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of appliances and fittings with the requirements set out in Annex I, or

   (c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.

Those implementing acts shall be adopted in accordance with the advisory procedure as provided for in Article 42(2).

2. Appliances and fittings that are in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex I.’;

(8) Article 14 is amended as follows:

   (a) paragraph 4 is replaced by the following:

‘4. Records and correspondence relating to conformity assessment of an appliance or a fitting shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures referred to in paragraphs 2 and 3 is established or in a language accepted by that body.’;

   (b) the following paragraph 5 is added:

‘5. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’;

(9) Article 15 is amended as follows:

   (a) paragraph 6 is replaced by the following:

‘6. The fitting shall be accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed.’;

   (b) the following paragraph 7 is added:

‘7. Where other Union legislation applicable to an appliance or a fitting requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex II to be included in the EU declaration of conformity and the instructions referred to in Article 7(7) shall be provided only in that digital product passport.’;

(10) in Article 23(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’;

(11) in Article 31, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.’

(12) in Article 40(1), point (f) is replaced by the following:

‘(f) the fitting is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;’;

(13) Annexes III and V are amended in accordance with Annex III to this Regulation.

Article 5

Amendments to Regulation (EU) 2023/1230

Regulation (EU) 2023/1230 is amended as follows:

(1) in Article 3, the following point (22a) is inserted:

‘(22a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application.’;

(2) Article 10 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of machinery or a related product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity, in digital format, in accordance with Article 21 and affix the CE marking in accordance with Article 24.’;

(b) in paragraph 8, the first subparagraph is replaced by the following:

‘Manufacturers shall ensure that the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity set out in Part A of Annex V can be accessed.’;

(c) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related products with this Regulation, in a language which can be easily understood by that authority.’;

(3) Article 11 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of partly completed machinery with the relevant essential health and safety requirements set out in Annex III has been demonstrated in the technical

documentation set out in Part B, of Annex IV, manufacturers shall draw up the EU declaration of incorporation, in digital format, in accordance with Article 22.';

(b) in paragraph 8, the first subparagraph is replaced by the following:

'Manufacturers shall ensure that the partly completed machinery is accompanied by the internet address or machine-readable code through which the EU declaration of incorporation set out in Part B of Annex V can be accessed.';

(c) in paragraph 10, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation, in a language which can be easily understood by that authority.';

(4) in Article 12(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the product within the scope of this Regulation;';

(5) in Article 13(9), the first sentence is replaced by the following:

'9. Importers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority.';

(6) in Article 14(8), the first sentence is replaced by the following:

'Importers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation in a language that can be easily understood by that authority.';

(7) Article 15 is amended as follows:

(a) in paragraph 2, point (b) is replaced by the following:

'(b) the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity referred to in Article 10(8) can be accessed;';

(b) in paragraph 6, the first sentence is replaced by the following:

'Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related product with this Regulation in a language that can be easily understood by that authority.';

(8) in Article 16(6), the first sentence is replaced by the following:

'Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation.';

(9) in Article 21, the following paragraph 5 is added:

'5. Where other Union legislation applicable to machinery or related products requires the economic operator to include the information that the product complies with the requirements

set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Parts A of Annex V to be included in the EU declaration of conformity and the instructions referred to in Article 10(7) shall be provided only in that digital product passport.';

(10) in Article 22, the following paragraph 5 is added:

'5. Where other Union legislation applicable to machinery or related products requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of incorporation or instructions in a digital product passport, the information required in Parts B of Annex V to be included in the EU declaration of incorporation and the instructions referred to in Article 11(7) shall be provided only in that digital product passport.';

(11) in Article 25, the following paragraph 6 is added:

'6. Where applicable, the manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in digital format.';

(12) Annexes III, V, VII, IX, and X are amended in accordance with Annex IV to this Regulation.

