Finland simplification proposals

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ENERGY

1. Energy Efficiency Directive (EED) (EU) 2023/1791

Simplification proposals:

The EED contains a broad range of excessive requirements for enterprises and the public sector, for example the vague energy efficiency first principle (Article 3) applied to investments, planning and procurement, and the excessive and vague requirements of the energy savings obligation (Article 8 and Annex V) concerning calculation, approval, verification and reporting of savings. To streamline regulation, a detailed review should take place concerning not only Articles 3 and 8 but also at least Articles 5, 6, 7, 11, 12, 22, 25 and 30.

Reasoning:

The EED is an extensive directive that contains regulation relating to reporting and implementation obligations for both businesses and administration that overlap, conflict or have limited relevance with regard to the objectives of the Directive. This results in a heavy body of regulation that could be made considerably lighter by removing the excessive requirements.

2. Renewable Energy Directive (RED III) (EU) 2022/2577

Simplification proposals:

To minimise the administrative burden, the database should in the initial stage be limited to the scope determined in the Directive, that is, from production plant to release for consumption (Article 31a).

Reasoning:

Article 31a, Union database: The database is only at the development stage, but its administrative burden on businesses covered by the regulation can be assessed as being quite significant. In addition, it can be assessed that the larger the volume of upstream data in the database, the more complex and administratively burdensome the database will become. In addition, the volume of data is significant, as the intention is to enter all transactions concerning liquid and gaseous fuels in the database.

The regulation on sustainability criteria for bioenergy is more detailed than before and, particularly now that the size limits have been lowered, applies to an increasing group of enterprises. For example, the greenhouse gas (GHG) reduction requirements of Article 29 will apply to around 300 operators, including smaller enterprises, over slightly different timeframes. However, as the GHG requirement is expected to be fulfilled by all operators in Finland, this would mainly involve updating the sustainability system or taking the requirement into account in the application stage. The administrative burden on enterprises will increase, but the impact is not assessed to be significant.

3. Methane Regulation 2024/1787/EU

Simplification proposals:

The administrative burden and particularly the provisions concerning the imports of fossil fuels (Articles 27–29).

Reasoning:

The Methane Regulation adopted in July 2024 applies to matters including methane emissions measurement obligations during mining, exploration, production and distribution of fossil energy, and schedules and plans for leak repair obligations. The obligations are being expanded to outside of the EU in the manner whereby the importers of oil, gas and coal must report information provided by the exporting country on their methane measurements, which should be equivalent to the EU Methane Regulation.

The administrative burden caused by the Methane Regulation is large in relation to the significance of the matter and the adverse effects on resilience. The Regulation is heavy while only able to address a fairly narrow section of methane emissions (with 1% of methane emissions in Finland and 19% of methane emissions in the EU as a whole covered by the Methane Regulation). In addition, the impacts of activities within the EU are minor, since fossil fuels are imported from third countries. It is difficult to address the activities of third countries by means of EU legislation.

Concerns have been voiced about the Methane Regulation's enforceability and its impacts on security of supply of gas in a situation where imports of energy from Russia are gradually being reduced. The most critical stance is expressed by industry and some of the Member States concerning the administrative burden caused by the Regulation and, in particular, the provisions concerning the imports of fossil fuels (Articles 27–29). The Methane Regulation has been presented as suitable for the omnibus and as similar to the CBAM, which applies to non-EU operators.

4. Electricity Market Directive (EU) 2019/944

Simplification proposals:
Article 31(3): The reference 'Distribution system operators shall update that information on a regular basis, at least quarterly' should be removed from the provision.

Reasoning:

Distribution system operators must publish the information relating to grid connection and update it at least quarterly. The requirement is unnecessarily strict and causes costs for distribution system operators. This increases consumers' distribution transmission prices, which account for a significant share of the electricity prices paid by consumers. The Action Plan for Affordable Energy published by the Commission regards the higher electricity prices as a problem.

5. Energy Performance of Buildings Directive (EPBD) (EU) 2024/1275

Simplification proposals:

1. *The Commission should conduct a revision and more detailed analysis (in accordance with Article 28 EPBD), but it should not propose the entry into force of new amendments to the EPBD within this time limit. The Directive currently sets specific targets for 2030, 2033 and 2035 as well as longer-term targets for 2040, 2045 and 2050. It is important to be able to assess the requirements and achievement of the targets before starting to discuss new requirements. The Directive also establishes the framework for National Building Renovation Plans, including how they should be renewed, for the entire timeline up to 2050, into a highly energy-efficient and decarbonized building stock by 2050, with the objective to transform existing buildings into zero-emission buildings. This provides the sector with the starting points for the requirements for a long time. If the EPBD is revised, the level of detail should be reduced and Member States should be provided with more opportunities to take into account their national building codes and national calculation and construction specifications.* Detailed simplification proposals are put forward for Article 14 (infrastructure for sustainable mobility, recharging points, car parks and derogation concerning SMEs) and Article 9 (building-specific thresholds for non-residential buildings) of the EPBD. *With regard to Article 14, it should be possible to regulate the minimum number of recharging points installed in non-residential buildings with more than 20 car parking spaces in accordance with the baseline established in the 2018 Directive (EU 2018/844) so that a high-power recharging point would be equivalent to a large number of slow recharging points.*

2. *In addition, Article 14 should be made clearer in particular with regard to this: 'the car park is physically adjacent to the building, and, for major renovations, renovation measures include the car park or the electrical infrastructure of the car park'. Derogations should be enabled.*

3. *Article 14 on sustainable mobility. Reintroduce the derogations concerning SMEs from the previous revision. Also disregard the requirements concerning bicycle parking, since these are not within the scope of application of the EPBD, and this should be regulated nationally and regionally in accordance with the principle of subsidiarity.*

4. *The European Commission provides guidance relating to the EPBD. The guidance should not be legally binding.*

5. With regard to Article 9, *the building-specific thresholds for non-residential buildings should be replaced by determining the targets for the improvement of the energy performance of the entire building stock. Member States should be able to decide how the energy performance of buildings is improved. In addition, it should be possible to apply an alternative approach nationally if the Member State is able to verify that the building stock is already transitioning into a highly energy-efficient and decarbonised building stock by 2050.*

Reasoning:

The EPBD is a highly detailed and frequently amended directive. New acts have been adopted before previous ones have even been implemented. Rapid amendments pose challenges for the construction sector. Prior to making new amendments, time is needed

to adapt to the existing provisions and to identify ways of fulfilling the most recent obligations in Member States.

