Home Appliance Europe

APPLiA's Recommendations for the Next Omnibus Simplification Package

ANALYSIS OF 14 KEY EU RULES

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By us, by you, for better lifestyles in Europe

The European Commission's 2025 work programme centered on "simpler and faster" regulation, directly aligns with the needs of European home appliance manufacturers. To fully realise this ambition, upcoming regulatory packages must build upon the initial Omnibus proposal, prioritising harmonisation and efficiency.

APPLiA's analysis of **14 key regulations** reveals critical overlaps and inconsistencies that impede the Single Market and inflate administrative burdens.

For instance, dual packaging requirements under the Ecodesign for Sustainable Products Regulation (ESPR) and the Packaging and Packaging Waste Regulation (PPWR), along with the disjointed application of the WEEE Directive, exemplify this problem. To prevent similar issues in future regulations, such as the Green Claims Directive, a proactive approach is crucial. We call upon the European Commission to leverage the initial Omnibus proposal as a foundation for a truly harmonised and simplified regulatory framework, grounded in robust evidence and balanced considerations.

This paper presents an analysis of the following legislation, detailing specific areas where simplification would yield significant benefits:

1. Ecodesign for Sustainable Products Regulation (ESPR)
2. Green Claims Directive
3. WEEE Directive
4. Batteries Regulation
5. Critical Raw Materials Act (CRMA)
6. Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
7. Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)
8. Drinking Water Directive
9. Regulation on Deforestation-free products
10. Packaging and Packaging Waste Regulation (PPWR)
11. Review of the Late Payment Directive
12. Network and Information Security (NIS) 2.0
13-14. Radio Equipment Directive Delegated Acts

1 Ecodesign for Sustainable Products Regulation (EU) 2024/1781 (ESPR)

Horizontal requirements Article 5 point 7 of the ESPR allows the EU Commission to adopt 'horizontal requirements' *where two or more product groups display one or more similarities*.	A **product-by-product approach** is essential for effectively implementing product measures through the ESPR. This approach ensures that each product is assessed individually, allowing for tailored measures that maximise impact.
Double regulation ESPR, and previously Ecodesign rules, applies both to finished goods such as refrigerators, but **also to components** that are inside appliances such as light sources, motors, fans and displays. This is an unjustified double regulation causing **unnecessary administrative burden** without any improved environmental result. The overall performance of appliances is regulated and guaranteed by the ESPR/Ecodesign rules. The current double regulation situation also makes it impossible to provide some spare parts to repair old appliances.	**Remove components and subassemblies from the ESPR scope**, including if placed on the market as spare parts, **for finished products already regulated by delegated acts under Ecodesign rules/ESPR.**

Requirement to track substances of concern in products Before entering the market, product groups covered by upcoming Delegated Acts must meet specific information requirements outlined in those acts. Article 7 of ESPR mandates that companies provide information to enable the tracking of substances of concern throughout a product's life cycle, including details like name, location, and concentration. This information will be included in the Digital Product Passport. The **definition of substances of concern is extensive**, not even considering substances potentially classified as concerning, due to their impact on reuse and recycling. This broad definition creates legal uncertainties and **overlaps with existing chemical legislation** like REACH, as **any substance could be targeted.**	We recommend that **tracking of substances of concern be focused on a list of relevant substances of concern to be identified for each product group** based on a stakeholder consultation. We recognise the need for improved value-chain transparency on substances of concern. Yet, it will not be feasible to track all substances of concern: according to a recent Ricardo report, more than 12000 substances of concern may be identified in upcoming years. It is neither technically feasible nor scientifically justified to track all substances of concern in all products covered by the coming Delegated Acts. This would simply lead to an unnecessary burden on companies trying to track substances that in any case are not necessarily present in such products. We also recommend removing any overlap between REACH and ESPR, by further clarifying that the ESPR shall not restrict for reasons related to chemicals safety.
Packaging ESPR provisions applicable to packaging used for certain products are redundant and would simply result in double regulation.	**Remove packaging from ESPR scope:** the Packaging and Packaging Waste Regulation (PPWR) already regulates packaging design with comprehensive provisions on packaging recyclability, recycled content, minimisation, restrictions on certain packaging formats, reuse, and labelling.