Article 6

Amendments to Regulation (EU) 2023/1542

Regulation (EU) 2023/1542 is amended as follows:

(1) in Article 3 the following point (23a) is inserted:

'(23a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application.';

(2) Article 17 is amended as follows:

(a) paragraph 4 is replaced by the following:

'4. Records and correspondence relating to the conformity assessment procedures of batteries shall be drawn up, in electronic form, in the official language or languages of the Member State where the notified body carrying out the conformity assessment procedures is established, or in one or more languages accepted by that body.';

(b) the following paragraph 5 is added:

'5. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.';

(3) in Article 18(2), the third sentence is replaced by the following:

'It shall be drawn up in electronic form.';

(4) Article 38 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. When placing a battery on the market or putting it into service, including for the manufacturers' own purposes, manufacturers shall ensure that the battery:

(a) has been designed and manufactured in accordance with Articles 6 to 10 and Articles 12 and 14, and is, for stationary battery energy storage systems, accompanied by clear, understandable and readable instructions and safety information in a language or languages which can be easily understood by end-users, as determined by the Member State in which the battery is to be placed on the market or put into service; and

(b) is marked and labelled in accordance with Article 13.

The instructions and safety information for stationary battery energy storage systems may be provided in electronic form. In the case of stationary battery energy storage systems intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, the safety information.

When the instructions are provided in electronic form, the manufacturer shall mark on the battery, or, where that is not possible, on its packaging or in an accompanying document, that they are accessible in the battery passport and how to request them in paper format.

The end-user may, at time of the purchase of the stationary battery energy storage systems, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.';

(b) in paragraph 7, the first sentence is replaced by the following:

'Manufacturers shall indicate on the battery their name, registered trade name or registered trademark as well as their postal address and digital contact, indicating a single contact point.';

(c) in paragraph 10, the second sentence is replaced by the following:

'That information and documentation shall be provided in electronic form.';

(5) in Article 39, the second sentence is replaced by the following:

'That information and documentation shall be provided, in electronic form, free of charge.';

(6) in Article 40(3), point (b) is replaced by the following:

'(b) further to a reasoned request from a national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the battery';

(7) Article 41 is amended as follows:

(a) in paragraph 3, the first sentence is replaced by the following:

'Importers shall indicate on the battery their name, registered trade name or registered trademark as well as their postal address and digital contact, indicating a single contact point.';

(b) in paragraph 8, the second sentence is replaced by the following:

'That information and the documentation shall be provided in electronic form.';

(8) in Article 42(6), the second sentence is replaced by the following:

'That information and the documentation shall be provided in electronic form.';

(9) Annexes VIII, IX and XIII are amended in accordance with Annex V to this Regulation.

Article 7

Amendments to Regulation (EU) 2024/1781

Regulation (EU) 2024/1781 is amended as follows:

(1) in Article 2, the following point (46a) is inserted:

‘(46a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’;

(2) in Article 24(2), the second sentence is replaced by the following:

‘Such information and documentation shall be provided, in electronic form, within 30 days of receipt of the request.’;

(3) in Article 27(10), the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, as soon as possible and in any event within 15 days of receipt of a request by that authority.’;

(4) in Article 28(2), point (c) is replaced by the following:

‘(c) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product, in a language that can be easily understood by that authority as soon as possible and in any event within 15 days of receipt of such a request; and’;

(5) in Article 29(8), the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, as soon as possible and in any event within 15 days of receipt of a request by that authority.’;

(6) in Article 30(5), first subparagraph, the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, within 15 days of receipt of a request by that authority.’;

(7) in Annex V, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, the manufacturer’s authorised representative.’.

Article 8

Transitional provision

Member States shall not impede the making available on the market of products which were placed on the market in accordance with Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1542 and (EU) 2024/1781 before [OP: *please insert 24 months after entry into force of this amending Regulation*)].

Article 9

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 5 and Annex IV shall apply from 20 January 2027.

The following provisions shall apply from [OP: *please insert 24 months after entry into force of this amending Regulation*]:

(a) Article 2, point(1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5), (7), (8) and (11);

(b) Article 3, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7) and (8);

(c) Article 4, point (1)(a), points (2)(a), (c) and (d), and points (3), (4), (5), (6), (8), (9) and (12);

(d) Articles 6 and 7;

(e) Annex I, point (1)(a) and (c), point (2)(a), point (3)(a), point (4)(a), point (5)(a), (d) and (e), and point (7)(a);

(f) Annex II, point (1)(a), point (3)(a), (c)(i) and (d)(i), point (4)(a), point (5)(a) and point (6)(a);

(g) Annex III, point (1)(a)(i), (c), (e) and(g) and point (2)(a);

(h) Annex V.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

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 alignment of common specifications

1.2. Policy area(s) concerned

Better Regulation, Competitiveness

1.3. Objective(s)

1.3.1. General objective(s)

To support the growth and development of companies, thus increasing their competitiveness and contribution to European welfare and prosperity.