1. The EPBD currently causes unnecessary costs, since low-power recharging points are not used during brief stops. The range of the current electric vehicle stock is so long (300–500 km) that basic charging is usually not useful during brief parking. Slow or basic charging is, in practice, only relevant at residential buildings or places where the car is kept for longer. For example, in Finland the electric vehicle recharging point network has developed rapidly and on market terms based on the choice of right locations and required technology. Member States could take into account relevant factors, such as an increase in the number of recharging points on market terms, the number and development of electric vehicles, methods and charging technology, and cost-effectiveness. This would not adversely affect the achievement of building stock emission reductions. Instead, it would bring much-needed cost-effectiveness to implementation and respect the building owners' right to property safeguarded under Article 17 of the Charter of Fundamental Rights of the EU (CFREU).

2. For example, at ski resorts in Lapland there are large car parks, some of which are located next to the ski lift base station and others much further away. Due to the large size of the site of the ski lift base station, all of the car parking spaces may be 'physically near' a building, although in practice a car parking space might not be located anywhere near buildings. The requirement to equip all cark parks located further away is insurmountable. There should be opportunities for derogations.

3. Article 14 on sustainable mobility. This Article is too detailed, contains retroactive requirements and may place a disproportionate burden on microenterprises and households. The previous revision of the EPBD included the opportunity to grant derogations to SMEs. It is unclear why these derogations were removed, especially with regard to microenterprises and voluntary organisations under consideration.

ENVIRONMENT AND CLIMATE

6. Nature Restoration Regulation (EU) 2024/1991

Simplification proposals:

1. *Art. 4(12) non-deterioration provision should be limited to areas that have been subject to restoration measures or are already in good condition. This change would not endanger the achievement of the targets of the Regulation while clarifying the legal framework for the Member States.*
2. *Art. 4.2 very common and widespread habitat types are defined very narrowly and the flexibility for defining target levels for those habitat types is insufficient. The "common and widespread" should be defined at Member State level and the target level should be based on ecological requirements.*
3. *Art. 4.13 non-deterioration at the level of each biogeographical region of the territory of a MS should be applicable also in situations where alternatives are not absent. The*

requirement for absence of alternatives makes the implementation of the provision ambiquent, legally difficult to implement and administratively heavy.

4. *Art. 4-5 restoration requirements should be restricted to habitat types and species that are not in favourable conservation status. Applying requirements to those Habitat types and Species that already are in favourable conservation status is not efficient use of public money.*
5. *Art. 12 the Member States should have more choice to select the most suitable forest indicators.*
6. *Art. 11(4) where duly justified, the extent of rewetting of peatland may be reduced also in cases where rewetting could take place on land other than agricultural land. In addition, justifications based on national or EU security, security of supply and food security should be taken into account.*
7. *Annex IV Grassland butterfly index should reflect species' abundance and range in the Member State. It should be allowed to compile a national meadow butterfly index based on species that are relevant to each Member State.*
8. *Art. 20(1)(j) monitoring requirement should start at the moment when the non-deterioration requirement comes into force, i.e. the date of publication of the national restoration plan of the MS. The monitoring and the related reporting requirement prior to that date is in contradictory, unnecessarily burdensome and difficult to implement.*

Reasoning:

For Finland, the implementation costs of the NRR are very high and raise serious concerns. The Commission has initially estimated that the costs (per capita and based on GDP) of implementation of the regulation in Finland are by far the highest in the EU. The most significant restoration costs arise from measures concerning water bodies, forests, and peatlands. These ecosystems are widely prevalent in Finland.

From this perspective, we look for different avenues on how to affect costs and keep the administrative burden to minimum. As an important element, we propose to simplify the NRR.

In the drafting process of the national restoration plan we have come across with parts of the Regulation that should be simplified with no substantial impacts on the set targets.

7. Implementation of LULUCF Regulation 2023/839/EU

Simplification proposals:

The necessity of the monitoring system should be assessed with regard to the objectives and reporting needs of subsequently adopted regulations on biodiversity. The monitoring system itself does not significantly affect the improvement of biodiversity.

It is proposed that the more detailed reporting system requirements laid down in paragraphs (a), (b), (c), (d), (e) be removed. The requirements of Part 3 of Annex V concerning the development of GHG inventories for the various tiers should be retained.

Reasoning:

The latest LULUCF Regulation was negotiated as part of the Fit for 55 package. The new LULUCF Regulation (EU 2023/839) sets the obligation to strengthen carbon sinks in the land use sector and requires Member States to report on sinks and removals in their national greenhouse gas (GHG) inventories. The fulfilment of the Member States' obligations is examined on the basis of the national GHG inventory.

Following the new LULUCF Regulation, part 3 of Annex V to the Governance Regulation (EU 2018/1999) was amended so that, in addition to the GHG inventory, Member States must establish a monitoring system on high-carbon stock land, sites of high importance in terms of biodiversity and restoration and sites with high climate risk. The monitoring of these is not actually related to the fulfilment of the obligations of the LULUCF Regulation. Instead, they serve other regulations the contents of which were not known during the negotiations (Nature Restoration Regulation, carbon certification). The aim is to seek synergies between climate change mitigation and adaptation measures and biodiversity measures.

According to an estimate made during the negotiations, the implementation of the monitoring system and reporting is expensive in terms of administration and difficult in terms of practical implementation. Currently the development of the GHG inventory alone has required a lot of national resources in Finland, so the creation of the monitoring system is still in its infancy.

8. EU Emissions Trading System 2 (EU ETS 2) 2003/87/EC

Simplification proposals:

A minimum threshold for fuel released for consumption (1,000 tonnes of CO_2 per year) should be added to the definition of 'regulated entity' (Article 3(ae).

Reasoning:

The new EU Emissions Trading System based on fuel released for consumption (EU ETS 2) does not set a minimum threshold for emissions included within its scope generated from fuel released for consumption by regulated entities.

Fuels are released for consumption by a wide range of actors, such as fuel distributors, importers and end users. In practice, in the absence of a minimum threshold, the regulation applies to a large number of small enterprises, which release very small quantities of fuel resulting in very low emissions. In Finland, the emissions of more than half of the regulated entities are below 1,000 tonnes per year. The aggregate emissions of these actors account for less than one per cent of the total emissions covered by the system.

EU ETS obligations place a considerable burden on small enterprises that could be eliminated without compromising the system's emissions coverage or climate targets. Limiting the number of regulated entities would also significantly reduce the burden on the competent authority. Under the current rules, it is foreseeable that a number of small enterprises will cease importing or distributing fuel, as adapting to the new obligations arising from EU ETS is very difficult for them.

9. Directive 2010/75/EU on industrial emissions

Simplification proposals:

The second (a and b) paragraph of Article 15(4) of the Directive could be deleted. This would simplify the rules of environmental performance under the environmental permit procedure. This would not significantly impact the level of requirements, as the level of ambition is in any case primarily determined in the process of drawing up sector-specific BAT conclusions, and the rules have no significant impact on this process.