Digital Product Passport The Digital Product Passport, as presented, will require **a very complex set of data for companies to gather** including product performance and construction, supply chain, material content, repair and refurbishment. Furthermore, the DPP shall be available online for each unit placed on the market and updated over the product lifetime, e.g. if repaired and a third-party data backup is required.	The use case for the Digital Product Passport data should be well **understood** and **concluded** to be beneficial **before data** is requested. For example: • Will recyclers retrieve and review data about every single unit they treat in the WEEE flow? • Will consumers be able to digest and make use of the information contained in a DPP? • Will repair companies consult a DPP before they repair an individual product? Is it likely that a repair company will update a specific Digital Product Passport for an individual product after it has performed a repair? We still do not have answers to the questions above and without clear knowledge about the practical benefits of the use of the information, DPP information should not be required. If the DPP should have any benefit with consumers, repairers and recyclers, the data format for the DPP would have to be **harmonised and centrally defined**: if each producer uses its own template, the DPP will fail. Information at batch or item level will require the creation of millions of individual Digital Product Passports with companies having to spend an enormous amount of resources to collect low added value data and print a different data carrier for each individual unit produced. For practical implementation, the **DPP would be most effective when applied at the product model level** (i.e., a specific group of product with similar technical characteristics) similar to the existing database on energy labelled products, EPREL. Products belonging to the same product model have the same environmental characteristics too.

Unsold consumer products An obligation to disclose annually the quantities of products a company discards through third-party. There are **many uncertainties** on what/how/where to report and **guidance is missing** on many aspects: • Unclear terms in the "unsold consumer product" definition: surplus stock, excess inventory and deadstock • 'Discarded' definition is missing • Collection of spare parts before a product is discarded: does the product fall in the scope? • Handling of returned products could result in many different use cases • Deadline for first disclosure	**Dismiss the third-party verification:** the ESPR already foresees a process to verify the accuracy of the reporting on unsold consumer products discarded through: - article 24 (2) - Chapter XI Companies already have existing systems to track their unsold consumer products and their delivery to waste treatment operations. These systems are already verified by national competent authorities. While these systems need to be adapted to the reporting format established by the ESPR, they already constitute a good basis for compliance with ESPR obligations. Consequently, **companies should be allowed to develop their own internal verification systems**, which would be auditable ex-post (i.e., after the information is disclosed) by national competent authorities. Finally, the reports are publicly available online, making it easy for any stakeholder to scrutinise the data. **Allow for additional transition time on reporting starting from the publication of the implementing act:** the implementing act shall apply one year after its date of entry into force and shall not retroactively impact information collected before its entry into force. For the reporting periods starting before the date of application of the act, economic operators should be able to disclose the information in a format of their choice in the absence of standardised requirements and, where necessary, in the form of estimates. This will give companies enough time to adjust their internal systems to the format established in the relevant implementing act. Finally, we ask the Commission to **provide guidance on concepts/definitions without further due.**

2 Green Claims Directive COM (2023) 166 (ongoing)

The proposed **Green Claims Directive**, currently under trilogue negotiations, introduces significant new requirements for businesses making voluntary environmental claims, including mandatory third-party verification and detailed substantiation. This raises concerns about increased costs, administrative burdens, and potential delays in bringing products to market. While the Directive aims to combat greenwashing and empower consumers, there are worries that its complexity and stringent requirements could discourage companies from communicating their environmental efforts. The potential for unintended consequences on innovation and the EU's green transition warrant careful consideration.

Both the European Parliament and the Council have proposed a **simplified procedure** for some claims, with the proposal for simplified procedure in the Council's GA **providing more clarity**.