To promote a favorable business environment and to reduce administrative burdens for companies, thereby enhancing their ability to innovate, create jobs, and contribute to economic growth.

1.3.2. Specific objective(s)

Removing paper format references for declaration of conformity for for manufactures who have to provide such declarations of conformity under New Legislative Framework ('NLF') directives and regulations,

Introducing possibility for the manufacturer to provide a digital format of the instructions for use,

To provide alternative options to give businesses legal certainty on compliance with the EU rules, in situations where harmonised standards do not exist, are not available or there is an urgent need.

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposal/initiative is expected to have the following effects on the beneficiaries/groups targeted:

- reduce burden of paper copies,

- Reduced administrative burdens: manufacturers will experience a reduction in administrative burdens, which will enable them to focus on their core business activities and improve their competitiveness

- Improved competitiveness: manufacturer will become more competitive, both domestically and internationally, which will enable them to increase their market share and contribute to European economic growth

- Job creation: The growth and development of manufacturers will lead to the creation of new jobs, which will contribute to reducing unemployment and promoting social cohesion

- Increased innovation: digitalisation of declarations of confirmity, of instruction will encouraged innovation and create new incentives to invest in data collection and processing with eGovernment solutions, which will contribute to improving the overall innovation capacity of the European economy

Target groups:

The proposal/initiative is targeted at the approximately manufacturers active in the field of the abovementioned directives.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

N/A

1.4. The proposal/initiative relates to: None of the below.

☐ a new action

☐ a new action following a pilot project / preparatory action[23]

☐ the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

This proposal concerns two omnibus acts amending EU legislation. It can therefore only be carried out at EU level.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

N/A

1.5.3. Lessons learned from similar experiences in the past

N/A

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

N/A

1.5.5. Assessment of the different available financing options, including scope for redeployment

N/A

[23] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☐ **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. Method(s) of budget implementation planned[24]

☐ **Direct management** by the Commission

– ☐ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated

– ☐ international organisations and their agencies (to be specified)

– ☐ the European Investment Bank and the European Investment Fund

– ☐ bodies referred to in Articles 70 and 71 of the Financial Regulation

– ☐ public law bodies

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees

– ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

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[24] Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx.

If more than one budget implementation method is indicated, please provide details in the 'Comments' section.

Comments

N/A

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

N/A

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

N/A

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

N/A

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

N/A.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the anti-fraud strategy.

N/A

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

Please note that an Excel tool is available on the BUDGpedia page on the Legislative Financial and Digital Statement to help you with the calculations. You are strongly advised to use it to facilitate filling in this template.

Please insert as many budget lines as needed in the two tables below.

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[25]	from EFTA countries [26]	from candidate countries and potential candidates [27]	From other third countries	other assigned revenue
	N/A	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.	from EFTA countries	from candidate countries and potential candidates	from other third countries	other assigned revenue
	N/A	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

25 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
26 EFTA: European Free Trade Association.
27 Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☐ The proposal/initiative requires the use of operational appropriations, as explained below

3.2.1.1. Appropriations from voted budget

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	

DG: <…….>			Year 2024	Year 2025	Year 2026	Year 2027	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[28]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>			Year 2024	Year 2025	Year 2026	Year 2027	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**

[28] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[29]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <….> of the multiannual financial framework	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	Number	

DG: <…….>	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

[29] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[30]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b +3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[31]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b +3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

[30] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

[31] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <….> of the multiannual financial framework	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• TOTAL operational appropriations (all operational headings)	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations Under Heading 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	**7**	'Administrative expenditure'[32]

[32] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

This section should be filled in using the 'budget data of an administrative nature' to be firstly inserted in the Annex to the Legislative Financial and Digital Statement (Annex 5[33] to the Commission Decision on the internal rules for the implementation of the Commission section of the general budget of the European Union), which is uploaded to DECIDE for interservice consultation purposes.