Reasoning:

In the update of the industrial emissions Directive in 2024, it was decided at the final stages of the negotiations that the requirements for environmental performance should be regulated in a very complicated manner. The environmental permit should set binding ranges for environmental performance and set binding environmental performance limit values for water consumption and non-binding environmental performance levels for other environmental performance. In addition, reference levels for environmental performance were maintained for the environmental management system.

10. Packaging and Packaging Waste Regulation (PPWR) (EU) 2025/40

Simplification proposals:

1. *Simplification of reporting obligations set for producers of packaging in the PPWR. The reporting obligations could be simplified by reducing the number and level of detail of the packaging categories reported on (Table 1 of Annex II, Table 3 of Annex XII).*
2. *Shorten the keeping period required for declaration of conformity documentation.*
3. *Remove the opportunity to provide declaration of conformity documents in paper form (Articles 15(10), 16(1), 18(8) and 19(6) PPRW).*

Reasoning:

The EU's new PPWR entered into force on 11 February 2025 and will be applied from 12 August 2026. During the negotiations, Finland was very active in influencing several aspects concerning the forest industry in particular and provisions on the packaging re-use targets (in particular beverage containers). In the negotiations, Finland succeeded in influencing several provisions of the Regulation, such as derogations concerning re-use.

Despite these derogations permitted by the Regulation, representatives of the business sector are still highly concerned about the re-use targets laid down in the Regulation, particularly the re-use target set for final distributors selling certain alcoholic and non-alcoholic beverages (Article 29(6)). Under the provision, at least 10% of certain beverages sold by a final distributor must be made available in reusable packaging by 2030. The sector is concerned about the new investments required and the costs incurred by the retail sector and beverages industry because of the obligation. The derogations permitted by the Regulation are not seen as taking sufficient account of the well-functioning

deposit-based return system delivering a very high return and recycling rate for single-use beverage containers. The doubts whether the required changes will have positive environmental impacts and considers that the re-use target for beverage containers should be re-examined from this perspective.

1. Simplification of reporting obligations set for producers of packaging in the PPWR. The Regulation requires considerably more detailed reporting than is currently the case on both the quantities of packaging placed on the market as well as the quantities of separately collected, recycled and treated packaging waste. Reporting in such detail, particularly on separately collected, recycled and otherwise treated packaging waste, is laborious and obtaining the information very difficult. The detailed reporting laid down in the Regulation is not necessary for assessing whether the targets set by the Regulation on reducing the quantity of packaging waste or separate collection and recycling are being met. Likewise, the design of the recyclability criteria for the proposed packaging categories does not require reporting by the Member States.

2. The PPWR requires economic operators to keep the documentation concerning the declaration of conformity for 5 years in the case of single-use packaging and for 3 years in the case of reusable packaging. Considering the short life and diverse range of packaging, this period could be shortened considerably. This would reduce the administrative burden of the economic operators. Articles 5–12 of the Regulation lay down provisions on product requirements concerning packaging. Articles 38–39 of the Regulation lay down provisions on the conformity assessment procedure and the EU declaration of conformity. Articles 15 and 18 of Regulation require that the manufacturer or importer of the packaging keeps a copy of the EU declaration of conformity at the disposal of the market surveillance authorities as regards single-use packaging for 5 years and as regards reusable packaging for 10 years from the date the packaging was placed on the market. Correspondingly, Article 22 lays down for economic operators the obligation to, upon request, provide information to the market surveillance authorities on the identity of any economic operator that has supplied them with packaging or packaged products or to which they have supplied packaging or packaged products. Economic operators must be able to provide the information as regards single-use packaging for 5 years and as regards reusable packaging for 10 years.

3. The PPWR lays down provisions on the format for the submission of information demonstrating the conformity of products submitted to and requested by the authorities. Under the PPWR, the information may be submitted in either electronic or paper form. As part of its broader set of simplification proposals, Sweden has proposed that the opportunity to provide the information in paper form be removed in this regard. The Finnish Ministry of the Environment welcomes Sweden's proposal. It is already currently the practice in market surveillance to submit the documents in electronic form.

11. Waste Framework Directive (WFD) 2008/98/EC

Simplification proposals:

1. *Remove the agricultural use of anaerobically digested or composted manure from the scope of application of the WFD (Article 2(2)(b)) if the use fulfils the requirements of*

other legislation (Animal By-Products Regulation 1069/2009, Fertiliser Products Regulation 2019/1009, Nitrates Directive 91/676/EEC).

2. *Develop the end-of-waste assessment criteria to better promote a circular economy (Article 6(1)). Propose* that the removal of the condition that 'a market or demand exists for such a substance or object' laid down in Article 6(1)(b) be considered.

3. *Propose the opportunity to derogate from the traceability requirement of the WFD concerning hazardous waste (Article 17) with regard to small quantities of waste*.

4. *Remove the last resort opportunity concerning the calculation of the quantity of waste, whereby the quantity of recycled municipal waste can be determined on the basis of average loss rates, and the authorisation of the Commission to adopt a delegated act establishing rules for the calculation of, verification and reporting of average loss rates (Article 11a(3) and (10)*.

5. *Simplification of reporting on oil products and waste oils (Article 37(4), Tables 1 and 2 of Annex VI to Commission Implementing Decision (EU) 2019/1004). Simplify the obligation of Member States to report the data on mineral or synthetic lubrication or industrial oils placed on the market and waste oils separately collected and treated*.

6. *Specification of the reporting obligation of establishments and undertakings collecting or transporting waste (Article 26). It is proposed that the registration obligation be specified with regard to those undertakings and establishments that collect or transport waste on a professional basis so that actors, whose principal activity is not the transport or collection of waste but that transport small amounts of waste generated in their activity (such as pieces of electrical wiring or piping) when pursuing their profession, be excluded from the obligation*.

7. *Easing the permit obligation for preparing for re-use (Article 23). The approval of preparation for re-use should be brought under the scope of the registration obligation*.

Reasoning:

1. The WFD does not apply to manure, except when it is delivered for landfilling, incineration or biological treatment. Since the waste legislation applies to the treatment of manure in a biogas or composting plant, processed manure generated in a plant is also to be regarded as waste and to fall within the scope of application of the WFD. The use of processed manure in agriculture therefore constitutes treatment of waste, which requires a permit from the competent authority under the WFD and must also otherwise comply with the requirements set out in the Directive for waste management (such as registration of transport, record keeping). On the other hand, according to EU case law, unprocessed manure is, under certain conditions, considered a by-product, with its use in those cases not falling within the scope of application of the WFD. Differential treatment of processed and unprocessed manure places an inappropriate administrative burden on the users of processed manure and places them on an unequal footing compared with the use of unprocessed manure. This may hinder and prevent investments in biogas and composting plants that promote a circular economy. The health and environmental risks of the use of processed manure can be managed by EU legislation concerning

animal by-products and fertilisers and by the Nitrates Directive, and the application of the WFD does not deliver any added value.