During the upcoming trilogue negotiations, the focus should be put on the following elements:

Simplify Verification Procedures: adopt a simplified procedure, similar to the Council's proposal, to minimise bureaucratic burdens and allow for rapid legal clarity and implementation. This would avoid lengthy testing processes by external verifiers for all claims.

Clarify "Explicit Environmental Claims": exclude hard-to-monitor oral statements from the definition of "explicit environmental claims" to ensure enforceability.

Go beyond minimum requirements and ensure consistent application of rules across all Member States: the principle of mutual recognition for approved claims should be implemented too to ensure a fair and functioning Internal Market.

Provide sufficient transition time: we support the Council's proposed 36-month overall transposition period, reducing the transposition period into national law to 18 months and then extending the transitional period for companies to comply by 18 months.

Legacy claims: the scope shall be clearly delimited with a cut-off date so that only claims referring to products that have been placed on the market up to a certain date are covered. This would create a manageable demarcation.

3 Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)

The current directive poses several issues and leaves significant loopholes which are outlined below:

Lack of harmonisation across Member States: Although the Directive provides a framework, each EU Member State has some flexibility in implementing the rules. This can lead to inconsistencies and make it challenging for businesses operating in multiple countries. National implementation of the Directive leads to diverging requirements and reporting structures (templates, monthly quarterly etc.), different calculation methodologies to establish the targets, on the definitions in different Member States. This adds to the high reporting burden regarding circularity and product compliance.

Issue of non-compliance: There is a growing problem where electrical and electronic equipment that does not meet the EU's Waste Electrical and Electronic Equipment rules is being sold online to EU consumers by sellers based outside the EU. These goods often lack the necessary markings, safety certifications, or proper recycling contributions required by EU WEEE regulations. This poses risks to consumers (safety hazards) and the environment (improper disposal). Online platforms facilitate these sales, connecting non-EU sellers directly with EU buyers. This makes it challenging to enforce WEEE rules, as the sellers are outside EU jurisdiction. This creates an uneven playing field for EU-based businesses that comply with WEEE rules, as they face competition from cheaper, non-compliant goods. Non compliant WEEE often ends up in improper waste streams, leading to pollution and hindering the EU's circular economy goals.

Harmonise reporting requirements and calculation methodologies, including in the upcoming revision of the WEEE legislation, taking into account that WEEE take back systems have been implemented in various different ways across Member States. This is important because Member States have implemented WEEE take-back systems in various ways, leading to discrepancies in data collection and reporting. Harmonisation would ensure that data is comparable and reliable, which is crucial for effective policymaking and monitoring of WEEE management. **The upcoming revision of the WEEE legislation provides an opportunity to address this issue and establish a level playing field.**

Stronger rules and enforcement mechanisms are needed to ensure that all EEE sold in the EU, regardless of origin, meets WEEE standards. The revision shall **address the specific challenges posed by online sales and clarify the responsibilities of online marketplaces** too.

Add the **all actors' principle** thereby requiring all actors **to report on WEEE collected** through universal standards of operation so that the reporting burden on manufacturers is more equally distributed across business partners, and WEEE system transparency and reliability is guaranteed.

4 Batteries Regulation (EU) 2023/1542

The EU Batteries Regulation introduces a comprehensive set of reporting obligations for economic operators involved in the battery lifecycle. These obligations aim to ensure transparency, traceability, and sustainability across the battery value chain.

When a manufacturer places a home appliance containing a portable battery on the market, it is also considered to be placing the battery on the market. This triggers the reporting obligations related to the quantity of batteries placed on the market. Manufacturers then may need to work with battery suppliers and Producer Responsibility Organisations to ensure they can fulfill their reporting and recycling obligations effectively. Manufacturers must register in the national register of producers in every EU Member State where they place batteries on the market. Manufacturers must report the quantity of portable batteries they place on the market in each member state. Manufacturers are responsible for financing the collection and recycling of waste batteries. They must report the quantity of waste batteries they collect, either directly or through a Producer Responsibility Organisation.