DG: <…….>		Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>		Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

EUR million (to three decimal places)

		Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
TOTAL appropriations under HEADINGS 1 to 7	Commitments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

[33] If you report the use of appropriations under Heading 7, completing Annex 5 is a compulsory requirement.

3.2.1.2. Appropriations from external assigned revenues

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	

DG: <…….>			Year 2024	Year 2025	Year 2026	Year 2027	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[34]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>			Year 2024	Year 2025	Year 2026	Year 2027	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[35]							

[34] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

[35] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <….> of the multiannual financial framework	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	Number	

DG: <…….>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[36]							

[36] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

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Optional: if more than one DG is involved in the proposal, please fill in the below tables; if not, please delete them.

DG: <…….>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[37]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**

[37] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

TOTAL appropriations under HEADING <….>	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• TOTAL operational appropriations (all operational headings)	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under Headings 1 to 6	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework (Reference amount)	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	**7**	‘Administrative expenditure’[38]

EUR million (to three decimal places)

DG: <…….>	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• Human resources	0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure	0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….> Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>	Year	Year	Year	Year	**TOTAL**

[38] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

		2024	2025	2026	2027	MFF 2021-2027
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

EUR million (to three decimal places)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL appropriations under HEADINGS 1 to 7	Commitments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2024**		Year **2025**		Year **2026**		Year **2027**		Enter as many years as necessary to show the duration of the impact (see Section1.6)						**TOTAL**	
	OUTPUTS																	
	Type[39]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[40]…																		

[39] Outputs are products and services to be supplied (e.g. number of student exchanges financed, number of km of roads built, etc.).

- Output																		
- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 ...																		
- Output																		
Subtotal for specific objective No 2																		
TOTALS																		

[40] As described in Section 1.3.2. 'Specific objective(s)'

3.2.3. Summary of estimated impact on administrative appropriations

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☐ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

3.2.3.1. Appropriations from voted budget

VOTED APPROPRIATIONS	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

==========

==========*3.2.3.2. Appropriations from external assigned revenues*

EXTERNAL ASSIGNED REVENUES	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.3.3. Total appropriations

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					

Human resources	0.000	0.000	0.000	0.000	**0.000**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together, if necessary, with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.4. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– ☐ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs)[41]

VOTED APPROPRIATIONS		Year **2024**	Year **2025**	Year **2026**	Year **2027**
• Establishment plan posts (officials and temporary staff)					
20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	0	0
20 01 02 03 (EU Delegations)		0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• External staff (inFTEs)					
20 02 01 (AC, END from the 'global envelope')		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**0**	**0**

3.2.4.2. Financed from external assigned revenues

EXTERNAL ASSIGNED REVENUES	Year **2024**	Year **2025**	Year **2026**	Year **2027**
• Establishment plan posts (officials and temporary staff)				

41 Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	0	0
20 01 02 03 (EU Delegations)		0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• External staff (in full time equivalent units)					
20 02 01 (AC, END from the 'global envelope')		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**0**	**0**

3.2.4.3. Total requirements of human resources

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES		Year **2024**	Year **2025**	Year **2026**	Year **2027**
• Establishment plan posts (officials and temporary staff)					
20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	0	0
20 01 02 03 (EU Delegations)		0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• External staff (in full time equivalent units)					
20 02 01 (AC, END from the 'global envelope')		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**0**	**0**

==========

Based on the detailed description in Annex V to the LFDS[42], the above tables should be accompanied by either of the below clarifications, depending on the option.

[42] For the purpose of estimating workload and staff needs, you may use the guidance on workload assessment prepared by DG HR.

Option 1: The additional human resources required for this proposal are fully covered by redeployments within the DG/service or exceptionally, from redeployments from the limited Commission redeployment pool, following the internal process applicable to that end. The duly justified clarification shall accompany the tables above and below. [Please refer to the Annex to the LFDS to identify redeployments within the DGs as clearly as possible]. If this option is applicable, the following comment should be included:

[Considering the overall strained situation in Heading 7, in terms of both staffing and the level of appropriations, the human resources required will be met by staff from the DG who are already assigned to the management of the action and/or have been redeployed within the DG or other Commission services.]

