

COM/2025/503 Proposal for a Directive as regards digitalisation and common specifications

COM/2025/504 Proposal for a Regulation as regards digitalisation and common specifications

Questions

1. **Can you provide more information on the nature and level of costs which businesses based in (or selling into) NI could face in complying with the proposed EU acts?**

Any costs resulting from the proposed EU acts would relate to actions required to amend systems and processes to support compliance with the new rules. While the level of any such costs is not known, responses to the UK Government's Product Safety Review indicated support for the introduction of voluntary digital labelling as a method of reducing business costs and this is consistent with the findings of the Commission's own consultation with stakeholders. It would be expected therefore that any initial costs associated with adopting the new approach would be recouped by lower ongoing business costs once the processes are established.

The EU Commission staff working document provides details on expected savings:

- The digitalisation of obligations related the provision of DoCs and the technical file will simplify and speed up the transmission of documents to national competent authorities.
- No significant costs are expected for manufacturers due to the foreseen flexibility regarding the digital means.
- Cost savings for manufacturers of the concerned products due to simpler document management and avoided paper and postage costs are estimated to be of a magnitude of approximately €1 million per year.

- The possibility to provide instructions for use in digital format could allow the manufacturers to save up to €300 million per year. As this depends on the (voluntary) uptake of this possibility by manufacturers, this estimate can only be seen as indicative. The overall savings for companies related to digitalisation are thus estimated at around €300 million per year.

Public authorities may have to invest in training staff to work with digital tools but in the longer term, the digitalisation of DoCs and the technical file could allow for increased automation and efficiency gains. None of this could, however, be estimated.

- The common specifications will provide a reliable and cost saving way for demonstrating conformity with EU requirements, in cases where harmonised standards are missing or insufficient. By mirroring the presumption of conformity for harmonised standards, common specifications provide an opportunity for businesses to avoid other more costly methods to demonstrate conformity. A full quantification of the overall savings is not possible in the absence of comprehensive granular data on the third-party assessment fees and the number of products placed on the market but given the prevalence of self-assessments based on a presumption of conformity, the total costs can be significant. The digitalisation is also expected to lead to environmental benefits related to saving paper. It is expected that this could save approximately 50 000 tons of CO2 emissions per year.

Annex:

Application of the 'one in, one out' approach			
[M€]	One-off (annualised total net present value over the relevant period)	Recurrent (nominal values per year)	Total
Businesses			

New administrative burdens (INs)	n/a	n/a	n/a
Removed administrative burdens (OUTs)	n/a	<p>An estimated EUR 1 million savings related to the provision of DoCs and technical file digitally</p> <p>EUR 300 million savings related to the possibility to provide instructions for use in digital format</p>	EUR 301 million
Net administrative burdens*	n/a	EUR -301 million	EUR -301 million
Adjustment costs**	Not quantifiable but likely to be very limited	n/a	
Citizens			
New administrative burdens (INs)	n/a	n/a	n/a

Removed administrative burdens (OUTs)	n/a	n/a	n/a
Net administrative burdens*	n/a	n/a	n/a
Adjustment costs**	n/a	n/a	
Total administrative burdens***	n/a	EUR -301 million	EUR -301 million

(*) Net administrative burdens = INs – OUTs;

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

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

I. Overview of Benefits (total for standardisation) – Preferred Option		
Description	Amount	Comments
Direct benefits		
Compliance cost reduction resulting from the availability of common specifications	On average 4 000 EUR per product, which would have required certification in the absence of a	The figure given is not an aggregated one. It represents the amount for a single conformity assessment of one individual product (placed on the market) in the absence of harmonised

	harmonised standard.	standards and when no alternative option exists for using the presumption of conformity (i.e. common specifications) under one of the legislative acts covered by the proposal. On top of this, the business would avoid costs related to legal uncertainty and finding alternative methods to demonstrate compliance, which cannot be quantified.
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2. **How - if at all - would the introduction of common specifications (where harmonised standards are absent) impact businesses based in (or selling into) Northern Ireland?**

Currently, businesses typically demonstrate product conformity through harmonised standards, which are developed by standardisation bodies (CEN, CENELEC & ETSI) and referenced in EU legislation. Where such standards do not exist, economic operators often have to resort to complex and costly third-party conformity assessments.