Economic operators (except SMEs) placing batteries on the market or putting them into service must establish a due diligence policy to address social and environmental risks linked to the sourcing, processing, and trading of raw materials. Companies must regularly assess their supply chains, identify and mitigate risks, establish grievance mechanisms, and engage third-party auditors to verify compliance. Those due diligence reports must be publicly available.

WEEE reporting covers the total weight of EEE collected, while the Batteries Regulation requires separate reporting on the weight and composition of the batteries within those appliances. This means manufacturers need to be able to separate battery data from overall EEE data. **The reporting obligations should be harmonised to reduce the burden on manufacturers.**

Postpone the due diligence requirements from August 2025 to August 2027 and streamline with the Corporate Sustainability Due Diligence Directive requirements.

Postpone the requirement for battery removability (Article 11).

5 Critical Raw Materials Act (EU) 2024/1252

Reporting obligations apply to a wide range of critical raw materials, including those used in home appliances, such as rare earth elements, cobalt, lithium among others. Manufacturers must comply with the specific deadlines set by the regulation and national authorities for implementing due diligence policies, conducting risk assessments, and submitting reports. Some reporting obligations may apply only to large companies or those manufacturing specific types of products. Obligation to declare products with permanent magnets and their environmental footprint. Labelling of products containing electrical motors, data carrier, web information on magnet recycled content, removability of magnets etc.	The waste management plan and environmental footprint product declarations must be fully consistent with other sectoral legislation, such as the ESPR. **The Critical Raw Materials Act should not create a parallel system, but build on provisions already applicable in sectoral/environmental product legislation.** The logic to introduce the product labelling requirement and data carrier for products containing electrical motors and permanent magnets is for recyclers to improve their processing and handling of those parts and increase the recycling rate of critical materials. Have recyclers been consulted and confirmed that such a label on products and information via a data carrier will help them to improve the recycling they perform? Can some other mechanism be more effective? Will recyclers in reality review individual labels on products that they handle in their WEEE processing plants? If this has not been investigated, and the benefit is not certain, then the **product labelling and data carrier obligations need to be postponed until the benefits of the proposed methods have been clarified and confirmed.**

6 Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

- Manufacturers must ensure that electrical and electronic equipment is designed and manufactured in accordance with Article 4, which restricts the use of hazardous substances.
- Manufacturers need to create technical documentation and conduct internal production control procedures, or have them carried out.
- Manufacturers are required to create an EU declaration of conformity and affix the CE marking to products that have demonstrated compliance.
- Technical documentation and the EU declaration of conformity must be kept for 10 years after the electrical and electronic equipment is placed on the market.
- Manufacturers must ensure that procedures are in place to maintain conformity in series production.
- A register of non-conforming electrical and electronic equipment and product recalls must be kept, and distributors must be informed.
- Manufacturers must ensure their electrical and electronic equipment has a type, batch, or serial number for identification, or provide this information on the packaging.
- Manufacturers must also indicate their name and address on the electrical and electronic equipment, its packaging, or accompanying documents.
- If electrical and electronic equipment is not in conformity, manufacturers must take corrective actions, inform the relevant national authorities, and provide details of the non-compliance corrective measures taken.
- Manufacturers must provide all necessary information and documentation to a competent national authority upon request.

Updated Exemptions (pack 22) are currently under discussion in a call for feedback from the Commission.

On the Exemption Pack 22:

- The **proposed expiry dates for several crucial exemptions are unreasonably short**, leaving insufficient time for industry to prepare renewal applications and adapt to the changes.
- **The rewording and split of exemptions introduce unnecessary complexity and administrative burdens without commensurate benefits for human health and environmental protection.**
- A more balanced approach is needed to consider sustainability and the needs of the home appliance industry to ensure continued innovation and economic growth.

7 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

The anticipated 2025 revision of the REACH regulation could involve tightening restrictions on hazardous substances, with PFAS being a particular focus. There may also be a move to reduce the need for individual authorisations and address potential critical information gaps. The revision is likely to place a greater emphasis on potentially restricting harmful chemicals across broad categories rather than case-by-case authorisations. This potential shift could mean that chemicals may face accelerated, category-wide restrictions.