Option 2: Exceptionally, if internal redeployments within the implementing DGs appear for duly substantiated reasons impossible or insufficient, the proposal may require additional human resources. The latter will be paid as appropriate[43] from an administrative support line of the programme/initiative or by a fee as external assigned revenue.

In this case, please specify the type of staff by filling in the below table.

Please specify how many of the staff requested for the initiative are already in place in the DG/service (current staff) and how many additional staff are requested (in the column corresponding to the type of budget from which they are to be financed).

Please fill in the table to illustrate this for staff at 'cruising speed' level.

The staff required to implement the proposal (in FTEs):

	To be covered by current staff available in the Commission services	**Exceptional additional staff***		
		To be financed under Heading 7 or Research	**To be financed from BA line**	**To be financed from fees**
Establishment plan posts			N/A	
External staff (CA, SNEs, INT)				

Description of tasks to be carried out by:

Officials and temporary staff	
External staff	

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

[43] Please note that such exception needs to be agreed with central services before the launch of the ISC.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 7 should be presented in the designated line.

The appropriations under Headings 1-6 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021 - 2027**
HEADING 7					
IT expenditure (corporate)	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Policy IT expenditure on operational programmes	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ☐ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

– N/A☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation

N/A

– ☐ requires a revision of the MFF

N/A

3.2.7. Third-party contributions

The proposal/initiative:

– ☐ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	Total
Specify the co-financing body					
TOTAL appropriations co-financed					

3.3. Estimated impact on revenue

– ☐ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

– ☐ on own resources

– ☐ on other revenue

– ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[44]			
		Year **2024**	Year **2025**	Year **2026**	Year **2027**
Article …….					

For assigned revenue, specify the budget expenditure line(s) affected.

N/A

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

N/A

4. DIGITAL DIMENSIONS

When completing this Section, it is acceptable to present the information in a table format, where appropriate.

4.1. Requirements of digital relevance

Requirement 1:

- Reference: Article 1(1), Article 2 (1a, 1c) and other
- High-level descrittion: Definition of ‘digital contact’: any up-to-date and accessible online communication channel
- Stakeholders: Economic Operators, Consumers and othe End-users, Member States Authorities.
- High-level processes: Market surveillance verification and monitoring.

Requirement 2:

- Reference: Article 1 (2)(3)(4)(5) and other
- High-level description: the products must be accompanied by the internet address or machine-readable code through which the EC declaration of conformity can be accessed.
- Stakeholders: Economic Operators, Member States Authorities.

[44] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

- High-level processes: Market surveillance verification and monitoring.

Requirement 3:

- Reference: Article 1(6)(a), Article 2(2a) and other
- High-level description: Definition of EC declaration of conformity, in electronic form.
- Stakeholders: Economic Operators, Member States Authorities.
- High-level processes: Market surveillance verification and monitoring.

Requirement 4:

- Reference: Article 1(6)(b) and other
- High-level description: include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EC declaration of conformity or instructions in a digital product passport.
- Stakeholders: Economic Operators, Member States Authorities.
- High-level processes: Market surveillance verification and monitoring

Requirement 5:

- Reference: Article 1 (7)(a) and other
- High-level description: Member States shall ensure that the Commission and any other Member State may, on a reasoned request, obtain all information, in electronic form.
- Stakeholders: Economic Operators, Member States Authorities, European Commission.
- High-level processes: conformity assessment procedure

Requirement 6:

- Reference: Article 1(7b) and other
- High-level description: Where appropriate, the manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.
- Stakeholders: Notified Bodies, Economic Operators
- High-level processes: Conformity assessment procedures

Requirement 7:

- Reference: Article 2 (1b) and other
- High-level description: 'a common specification' can be digital or structured in a manner that can facilitate interoperability.
- Stakeholders: European Commission, Economic Operators, Notified Bodies, Market Surveillance Authorities.
- High-level processes: Conformity assessment procedures, Market surveillance verification and monitoring.