The proposals, therefore, introduce common specifications as a legally binding fallback option, adopted directly by the Commission to fill gaps where harmonised standards are unavailable. The new common specifications aim to provide an alternative, uniform framework for demonstrating conformity across relevant product legislation and reduce costs and delays associated with conformity assessments.

This measure aims to streamline market access and may reduce legal uncertainty, particularly benefiting manufacturers of innovative or niche products without existing harmonised standards for businesses based in or selling into Northern Ireland.

As noted in the EM Business Impacts section:

Businesses who place products on the NI market would be required to comply with the updated EU requirements. In such cases, they could face initial costs in transitioning to the digital requirements of the legislation. However, it is noted that the EU impact assessment describes the changes as 'limited and targeted' with a focus on simplification. Therefore, businesses supplying the NI/EU market may benefit from reduced administrative burdens.

Manufacturers must also ensure that their distributors and importers meet their new obligations under the regulations associated with common specifications.

The purpose / spirit of introducing common specifications is to benefit from enhanced safety, performance, harmonisation across markets and supporting responsible innovation.

3. **The assessment of impact states that the evidence available points to “a difference in approach compared to Great Britain” arising from applying the proposed EU acts in NI. What would be the likely impact on businesses based in (or selling into) Northern Ireland of any GB-NI divergence arising from applying the proposed EU acts in NI?**

Northern Ireland-based businesses that deal with those areas where physical documentation is still required by some UK product rules would have to maintain systems and processes which meet those requirements as well as the digital approach mandated by the new EU rules. This dual-track approach is likely to be less efficient than a single approach based on only one set of rules. Similarly, businesses based in Great Britain and selling into Northern Ireland who are required to be compliant with the UK rules requiring physical documentation for the Great Britain market would also have to have systems and processes that would enable them to comply with the EU's proposed digital requirements.

As the EU's proposals would amend the technical information that is supplied with the product, with the exception of safety information, mandate digital declarations of conformity, and ensure information can be supplied digitally. This has the potential to

introduce a difference in approach for products in NI and for the EU rules currently still recognised in Great Britain, with some, but not all, UK product rules still requiring physical documentation.

However, as set out in its response to the Product Safety Review and during the debates on the Product Regulation and Metrology Bill, the Government is considering the direction of UK regulation in this area. The UK Government has indicated that they will consider the EU's proposals, working with business and consumer groups, as well as potential options for UK policy development.

4. **Can you provide more information on the number of product sectors, or overall number of businesses, likely to be impacted by any such divergence?**

Data on this has been compiled by Analytical Services and will be send as an additional document.

5. **The assessment of impact states that not applying the proposed EU acts “*would cause a significant impact, namely a barrier to trade with the EU.*” Can you provide more detail on the nature and extent of the barrier(s) to trade with the EU which would arise if these proposed EU acts were not applied in Northern Ireland?**

Compliance with EU rules is essential in order to be able to participate in the EU market. Failure to comply with the proposed EU acts would render Northern Ireland businesses ineligible to trade with that market.

6. **The assessment of impact states that DfE has not carried out any departmental engagement in relation to the proposed EU acts. UKG's EM states that “*it is not for the UK to consult on the EU's legislative proposals*” but notes that it has consulted on the possibility of the UK adopting similar measures. Does DfE intend to engage with NI-based stakeholders in relation to the impact of applying / not applying these proposed EU acts in Northern Ireland?**

This proposal mainly covers reserved matters across 16 separate product sectors where subject matter expertise sits with UKG. There has been limited time available to engage with NI stakeholders. However, DfE have issued a 'Call for Comment' on both

proposals via InvestNI's weekly bulletin linking to a related article on the NI Business Info website. The deadline for comment expires on 23.09. 25. InvestNI's weekly bulletin issues to 17,000 individuals – in the main this audience is made up of NI business representatives.

The departmental will forward the committee a summary of any comment once reviewed and collated.

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Contribution from Manufactured Goods Regulations, Department for Business and Trade on Questions 2, 3 & 5.