The EU is moving towards a complete ban on PFAS. However, the introduction of essential-use criteria is being considered, which could allow specific applications of PFAS where no viable substitutes are currently available and the chemicals are deemed critical for health or technology.

The revision is also expected to prioritise closing information gaps in chemical safety, particularly regarding the health and environmental impacts of chemicals. Enhanced data requirements might be introduced for chemicals known to be endocrine disruptors or highly persistent in the environment. The new framework could mandate better documentation and traceability of chemicals throughout the supply chain.

In alignment with the Clean Industrial Deal and Circular Economy Act, the 2025 REACH updates are anticipated to support sustainable chemical use and a circular economy. By potentially restricting hazardous chemicals and encouraging safer alternatives, the revision may aim to reduce dependency on virgin materials and foster resource-efficient industry practices across the EU.

The **Essential Use concept should be firmly rooted in scientific assessment and applied only where an unacceptable risk is identified**. The use of hazardous chemicals in home appliances is already strictly regulated.

Decisions to be made by a politically accountable body that is empowered to take both decisions and liable for these decisions.

Decision-making to be very transparent and involve representatives from across the stakeholder community, including industry and civil society, to ensure legitimacy of the process.

To streamline information sharing and avoid redundant obligations, the requirement for the database specified in the first sentence of Article 9(2) of the Waste Framework Directive should be deleted. **The 'Substances of Concern' in articles or in complex Products' database (SCIP) has not demonstrated its effectiveness and is not the optimal tool for integration with the future Digital Product Passport, potentially leading to duplicative information requirements.**

Details: Article 9(2) of the Waste Framework Directive (Directive 2008/98/EC, as revised in 2018) tasks the European Chemicals Agency (ECHA) with creating the SCIP database. This database collects information on articles containing REACH candidate list substances above 0.1% w/w, intended for access by waste treatment operators and consumers. However, its value and its compatibility with emerging digital tools like the DPP warrant reconsideration.

8 Drinking Water Directive (EU) 2020/2184

This legislation affects the design of appliances that are connected to the distribution systems of drinking water in buildings. Article 11 sets up a framework for minimum hygiene requirements for materials in contact with drinking water, which the Commission has implemented through three Implementing and three Delegated Acts. Hafnium, which is an indispensable substance for the manufacturing of enamelled products such as water heaters, has not been included in the Implementing Act on the European Union Positive List on the substances, compositions and constituents that can be used in the manufacture of such final materials/products. Its omission results in a de facto withdrawal from the market of enamelled products. During the transitional period between 2027-2032, certain Member States will recognise national certificates for conformity that have been valid before the date of application on the last day of 2026. In Member States where such certificates do not exist, this is unclear and could result in internal market fragmentation.	**Issuing an amendment of the Implementing Act to include hafnium on the European Union Positive List before the date of application** at the end of 2026. About the transition period, **mutual recognition of national certificates for conformity** among the Member States before the date of application at the end of 2026. Even if Member States can implement this legislation differently as it is a Directive, the **requirements for hardware placed on the EU market, e.g. appliances, need to be harmonised** and in practice be the same at EU level. An appliance that is compliant in one EU Member State must also be considered as compliant in all other EU Member States.

9 Packaging and Packaging Waste Regulation (EU) 2025/40 (PPWR)

Of particular concern are provisions in Article 4(3), Article 29(15 and 16), and 51(2)(c), which allow Member States to individually set higher reuse targets, potentially for products beyond those already specified, and to maintain or introduce their own sustainability or information requirements. This could lead to a patchwork of rules across the EU. Varying national rules on packaging, labeling, and information, along with restrictions on packaging material will create obstacles that increase operational costs and complexity. Another issue is that certain types of transport packaging used within a Member State are subject to a complete reuse target of 100% by 2030. This applies to a wide range of packaging, including pallets, boxes, crates, and even pallet wrappings. However, well-functioning recycling systems already exist for many of these items, and reusable alternatives are not always available.	To ensure a harmonised and functional EU market, it is crucial to **avoid fragmentation caused by diverging national rules.** Therefore, **provisions that allow Member States to maintain or introduce their own sustainability or information requirements should be removed.** This includes: • Article 4(3) • Article 29(15)&(16) • Article 51(2(c))