2. End-of-waste assessment criteria are key tools in the productisation of secondary materials. The condition laid down in Article 6(1)(b) WGD, which is proposed for removal, does not add any material value compared with the other assessment criteria in the provision: point (a) 'the substance or object is to be used for specific purposes', point (c) 'the substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products' and point (d) 'the use of the substance or object will not lead to overall adverse environmental or human health impacts'. The requirement that a market or demand must already exist before an end-of-waste product is placed on the market sends the wrong signal to industry, businesses and research institutes seeking to innovate and develop a market for waste-based products and raw materials. It may also prevent or slow the creation of innovations that promote a circular economy.

3. The traceability requirement, together with Article 35 (record keeping) of the WFD, means, for example, that when a small enterprise or organisation (retail or other business, office, etc.) takes WEEE and waste batteries and accumulators to a retail outlet or other collection point, it must keep a record of hazardous waste and submit the data to the registry of the authority. However, a corresponding traceability requirement also applies to the retail outlet or other collection point where the small enterprise or organisation delivers the hazardous waste. The operator of the retail outlet or collection point must keep a record of and notify to the registry the data on the hazardous waste received and delivered for further treatment. Waste generated in households that is comparable to hazardous waste in terms of either category or quality or discarded consumer products classified as hazardous waste delivered to a collection point organised by a municipality, producer or distributor could be excluded from the traceability requirement. Consideration should also be given to whether a similar derogation opportunity is needed for the Persistent Organic Pollutants (POP) Regulation (2019/1021).

4. It has proved to be very difficult to establish the rules, and the preparation of the Commission's delegated act has been delayed by several years. It can be presumed based on the Commission's draft acts that the rules would result in a system that is complex and administratively burdensome for both enterprises and authorities, without providing significant benefit compared with the administrative burden caused. Based on experiences gained from the implementation of the WFD, the quantity of recycled waste can be calculated reliably without the need to rely on average loss rates, and average loss rates might even reduce the reliability of the data.

5. Data collection for the current reporting places a disproportionate administrative burden on both businesses and authorities compared with the benefits obtained.

6. Based on the case law of the Court of Justice of the European Union (C-270/03 and C-311/99), such actors should also be regarded as professional transporters of waste.

7. Actors carrying out preparation for re-use are often very small enterprises. Their operations are usually very small in scale and do not cause significant adverse impacts on the environment or health. The treatment permit required by the WFD is often an overly burdensome procedure for approving such operations and does not incentivise business activity based on preparation for re-use.
8. Review cycles should be harmonised to facilitate joint information acquisition and preparation.

12. Council Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture

Simplification proposals:

Repeal or simplify the provisions concerning the obligation of Member States to keep records as well as to report to the Commission and publish the data on the places where sewage sludge is used in agriculture based on spatial data (Article 10(1)(d) and 2nd paragraph, Article 10(2) and Article 17, 2nd paragraph).

Reasoning:

The collection of data based on spatial data from areas where sludge is used has proved to be problematic. This places an excessive administrative burden on sludge producers and users as well as the authorities. In addition, the data collection involves data protection challenges, as the farmers using sludge may be identified based on the spatial data provided. Due to the challenges mentioned above, the data reported by the Member States is not comparable and its publication on a map nationally and in the EU may lead to misunderstandings and unfair interpretations concerning places where farmers and food producers use sludge. The benefits of the reporting obligation are insignificant compared with the adverse effects and administrative burden it causes.

13. Directive on the reduction of the impact of certain plastic products on the environment (SUP Directive) 2019/904

Simplification proposals:

The easing of the producer's cost responsibility referred to in Article 8(2), (3) and (4) of the SUP Directive should be considered. Consideration could be given to repealing the producer's cost responsibility for waste collection for products discarded in public collection systems and for cleaning up litter resulting from products (Article 8(2)(b) and (c), (3)(b) and 2nd paragraph and the provisions of (4) on costs of cleaning up litter). The producer should, however, be left with the obligation to cover the costs arising from the awareness raising measures to reduce litter referred to in Article 10 of the Directive.

In addition, the impact of regulation could be improved and the burden arising from regulation could be reduced by laying down a prohibition on placing on the market of tobacco products and filters containing plastic in accordance with Article 5 of the Directive instead of applying the producer's cost responsibility.

Reasoning:

The producer's cost responsibility stated in the simplification proposal above for the collection of products as waste in public collection systems and for cleaning up litter caused by products generates significant regulatory costs compared with the environmental benefit delivered by the regulation. In Finland, the regulation laid down to implement the Directive generates costs for the producers arising from aspects including establishing the composition of the litter collected and cleaned up, and for the authorities from aspects such as determining the litter collection and cleaning-up costs and monitoring actual costs. The procedures relating to compensation for costs also generate additional work for the authorities and producers.

14. Urban Wastewater Treatment Directive (UWWTD) (EU) 2024/3019

Simplification proposals:

Stakeholders have drawn attention to the impacts of the UWWTD on the pharmaceutical and cosmetics industries. Impacts on the costs of the pharmaceuticals and cosmetics industries could be reduced by, for example, lengthening the timeline for the quaternary treatment obligation.

15. CLP Regulation 1272/2008 and refill sales of fuels

Simplification proposals:

Remove the information requirement for fuel refill sales situations.

Reasoning:

In addition to the proposals included in Omnibus VI, a need has been identified to amend the CLP Regulation particularly as regards the refill sales of fuels, that is, situations where fuel is bought into a portable container (such as a jerrycan), in most cases at a staffed attended service station or at an unstaffed station. When selling liquid fuel into a portable container for a customer, under Article 29(3) of the CLP Regulation, the information specified in Article 17 of the Regulation should be supplied to the customer.

The operator selling liquid fuels should supply the above information to the customer in the form of, for example, a separate label or a paper document containing the equivalent information. The functionality, controllability and proportionality of the requirement was already questioned in conjunction with the previous revision of the CLP Regulation, but no amendments to the Annex were made in that context. Compliance with the requirement is particularly difficult in a large country like Finland where there is a large number of unstaffed filling stations.

The removal of the information requirement is also supported by the fact that fuel pumps must contain markings ensuring safe use in accordance with the CLP Regulation. The requirement appears to constitute overregulation when also considering that the hazardousness of liquid fuels is commonly known and the equivalent markings enabling safe use are mandatory on fuel pumps.