Questions

On Question 2 we thought this additional wording would be helpful as we noted the question makes specific reference to common specifications:

“Businesses who place products on the NI market would be required to comply with the updated EU common specification requirements where harmonised standards do not exist, or where standards have not yet been harmonised. While some adjustment costs are associated with this, which are assessed to be limited, common specifications have been introduced to simplify business processes by removing the need to find alternative methods to demonstrate conformity with EU regulatory requirements in the absence of harmonised standards. Therefore, businesses supplying the NI/EU market may benefit from reduced administrative burdens and costs.”

On Question 3 we suggest including the following on UK requirements:

“The requirement for physical declarations of conformity remains in place in the UK, with the exception of a small number of products for which derogations exist.

In developing its approach to the provision of a wider set of product information, dependent on product type and its suitability for different audiences, the UK Government will consider whether to facilitate similar principles to the EU in moving wholesale towards the provision and sharing of information digitally.”

On Question 5 we suggest adding words to the effect of the below for specificity:

“Were these proposals not to apply in NI, products circulating in NI would not be compliant with the rules of the EU single market. This would likely be seen as unacceptable by the EU, and would lead to remedial measures being pursued under the Windsor Framework. The precise impacts of such measures are unclear, given that it is unprecedented.”

Proposed EU Directives & Regulations for Digitisation and Common Specifications

Approach

We examined the EU Directives and EU Regulations mentioned in the two EU proposals and used our judgment to determine the sectors of the economy they are likely to apply to. This analysis is indicative and non-exclusive i.e. the regulations and directives could in practice apply in other sectors not included in this analysis.

The Standard Industrial Classification (SIC) codes for the identified sectors were collected. Where possible, we attempted to match these directives and regulations at the sub-sector SIC2 level. Where this was not possible, the sector level was used.

We have provided the data for the SIC sector and subsector we judged each regulation/directive to be related to, but **this does not mean that each directive and regulation will be related to the whole of the sector or subsector as these definitions can be quite broad.**

Note there may be other additional sectors that are related to the directives and regulations that have not been captured in this exercise.

Top-Level Summary of Findings

Through our analysis of the proposed **EU Regulations**, we found that nearly all of the regulations were linked to the Manufacturing industry. The market surveillance regulation appeared to be overarching, potentially covering a range of sectors.

The following sectors may also be related to the proposed regulations: Human health and social activities, Construction and Wholesale and retail trade.

Through our analysis of the proposed **EU Directives**, we have linked the Manufacturing industry to 12 of the 13 directives.

The following sectors have also been found to be related to some of the proposed directives: Agriculture, Forestry and Fishing, Construction, Mining & Quarrying, Water Supply, Sewerage, Waste Management and Remediation Activities, and Administration and Support Service Activities.

Data

Tables 1 and 2 provides the industry sectors and subsectors that are related to the EU regulations and directives. The Standard Industrial Classification (SIC) code and the SIC code description are reported along with the employment level for that sector, the number of businesses operating in the sector and the gross value added for the sector/subsector.

The analysis does not say how many of these businesses or employees could be affected by the EU regulations/directives, it only provides numbers of both in that sector/subsector.

The data is provided for the most recent year that it is available e.g. the employment data is for 2022, while the number of businesses is from 2025. This is due to the different reporting periods for data at this level of granularity.

Table 1: Employment & Business Data on the Sectors related to the proposed EU Regulations

Regulations	Industry	Sector / SIC2 code	SIC2 Code Description	Employment , 2022	Number of businesses, 2025	Gross Value Added (£m), 2023
(EU) No 765/2008 market surveillance relating to the marketing of products	*	*	*	*	*	*
(EU) No 2016/424 cableway installations	Manufacturing	C:25	Manufacture of fabricated metal products, except machinery and equipment	8,494	895	618
		C:28	Manufacture of machinery and equipment n.e.c.	8,100	315	650
(EU) No 2016/425 personal protective equipment	Manufacturing	C:32	Other manufacturing	1,521	200	123
	Human health and social activities	Q:86	Human health activities	76,245	1,435	4,652
	Construction	F:41	Construction of buildings	8,631	3,520	1,012
		F:42	Civil engineering	9,738	940	1,634
		F:43	Specialised construction activities	19,616	7,010	2,058
(EU) No 2016/426 appliances burning gaseous fuels	Manufacturing	C:27	Manufacture of electrical equipment	2,227	95	209
		C:28	Manufacture of machinery and equipment n.e.c.	8,100	315	650
	Construction	F:43	Specialised construction activities	19,616	7,010	2,058
(EU) No 2023/1230 on machinery	Manufacturing	C:28	Manufacture of machinery and equipment n.e.c.	8,100	315	650