10 Regulation (EU) 2023/1115 on deforestation-free products

Companies are to publicly report on the company due diligence system, including on the steps taken to fulfil obligations without a set minimum threshold and a single shipment of one label included in the scope.	**Set a threshold on quantities of imports that will be covered by the Regulation.** For example, CBAM currently has a de minimis threshold of 150€ value. Apply the same concept to EUDR. In addition, add a further de minimis threshold of 250 kg weight. A % of total imports could be foreseen too. More concretely, set a threshold on quantities of imports that will be covered by EUDR Annex I. In this way, unfilled packaging & spare manuals below a specific threshold relative to the total amount of imports of packaging & manuals carrying, supporting, or protecting a product, should be excluded. This will prevent costly and onerous administrative processes for insignificant products which are not economic operators' primary business or source of revenue but rather supporting/logistical necessities. **Remove rubber from the scope of the Regulation until an impact assessment has been carried out.** Rubber was not part of the Commission proposal and was added in the scope of the Regulation by the EU Parliament without any impact assessment. The scope of the Regulation is based on the customs CN numbers for the different goods/materials. Unfortunately the same CN number applies to synthetic rubber (no trees involved) and natural rubber (trees involved). This will jeopardise compliance control and also makes it impossible for the customs to evaluate if imported rubber items fall under DFR or not. Rubber can be added to the scope again once this practical problem with the scope / CN numbers has been resolved and an impact assessment for rubber has been completed. We procure the majority of the material numbers affected by the EUDR from within the EU. For these, another economic operator will have already invested resources before us to create a DDS. From everything we have heard from other players, in practice this first statement - for low-risk business partners - will by and large only be 'cope pasted' - even several times within a year (for individual batches) and possibly for different subsidiaries (e.g. sales companies in different EU countries). In our view, this creates no added value, but a lot of additional work. This is where we currently see the biggest pain point and therefore the potential for better, more efficient implementation of due diligence obligations. **Once the requirements in the EU have been met and the responsibility has been fulfilled, the review process should - as with other legislation - be completed and not repeated over and over again. It is important to bundle the obligations r**elating to the statement at neuralgic points such as the importers. The fact that new statements are created again and again afterwards makes no sense and creates no added value.

11 Review of the Late Payment Directive COM (2023) 533 (ongoing)

Commission proposal **to limit all payment terms to 30** days for all commercial transactions.	The proposal should be withdrawn. Payment terms including the duration to pay is **a competitive element between companies** acting on the EU market. Terms are regulated by the contractual agreements between the parties. A relatively long payment term, that has been agreed by the parties, is not equivalent to a late payment that does not comply with the terms agreed by the parties. EU legislation should not intervene in this aspect of the market. From a practical standpoint, shorter payment terms **create obvious problems for cash flow and liquidity**. Retailers could delist products with a long shelf life (such as household appliances) / refrain from new listings because flexible payment terms by product category are no longer possible and short-term pre-financing is a burden on retailers. Warehousing would be transferred to manufacturers more often, more goods would have to be delivered "just in time". Manufacturers who are not based/do not produce in the EU benefit from the regulation (are paid earlier and do not have to pay their non-EU suppliers in the same period). **We support the very critical stance of the Council of the EU as a whole.**

12 Network and Information Security (NIS) 2.0 Directive

The transposition in several Member States is late, which risks having different transpositions in each Member State.
For instance, two areas already exhibit differences among Member States are:

- The categorisation of entities varies: 'Not Applicable', 'Important', 'Essential' entities are not aligned. Consequently, different security requirements are imposed in different countries. As a global company, it is not feasible to manage different types of security requirements on a country level.