DIGITAL AND DATA PROTECTION

16. Digital Services Act (DSA) (EU) 2022/2065

Simplification proposals:

1. *Article 11(3) DSA could be simplified, for example, so that it would not apply to small and microenterprises providing intermediary services other than an online platform service.*

2. *The Commission could also assess whether Articles 9 and 10 DSA should be amended so that the authorities' obligations laid down in paragraphs 3 and 4 of both Articles would apply only to cross-border orders issued by the authorities (relating to illegal content in a service or the provision of information about service users).*

Reasoning:

With regard to the DSA ((EU) 2022/2065), it has been recognised that Article 11 places an unnecessary and in part disproportionate administrative burden on small enterprises and on those service providers being intermediary services but not online platform services.

1. Article 11 DSA obligates providers of intermediary services to designate a single point of contact to enable them to communicate directly with Member States' authorities, the Commission and the European Board for Digital Services referred to in Article 61 DSA. In addition, paragraph 3 of the Article lays down provisions on matters including specifying the language used in the communication on the service interface. This means that an enterprise operating in Finland would have to publish, alongside details such as the email address of the point of contact, the information that, in addition to Finnish and Swedish, a language such as English can be used to communicate with the point of contact.

   The requirements of Article 11 DSA apply to providers of intermediary services regardless of their size, including microenterprises and small enterprises, whether providing 'mere conduit' services (such as local telephone companies) or online platform services.

   The Finnish Transport and Communications Agency (Traficom) is not aware of any situations where the authorities of another Member State (let alone the Commission or the Board) would have needed to communicate directly with a Finnish provider of intermediary services. Should such a need emerge (and where the enterprise has not published the point of contact details required by Article 11), the Digital Services Coordinator of the other Member State, the Board or the Commission could request assistance from Traficom to reach the service provider. The Digital Services Coordinators cooperate with each other, the Board and the Commission (Article 49).

2. Articles 9 and 10 in turn place an unnecessary administrative burden on authorities issuing orders and on Digital Services Coordinators.

   According to the DSA, service providers are obligated to respond to orders from national judicial or administrative authorities to act against one or more specific items of illegal content in their service (usually to disable access to the illegal content) or to provide information about, for example, the recipients of their service. An order issued by a national judicial or administrative authority referred to in Articles

9 and 10 DSA is not enforceable under the DSA or binding on the recipient of the order, and the DSA does not provide the national authority with the competence to issue orders to a service provider established in another Member State.

Under Articles 9 and 10 DSA, the authority or court issuing an order must transmit the order, along with any information received from the provider of intermediary services concerning the effect given to that order, to the national Digital Services Coordinator, which in Finland is Traficom. Traficom must in turn notify the order issued to the service provider as well as any response provided by the service provider to the Digital Services Coordinators of the other Member States. In practice, the Digital Services Coordinators enter the orders referred to here in the electronic information system established for the DSA, which is very difficult and cumbersome to use and which, at least for the time being, does contain a translation function for orders issued in national languages.

It has so far remained unclear to Traficom why the issuers of orders have to transfer the orders referred to in Articles 9 and 10 to Traficom. This is quite difficult to justify to, for example, our court system. According to Traficom's knowledge, courts issuing orders referred to in Article 9 or 10 do not automatically receive the information about any follow-up by the recipient of an order. The provision of the information required by Articles 9 and 10 to them would place an additional administrative burden on Traficom.

It has also remained unclear what the significance is of the requirement that each Member State must notify the orders issued in its national languages to the Digital Services Coordinators of the other Member States.

17. ePrivacy Directive 2002/58/EC

Simplification proposal:

We propose a further simplification relating to the ePrivacy Directive.

Reasoning:

In 2017, the Commission issued a proposal for an ePrivacy Regulation aimed at updating and partly lightening regulation, but the negotiations reached a deadlock. The proposal for the regulation has been withdrawn. The Commission proposal for Digital Omnibus already addresses certain issues related to simplification of the ePrivacy Directive. There is, however, still a need to further simplify and update the ePrivacy Directive.

18. EU Artificial Intelligence Act 2024/1689/EU

Simplification proposals:

The restrictions imposed and caused by the Artificial Intelligence Act and their undesirable effects should be examined with this regard going forward, and the Act should be adapted so that it will not jeopardise the capacities of European enterprises for innovation more than is necessary to achieve the objectives set. A set of simplification measures are already included in the

Commission proposal for Digital Omnibus, but more comprehensive assessments would be necessary to examine whether further simplification would be necessary.

Reasoning:

Regardless of its good general intentions (restrictions aimed to safeguard the rule of law and democracy), the Artificial Intelligence Act may nevertheless have certain undesirable sector-specific effects that reduce the capacity of actors in those sectors to innovate AI-based and ancillary solutions within the EU. This may potentially lead to the development of these innovations and commercial investments taking place to considerable extent outside the EU.

19. Directive (EU) 2019/1024 of the European Parliament and of the Council on open data and the re-use of public sector information

Simplification proposals:

The Directive should only apply to the authorities as laid down in its Article 2. This would also be in line with Chapter II of the Data Governance Act.

The Directive could also be simplified and clarified, particularly with regard to its interaction and overlaps with the GDPR and the Data Governance Act, and with the INSPIRE Directive and other sector-specific regulation of availability of data. The concept of 'data' ('document') should also be harmonised in EU legislation on digitalisation. The Commission proposal on Digital Omnibus already addresses certain issues related to simplification of Open Data Directive and Data Governance Act. However, more comprehensive assessment would still be necessary to address all the issues mentioned above.

Reasoning:

When the Directive was recast, its scope was expanded to apply not only to the authorities but also to certain undertakings over which public sector bodies exercise a dominant influence. In practice, this expansion has not actually promoted the re-use of open data. Because of the statutory obligation, these enterprises are required, however, to spend time and effort to check whether their datasets are within the scope of the legislation and whether they have to be made available as laid down in the Directive.

20. General Data Protection Regulation (GDPR) (EU) 2016/679

Simplification proposals:

A set of simplification measures are already included in the Commission proposal for Digital Omnibus, but more comprehensive assessments would be necessary to examine whether further simplification would be necessary, for example:

1. *Administrative burden is created by ambiguities included in the regulation with regard to interplay between different acts, ambiguities in terms of content, and divergent definitions. To ensure interoperability, it would be justifiable, among other measures, to:*

- *horizontally examine the notification and reporting obligations of EU regulation;*
- *Examples of notification and reporting obligations that overlap with and/or are stricter than EU data protection regulation:*
    i. *Artificial Intelligence Regulation (Article 27(4); impact assessment)*
    ii. *Platform Work Directive (Article 8; impact assessment)*

- *ensure that the definitions of other EU regulation concerning the processing of personal data correspond to definitions in EU data protection regulation;*
- *Examples of ambiguous/differing definitions:*
    i. *Artificial Intelligence Regulation (Article 3(34–36); biometric data)*
    ii. *Platform Work Directive (Article 7(1); data belonging to specific categories of personal data)*

- *recommend that the Commission continue its work to update the rules on privacy of electronic communications (ePrivacy Directive) and to clarify its relationship with the GDPR and to ensure consistency.*

Reasoning:

In addition to the GDPR, regulation concerning the processing of personal data is included in a large amount of regulation. It would be important to ensure that EU regulation does not include additional regulation creating any unnecessary administrative burden in relation to the EU's generally applicable data protection regulation. It should be assessed whether the administrative burden could be reduced by practical and tailored guidelines and/or other tools as well as by means of cooperation between the authorities across sectoral boundaries, or whether there is a need to consider legislative amendments to ensure the interoperability of EU regulation and reduce the administrative burden. Administrative burden on those applying the law is also created by ambiguities included in the regulation with regard to interplay between different acts, ambiguities in terms of content, and divergent definitions.