(EU) No 2023/1542 batteries and waste batteries	Manufacturing	C:27	Manufacture of electrical equipment	2,227	95	209
	Manufacturing	C		88,026	4,710	6,538
(EU) No 2024/1781 requirements for sustainable products	Wholesale and retail trade; Repair of motor vehicles and motorcycles	G		127,854	12,840	7,918

Sources: [Business Register and Employment Survey \(BRES\), Northern Ireland, September 2022, NISRA](#), [Inter Departmental Business Register, NISRA](#), [Regional gross value added \(balanced\) by industry: all International Territorial Level \(ITL\) regions, ONS](#)

Notes *When analysing the regulations we found that no one SIC code would be related to the regulation, (EU) No 765/2008 market surveillance relating to the marketing of products. This regulation could be related to almost every industry. Therefore, no data has been captured for this regulation.

Table 2: Employment & Business Data on the Sectors related to proposed EU Directives

Directive	Industry	Sector / SIC2 code	SIC2 Code Description	Employment , 2022	Number of businesses , 2025	Gross Value Added (£m), 2023
2000/14/EC equipment for use outdoors;	Construction	F		37,985	11,470	4,704
	Agriculture, Forestry and Fishing	A		1,044	19,050	781
	Water Supply, Sewerage, Waste Management and Remediation Activities	E: 38	Waste collection, treatment and disposal activities; materials recovery	5,670	160	346
	Administrative and Support Service Activities	N. 81	Services to buildings and landscape activities	11,974	1,070	395
2011/65/EU hazardous substances in electrical and electronic equipment;	Manufacturing	C: 26	Manufacture of computer, electronic and optical products	4,101	90	469
		C:27	Manufacture of electrical equipment	2,227	95	209
2013/53/EU recreational craft and personal watercraft;	Manufacturing	C: 30	Manufacture of other transport equipment	6,160	60	345
2014/29/EU simple pressure vessels;	Manufacturing	C: 25	Manufacture of fabricated metal products, except machinery and equipment	8,494	895	618
2014/30/EU electromagnetic compatibility;	Manufacturing	C: 26	Manufacture of computer, electronic and optical products	4,101	90	469

2014/31/EU non-automatic weighing instruments	Manufacturing	C: 28	Manufacture of machinery and equipment n.e.c.	8,100	315	650
2014/32/EU measuring instruments;	Manufacturing	C: 26	Manufacture of computer, electronic and optical products	4,101	90	469
2014/33/EU lifts and safety components for lifts;	Manufacturing	C:28	Manufacture of machinery and equipment n.e.c.	8,100	315	650
2014/34/EU equipment and protective systems intended for use in potentially explosive atmospheres	Mining & Quarrying	B		1,974	95	153
	Manufacturing	C		88,026	4,710	6,538
2014/35/EU electrical equipment designed for use within certain voltage limits;	Manufacturing	C:27	Manufacture of electrical equipment	2,227	95	209
	Manufacturing	C:28	Manufacture of machinery and equipment n.e.c.	8,100	315	650
2014/53/EU radio equipment;	Manufacturing	C: 26	Manufacture of computer, electronic and optical products	4,101	90	469
2014/68/EU pressure equipment;	Manufacturing	C:28	Manufacture of machinery and equipment n.e.c.	8,100	315	650
2014/90/EU marine equipment;	Manufacturing	C: 26	Manufacture of computer, electronic and optical products	4,101	90	469
		C: 28	Manufacture of machinery	8,100	315	650

		and equipment n.e.c.			
	C: 30	Manufactur e of other transport equipment	6,160	60	345

Sources: [Business Register and Employment Survey \(BRES\), Northern Ireland, September 2022, NISRA](#), [Inter Departmental Business Register, NISRA](#), [Regional gross value added \(balanced\) by industry: all International Territorial Level \(ITL\) regions, ONS](#)