- The interpretation of Article 33.2.b, which mandates targeted security audits carried out by an independent body or a competent authority, has led MS to authorise a specific list of competent authorities (audit firms) to perform these audits.

This interpretation excludes the consideration of internal audit and compliance functions within larger organisations as independent bodies, including the integration of cybersecurity within the statutory audit or the possibility of engaging a single auditor to cover all countries within scope. Consequently, local audit firms are required to conduct these audits, resulting in significant inefficiencies and increased costs, given that many processes are managed on a global level.

If reporting obligations in the Cyber Resilience Act were supposed to be aligned with NIS 2.0, there is a risk that they could be contradictory or not aligned in terms of timing, both because of the missed deadlines of the Member States but also the differences in requirements per Member State.

Establish a **unified framework for categorising entities across all Member States.** This framework should clearly define the criteria for 'Not Applicable', 'Important' and 'Essential' entities, ensuring consistent application and reducing the burden on global companies to comply with different requirements in each country.

Simplify the interpretation of Article 33.2.b: it is proposed to broaden the definition of independent body to include internal audit and compliance functions within larger organisations, allowing to conduct targeted security audits from an established unified audit framework. Simplifying one step further would be to integrate cybersecurity within the statuory audit.

Standardised audit criteria across Member States and **enhanced collaboration** between Member States and global companies would further streamline the process, reducing inefficiencies and costs associated with the current requirement for local audit firms to conduct these audits, and a single auditor should be permitted to cover all countries within scope, instead of a dedicated one per country.

13 Radio Equipment Directive Delegated Act art. 3.3 d), e), f) vs. Artificial Intelligence Act

The interplay between the Radio Equipment Directive Delegated Act and Artificial Intelligence Act when it comes to high-risk AI Systems identification is problematic.

The current European Commission interpretation may lead to the situation that in case of lack of standards listed under the Radio Equipment Directive Delegated Act, all connected products, using AI System for safety purposes, would be automatically "labelled" as high-risk AI without any other condition being met.

The mere fact of formal **lack of listing of standards in the EU Official Journal under respective legislation, cannot lead to the conclusion that the product using AI System for safety purposes is automatically a high risk one.**

There is also a draft Commission interpretation - „EG RE (19)21 - COM - Interplay RED-AI Act" - suggesting that even if the harmonised standards exist, are listed and manufacturers use them, still the AI systems used for safety purposes would declare products as being AI high-risk in each case. This **draft interpretation should be completely withdrawn**.

If the interpretation were to be endorsed, it would mean de facto that each product falling under RED DA 3(3)(d-f) and using cybersecurity components would be automatically classified as high-risk, even irrespectively of the existence of a harmonised standard. That is not what neither RED nor AI Act says.

It would even lead to the unintended situation that actual safety components under Article 3 (1) of the RED are not considered high-risk, while radio equipment using AI-based cybersecurity components are automatically considered high-risk – directly contradicting the clear intention of Article 6 of the AI Act aiming at safety aspects.

We strongly advise the European Commission to **re-think this interpretation and align it closely to the legal text of the AI Act and Radio Equipment Directive.**

Additionally, **future guidelines should make it clear that products with an AI System are considered "high-risk" in exceptional cases, not by default**.

14 Radio Equipment Directive, Delegated Act art. 3.3 d), e), f) vs. Cyber Resilience Act

The interplay of this Delegated Act in the Radio Equipment Directive with the newly adopted Cyber Resilience Act is problematic and could possibly lead to double regulation. The two pieces of legislation address to a large extent the same issues and their requirements would be applicable to the same products at the same time.	**Withdraw Radio Equipment Directive Delegated Act once the Cyber Resilience Act is fully applicable.** To secure proper transition from the moment when Radio Equipment Directive Delegated Act is fully applicable (01/08/2025) and the moment when Cyber Resilience Act is in force, but not yet fully applicable (until circa Nov 2027).