AGRICULTURE, MARITIME AND FISHERIES

21. Amending the rules of the European Maritime, Fisheries and Aquaculture Fund (EMFAF) 2021/1139

Simplification proposals:

1. *EMFAF regulation should be amended so that a derogation from the detailed rules would be permitted for financial instruments (loans and loan guarantees) in the same way as in CAP funding. In addition, a corresponding derogation should also be laid down for RDI projects of public interest.*

2. *The regulation of fishing vessel investment projects should be lightened so that improvements of energy efficiency and use of renewable energy sources could be supported with EMFAF resources.*

3. *The funding condition concerning the minimum activity of fishing vessels should be amended so that it does not apply to small-scale fishing.*

Reasoning:

1–2. The energy transition in fisheries is important for both the competitiveness of the sector and for the achievement of the EU's carbon dioxide emissions reduction targets. The current EMFAF rules do not, however, enable funding for the construction of energy-efficient vessels or the modernisation of existing vessels if the measures increase the vessel's power or capacity. There are no derogations even with regard to research and development measures or loan guarantees.

3. Amending the funding condition concerning the minimum activity of fishing vessels would better enable support to fishers who are new and starting up and clarify the current unclear legal situation in terms of support for small-scale fishing.

22. Common fisheries policy (CFP) control system 2023/2842/EU

Simplification proposals:

1. *The implementation of the Regulation revising the monitoring system (EU) 2023/2842 must be deferred until the outcome of the omnibus exercise is known.*
2. *Regionalisation, a key CFP principle, must also be adopted as the starting point for legislation concerning CFP control. Control requirements must be adapted to best apply to the conditions of each marine area and Member State.*
3. *The rules concerning the margin of tolerance in fishing logbook estimates must be moderated.*
4. *The requirements set for the accuracy of catch reporting must be moderated.*
5. *It must be made possible to use small vessels for many different purposes, that is, the rule whereby each trip of a vessel registered as a fishing vessel is a fishing trip that must be reported to the authorities must be removed.*

Reasoning:

2. Harmonisation creates unnecessary additional control, bureaucracy and costs for all.

3. The new rules that are too detailed and inflexible are a major problem for all Baltic Sea countries.

4. This helps to avoid excessive investments in control and consequences to fisheries operators that are unreasonable and even threaten security of supply.

23. INSPIRE Directive 2007/2/EC and GreenData4All initiative

Simplification proposals:

It is important from the Finnish perspective that the implementation of the INSPIRE Directive is simplified on the basis of the initiative with measures including enabling the simplification of the strict implementation rules of the INSPIRE Directive with regard to producers of information, and by providing the opportunity to introduce lighter national administrative structures for the guidance and monitoring of implementation.

24. Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

Simplification proposals:

1. ***Point 1.5.2.5 of Part II of Annex II.*** *Amend point 1.5.2.5 as follows: The withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal shall be twice the withdrawal period, only if the chemically synthesised allopathic veterinary medicinal product in question, including of an antibiotic, has been specified a withdrawal period and, in case, if the withdrawal period is other than zero in the summary of product characteristics (SPC) referred to in Article 35 of Regulation (EU) 2019/6.*

2. ***Point 3.1.4.2(f) of Part II of Annex II.*** *Amend point 3.1.4.2 as follows: The withdrawal period for allopathic veterinary treatments and parasite treatments in accordance with point (d), including treatments under compulsory control and eradication schemes shall be twice the withdrawal period, only if the chemically synthesised allopathic veterinary medicinal product in question, including of an antibiotic, has been specified a withdrawal period and, in case, if the withdrawal period is other than zero in the summary of product characteristics (SPC) referred to in Article 35 of Regulation (EU) 2019/6.*

   If an organic food-producing animal of a certain animal species is treated with a veterinary medicinal product used outside the terms of the marketing authorisation for the animal species in question, the withdrawal period shall be twice the relevant withdrawal period set out in Article 115(1) of Regulation (EU) 2019/6, and at least 48 hours.

3. ***2018/848 Article 24(1).*** *Remove Article 24(1)(e), (f) and (g) of Regulation (EU) 2018/848. Thereby the amended Article 24(1) would read as follows: The Commission may authorise certain products and substances for use in organic production, and shall include any such authorised products and substances in restrictive lists, for the following purposes: (a) as active substances to be used in plant protection products; (b) as fertilisers, soil conditioners and nutrients; (c) as non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin; (d) as feed additives and processing aids.*

4. ***2018/848 Article 24(1).*** *If the previous simplification proposal (in 3 above) is not applied, amend Article 24(1) as follows: The Commission may authorise or prohibit certain products and substances for use in organic production, and shall include any such authorised or prohibited products and substances in restrictive lists, for the following purposes: (a) as active substances to be used in plant protection products; (b) as fertilisers, soil conditioners and nutrients; (c) as non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin; (d) as feed additives and processing aids; (e) as*

products for the cleaning and disinfection of ponds, cages, tanks, raceways, buildings or installations used for animal production; (f) as products for the cleaning and disinfection of buildings and installations used for plant production, including for storage on an agricultural holding; (g) as products for cleaning and disinfection in processing and storage facilities.

5. ***2018/848 Point 1.2.2(a) of Part II of Annex II.*** *Remove the requirement of at least three quarters of the lifetime of an animal from the conversion periods provision in the case of bovine animals and equine animals for meat production. Thereby amend point 1.2.2(a) as follows: 12 months in the case of bovine animals and equine animals for meat production;*

6. ***2018/848 Point 1.4(a) of Part I of Annex II.*** *Amend as follows: growing plants for the production of ornamentals and herbs in pots to be sold together with the pot or as cut plants to the final consumer;*

7. ***2018/848 Point 1.5 of Part I of Annex II.*** *Amend point 1.5 as follows: By way of derogation from point 1.1, growing crops in demarcated beds shall be permitted as a permanent method for greenhouse production systems, provided that the cultivation is carried out in year-round manner.*

8. ***2018/848 Point 1.9.2(b) of Part I of Annex II.*** *Amend as follows: in the case of greenhouses or perennial crops other than forage, by alternative practices adapted to permanent structures. Member States may define specific derogations based on climatic and structural constraints; and*

Reasoning:

1. The Regulation currently requires double the withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product and the production of organically produced foodstuffs from that animal even if the withdrawal period in the summary of product characteristics (SPC) is zero or not determined at all. In addition, under the current provision of the Regulation, the withdrawal period for a chemically synthesised allopathic veterinary medicinal product is in any case at least 48 hours.