Requirement 8:

- Reference: Article 3(2) and other
- High-level description: The instructions and safety information may be provided in electronic form. It could be further specified that the format should comply with the accessibility requirements.
- Stakeholders: Economic Operators, Consumers and other End-users, Market surveillance authorities

4.2.Data

The definition "electronic form" allows plain text files, PDF files, Microsoft Word Documents, Web pages. While this is an improvement compared to the paper format, interoperability can be further improved by using a format which allows interconnection of IT systems.

4.3.Digital solutions

N/A

4.4. Interoperability assessment

Digital public service: Market surveillance monitoring/verification/investigations. Certification services.

Legal layer interoperability: Further interoperability can be achieved with the revision of the NLF.

Semantic layer potential barrier: The structure of the digital contact, EU declaration of conformity and common specifications could be better defined.

Technical interoperability potential barrier: The "electronic form" definition can hinder interoperability because it is possible to use formats which are not interoperable, like websites, unstructured word documents and PDF files, even videos or photos.

4.5. Measures to support digital implementation

The revision of the NLF and the Digital Product Passport Implementing Acts will take into consideration all digital requirements for further interoperability in all processes in scope of this directive. Particular attention will be paid to the cybersecurity aspects.

The Commission will ensure that the common specifications are defined in the implementing acts in a structured manner, to allow interoperability. The verification and certification processes could be further defined to allow automatisation and require measures to address cybersecurity possible threats.

EUROPEAN
COMMISSION

Brussels, 21.5.2025
COM(2025) 504 final

ANNEXES 1 to 5

ANNEXES

to the

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

{SWD(2025) 130 final}

ANNEX I

Annexes III to IX to Regulation (EU) 2016/424 are amended as follows:

(1) Annex III is amended as follows:

(a) in point 3, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 4, points 4.2 and 4.3 are replaced by the following:

‘4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;’;

(c) in point 6, first subparagraph, the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, any conditions for its validity, the necessary data for identification of the approved type (subsystem or safety component) and if relevant, descriptions of its functioning.’;

(2) Annex IV is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 3.3., first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(3) Annex V is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) point 4.1 is replaced by the following:

‘4.1. All subsystems or safety components shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Regulation.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(c) point 5.2. is replaced by the following:

'5.2. A random sample shall be taken from each lot. All the subsystems or safety components in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(4) Annex VI is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3.2., paragraph 1 is replaced by the following:

'The notified body shall examine the technical documentation for the subsystem or the safety component and shall carry out the appropriate examinations and tests set out in the relevant harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the subsystem or the safety component with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.';

(5) Annex VII is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3.2., point (b) is replaced by the following:

'(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means, including other relevant technical specifications, that will be used to ensure that the essential requirements of this Regulation will be met;';

(c) in point 3.3., first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.';

(d) in point 3.6.2., point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer;';

(e) in point 3.6.3, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’;

(6) in Annex VIII, point 2, point (c) is replaced by the following:

‘(c) a list of the harmonised standards referred to in Article 17, applied in full or in part, the references of which have been published in the Official Journal of the European Union, or a list of common specifications, applied in full or in part, and where those harmonised standards or common specifications, have not been applied descriptions of the solutions adopted to meet the essential requirements of this Regulation including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(7) Annex IX is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’.

ANNEX II

Annexes II, III, V, VII, VIII, and IX to Regulation (EU) 2016/425 are amended as follows:

(1) in Annex II, point 1.4 is amended as follows:

(a) in the first subparagraph, the first sentence is replaced by the following:

‘In addition to the name, postal address and digital contact of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:’;

(b) points (k) and (l) are replaced by the following:

‘(k) references to the relevant harmonised standard(s) or common specification (s) used, including the date of the standard(s) or specification(s), or references to the other technical specifications used;

(l) the internet address or machine-readable code through which the EU declaration of conformity can be accessed.’;

(2) in Annex III, points (f) and (g) are replaced by the following:

‘(f) the references of the harmonised standards referred to in Article 14 or the common specifications referred to in Article 14a that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts which have been applied;

(g) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;’;

(3) Annex V is amended as follows:

(a) in point 3., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 4, points (d) to (f) are replaced by the following:

‘(d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications as well as the elements which have been designed in accordance with other technical specifications;

(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

(f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.’;

(c) point 6.2., is amended as follows:

(i) point (b) is replaced by the following:

‘(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, the latter's name, postal address and digital contact;’;

(ii) point (e) is replaced by the following:

‘(e) where harmonised standards or common specifications have been fully or partially applied, the references of those standards or specifications or parts thereof;’;

(d) point 7.6. is amended as follows:

(i) point (a) is replaced by the following:

‘(a) his name, postal address and digital contact and data identifying the EU type-examination certificate concerned;’;

(ii) point (b) is replaced by the following:

‘(b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or common specifications or other technical specifications applied;’;

(4) Annex VII is amended as follows:

(a) in point 3., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact;’;

(b) point 4.3. is replaced by the following:

‘4.3. An adequate statistical sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined, and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.’;

(5) Annex VIII is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(6) Annex IX is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:’.

ANNEX III

Annexes III and V to Regulation (EU) 2016/426 are amended as follows:

(1) Annex III is amended as follows:

(a) point 1.3.1. is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point (c), point (4) is replaced by the following:

‘(4) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iii) in point (e), the second sentence is replaced by the following:

‘(e) This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(b) in point 1.4., points 1.4.3. and 1.4.4. are replaced by the following:

‘1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Regulation;’;

(c) in point 1.6., first subparagraph, the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity, the necessary data for identification of the approved type, such as the type of gas, appliance category and gas supply pressure, and, if relevant, descriptions of its functioning.’;

(d) In point 2.3, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final appliances or fittings taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to check the conformity of the appliance or the fitting with the relevant requirements of this Regulation.’;

(e) in point 3.3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(f) in point 3.3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(g) in point 4.3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(h) in point 4.3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(i) point 5.4.1. is replaced by the following:

‘5.4.1. All appliances or fittings shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specifications, and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify conformity with the approved type described in the EU type-examination certificate and with the appropriate requirements of this Regulation.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(j) point 5.5.2. is replaced by the following:

‘5.5.2. A random sample shall be taken from each lot in accordance with the requirements of point 5.5.3. All appliances or fittings in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(k) in point 6.2.1., point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.’;

(l) in point 6.4., the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards or common specifications and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the appliances or fittings with the applicable requirements of this Regulation, or have them

carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.';

(2) Annex V is amended as follows:

(a) point 2 is replaced by the following:

'2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:';

(b) paragraph 6 is replaced by the following:

'6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared'.

ANNEX IV

Annexes III, V, VII, IX, and X to Regulation (EU) 2023/1230 are amended as follows:

(1) Annex III is amended as follows:

(a) in point 1.7.4.2., point 1 is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the business name, full postal address and digital contact of the manufacturer and, where applicable, of its authorised representative;’;

(ii) point (c) is replaced by the following:

‘(c) the EU declaration of conformity, or the internet address or machine readable code, through which the EU declaration of conformity can be accessed, in accordance with Article 10(8);’;

(b) point 4.3.1. is amended as follows:

(i) the first subparagraph is replaced by the following:

‘Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name, postal address and digital contact of the manufacturer and the identifying reference of the relevant certificate.’;

(ii) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;’;

(2) Annex V is amended as follows:

(a) in Part A, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.’;

(b) in Part B, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.’;

(3) Annex VII is amended as follows:

(a) in point 3., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’;

(b) in point 6.2., point (b) is replaced by the following:

‘(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’;

(c) in point 7.6., point (a) is replaced by the following:

‘(a) its name, postal address and digital contact and data identifying the EU type-examination certificate concerned;’;

(4) in Annex IX, point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’;

(5) Annex X is amended as follows:

(a) in point 2., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’.

ANNEX V

Annexes VIII, IX and XIII to Regulation (EU) 2023/1542 are amended as follows:

(1) in Annex VIII, Module D1: Quality assurance of the production process, point 5.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the manufacturer’s authorised representative, its name, postal address and digital contact as well,’;

(2) in Annex IX, point 2 is replaced by the following:

‘Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative:’;

(3) in Annex XIII, point 1, the following point (t) is added:

‘(t) ‘clear, understandable and readable instructions for use in a format that makes it possible to print, download and save them on an electronic device so that the user can access them at all times, in particular during a breakdown of the battery (only for stationary battery energy storage systems).’