   If the withdrawal period for a chemically synthesised allopathic veterinary medicinal product is zero, the same zero withdrawal period should also be applied when that veterinary medicinal product is used for the animal in the production of organically produced foodstuffs. In addition, if there is no withdrawal period determined for a chemically synthesised veterinary medicinal product, the Regulation should in that case also not require a withdrawal period of at least 48 hours. The removal of the withdrawal period of at least 48 hours could also improve the wellbeing of organic animals when taking into account, for example, pain medication with a zero withdrawal period.

2. As in item 1: Remove the double withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product and the production of organically produced foodstuffs from that animal in situations where the withdrawal period in the summary of product characteristics (SPC) or in conventional agricultural use is zero or has not been determined.

3. Products used for cleaning and disinfection are already subject to authorisation procedures and restrictions under existing frameworks, such as the REACH Regulation, the CLP Regulation and the BPR Regulation.

4. A simplification proposal only in case the proposal given in item 3 cannot be applied: Amend the regulation so that it would enable the Commission to authorise and prohibit products and materials used in organic production and include them in restrictive lists. Exclusive criteria ('negative list') for products for cleaning and disinfection is more manageable than a list of permitted materials ('positive list'). Applying exclusive criteria to products for cleaning and disinfection keeps the administrative burden manageable while maintaining the integrity of organic production and compliance with production rules.

5. There are differences between Member States in the interpretation of the requirement 'in any case no less than three quarters of their lifetime'. At its strictest, the interpretation leads to unreasonably long conversion periods. The 12-month conversion period in the case of bovine animals and equine animals for meat production should be sufficient.

6. Permit the sale of pot plants together with the pot also as cut plants. The present requirement for pot plants to only be sold with the pot is a major obstacle to profitable competitiveness of organic greenhouse production and organic products. Retailers, consumers and the HoReCa sector favour products without pots. In addition, the HoReCa sector cannot even accept soil-based raw materials. Misleading the consumer can be prevented with appropriate labelling, as is also the case with other organic products.

7. Enable the growing of crops in demarcated beds as a permanent method in organic greenhouse production. This is currently only permitted by way of derogation, and the derogation will expire on 31 December 2031.

8. This enables alternative practices in organic greenhouse systems and maintains the fertility and biological activity of the soil. Short-term green manure crops and legumes as well as the use of plant diversity are not very well suited to greenhouse production systems. Greenhouses are designed and constructed for the growing of a specific crop. Therefore, the requirement for plant diversity may be difficult to implement, and this generates additional costs. The same requirements are also not necessarily suitable for all Member States due to different climatic and structural constraints. Therefore, there should be flexibility for certain derogations.

25. Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition

Simplification proposals:

1. Avoid bureaucracy with regard to enterprises and regulators, for example the requirement to renew the authorisation of feed additives every ten years is not necessarily needed in all cases, in particular those where the additive has a long history of safety in use.

2. Another example of an unnecessary burden is the process involved in changing the holder of an authorisation.

Reasoning:

The current Regulation on additives for use in animal nutrition (EC No 1831/2003) appears to be outdated in light of the scientific and technological advancements that have taken place in 2003–2025, which increases the workload and uncertainty. The aim to update the Regulation has been in place for several years.

26. Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene

Simplification proposals:

1. The Regulation laying down requirements for feed hygiene appears to be outdated in some parts; for example, the Annexes do not reflect the functionalities of current additives. For example, mycotoxin binders or physiological condition stabilisers, whose role is increasing in current feed types, are not recognised.

2. Another example of outdated regulation is Articles 23 (Imports) and 24 (Interim measures). According to Article 24, imports continue to be authorised under the conditions laid down in Article 6 of Directive 98/51/EC until the lists provided for in Article 23(1)(a) and (b) have been drawn up.

3. With regard to operations associated with primary production (Article 5), the on-farm slaughter of insects for feed at farms using authorised methods should be recognised as primary production.

Reasoning:

1.–2. Over the past 20 years, the Commission has not drawn up the lists required, and references to outdated legislation (Directive 98/51/EC) have resulted in inconsistent interpretation of the regulation by feed business operators and competent authorities.

3. The transport of live insects from the processing site to the handling facility is logistically challenging and increases both costs and the risk of insects escaping into the environment. The slaughter of insects cannot be equated with the slaughter of other farmed species.

27. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products

Feed of plant origin does not require as strict import requirements (such as the obligation to import via a border control post and the detailed requirements relating to documents), as the disease risks are not comparable with risks relating to feed of animal origin. At least no new feed types or countries of origin should be added to the scope of application of Article 47 of the Regulation on official controls.

28. Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

Simplification proposals:

1. *The TSE Regulation should be modernised and simplified. In addition, it should be further adapted to Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002, and to feed regulation.*
2. *TSE regulation should be made more flexible with regard to the feed ban so that it would reflect current scientific evidence and risk assessments. With regard to ruminants, this would mean authorising meal of aquatic animal origin (fish, crustaceans) in ruminant feed. In addition, the manufacture of fishmeal and insect meal should be permitted in the same establishment in the manner whereby adequate cleaning takes place between them to avoid cross-contamination.*
3. *The registration requirement for all complementary and complete feeds containing PAP (including fishmeal) should be repealed.*

Reasoning:

1. TSE legislation causes unnecessary costs for the meat industry and hinders the application of circular economy principles in feed production.

2. Fishmeal batches are tested to establish whether they contain protein from terrestrial animals and, when it is not found, there is no TSE risk to ruminants. The removal of the requirement for a specific production line for the manufacture of feed for porcine animals or for poultry in establishments that also produce feed for ruminants would simplify production opportunities. The prohibition concerning fishmeal in feed intended for ruminants currently results in significant costs for operators due to the need for separate feed production lines and related measures.

3. The feed manufacturer has already ensured that a PAP product is sourced from an appropriate producer or supplier.

29. Commission Regulation (EU) No 517/2014 health rules as regards animal by-products and derived products not intended for human consumption

Simplification proposals:

Update the standard processing methods specified in by-products legislation to better reflect current practices and to make them applicable to the raw materials and end products used, in particular feed.

Reasoning:

For example, methods 1–6 are totally unsuitable for the processing of insects. The validation process for method 7 is long and cumbersome for operators.

30. Regulation (EU) 2015/2283 on novel foods and Regulation (EC) 1829/2003 on genetically modified food and feed

Simplification proposals:

To boost the global competitiveness of the EU, it is important for the EU to facilitate innovations by lightening regulation.

Reasoning:

The authorisation procedures for novel foods and genetically modified food and feeds take too long and are too burdensome for all (applicant, authorities, European Commission and EFSA)

DEFENCE

31. Defence and Security Procurement Directive (DSPD) 2009/81/EC

Simplification proposals:

As regards the DSPD, the EU thresholds should be raised to enable national, simpler procedures. In addition, the provisions on subcontracting should be removed entirely. The amendments should be made by the next MFF period without prejudice to the outcome of the next MFF negotiations.

Reasoning:

The reasoning for the raising of the threshold is that the procedural requirements are highly detailed for procurement exceeding the EU threshold. Raising the threshold would enable the speedier completion of procurements, which is needed in the current situation, considering Europe's security situation and the growing procurement volume. In addition, the raising of the EU thresholds would enable more flexible national regulation: Current EU thresholds (e.g. goods and services: EUR 443,000) restrict the use of national procedures even though many security and defence procurements are national by nature and directly relate to security of supply.

The regulation concerning subcontracting has not been applied once since its entry into force. EU-wide application has also, in practice, been non-existent, whereby the provisions could be removed as redundant regulation. The preamble to the Directive states that national security remains the sole responsibility of each Member State. This means that Member States must have sufficient flexibility to carry out procurements with national procedures, particularly when it comes to security of supply or critical capabilities. Subcontracting obligations may restrict the opportunities of contracting entities to select reliable and security-critical suppliers and providers. Many Member States have circumvented the application of the Directive by relying on the security exemption under Article 346 TFEU, which

shows that the current form of the Directive does not meet practical needs. This indicates that the Directive's regulatory framework should be reviewed to better align with the security interests of Member States. The Directive aims to promote the diversity of the European defence-related supplier base and the involvement of SMEs. Simpler procedures and the removal of the subcontracting obligation could facilitate these actors' access to the market.

32. Defence industry funding programmes (in particular EDF) 2021/697/EU

Simplification proposals:

1. The derogations from the evaluation criteria determined in the EDF Regulation and the funding bonuses should be minimised – except for SME bonuses.

2. The reporting obligation of enterprises (particularly SMEs) and research actors during project implementation should be reduced from the beginning of the next MFF period without prejudice to the outcome of the next MFF negotiations.

3. The EDF application stage should be made lighter.

4. As regards development projects, interadministrative project preparation should be made smoother. For example, uniform contract procedures and entries in the EDF Regulation on the utilisation of project results would be necessary.

Reasoning:

The number of application documents and appendices is considerable and raises the threshold for actors to apply for funding.

33. Voluntary certification of defence exemption processes by the European Defence Agency (based on EDA REACH / Code of Conduct)

Simplification proposals:

The Member States should, also going forward, decide independently on REACH defence exemptions and any reciprocal acknowledgement. Reciprocal acknowledgment could be facilitated if an external actor audited the Member States' defence exemptions process (e.g. whether in compliance with the Code of Conduct requirements) and, should the process be compliant, would issue the certificate. The certifier could be, for example, the European Defence Agency (EDA), and the certification would be voluntary for the Member States. In this context, there would be no need to process information to be kept secret for reasons of national security. Instead, the documents processed would only concern the process and, where necessary, guidance documents concerning the processing of defence exemptions and requirements.

Reasoning:

Certification would pave the way for reciprocal acknowledgment of defence exemptions and would therefore facilitate the activities of the defence industry.

HEALTH

34. Medical Device Regulation (MDR) 2017/745/EU

Simplification proposals:

1. *The risk classification of devices and conformity assessment procedure consistent with it must be proportionate.*

- *It is difficult to make classification rules all-encompassing, whereby the potential to enact mechanisms enabling binding decisions on changing classifications at the Union level in a timely and efficient way should be examined.*
- *Challenging borderline cases and classification problems could be resolved in an EU-level procedure, with regulatory authorities of other sectors also taking part where necessary.*
- *Conformity assessment procedures and related costs should take account of small and medium-sized enterprises, of which there is a large number in the sector.*
- *Measures to simplify regulation should be planned carefully, taking into account the special characteristics of various devices that have been in use for a long time and the applicability of new regulatory provisions to them. Special attention should be paid to devices that have been in use for a long time that are based on established technologies and have a well-documented safety record.*
- *Conformity assessment conducted by an independent notified body is important but expensive. As regards each risk class, the scope and level of external assessment should be evaluated carefully, and it should be established whether conformity requirements for lower risk classes could be eased.*

2. *Specific procedures for new and innovative devices and orphan devices. Alternative procedures that ensure safety while ensuring speedier access by patients to life-saving innovative devices (such as conditional certification) should be explored.*

3. *As regards administrative burden, it should be carefully evaluated to which extent there are overlaps in reporting obligations and whether these can be simplified without losing essential information.*

4. *Periodic safety update reports (Article 86). Extending the reporting interval or simplifying reporting, even lifting the obligation for low risk class products, in order to reduce the burden on operators and enable more efficient resource allocation.*

5. *Reprocessing and further use of single-use medical devices (Article 17). Reprocessing and further use could be enabled without assessment by a notified body, limiting this, however, to healthcare units. The reprocessor would be responsible for the reprocessing and use.*

6. *Reformulating the assessment of the independence of notified bodies (Section 1.2 of Annex VII) could facilitate and speed up the assessment process, particularly when the notified body is part of a larger organisation.*

7. *Clinical investigations with devices bearing the CE marking used in accordance with their intended use (Article 74). The simplification of legislation and lifting of the authorisation requirement for investigations regarding devices bearing the CE marking and used in*

accordance with their intended use would reduce the administrative burden and costs and could increase the attractiveness and competitiveness of research and development activity.

8. *Assessment by the Member State involving only two options concerning an investigation: authorisation or refusal (Article 71). A major shortcoming concerning clinical investigations of devices (and performance studies) is that Article 71 only enables the authorisation or refusal of applications for authorisation of investigations. There are situations, such as exhaustion of funding, change negotiations in the enterprise and project closures and bankruptcies, where it should be made possible to withdraw an application for authorisation of investigations in the middle of the process*.

Reasoning:

1. In 2025, the Commission evaluated the Medicinal Devices Regulation ((EU) 2017/745, MDR) and the Regulation on in vitro diagnostic medical devices ((EU) 2017/746, IVDR), the implementation of which has involved significant challenges, particularly from the perspective of obligations on enterprises. Finland has also regarded it as important to update the regulations in an orderly manner. Regulatory requirements, including conformity assessments conducted by third parties, should be in the right balance from the perspective of patient safety and the availability of devices.

2. The current conformity assessment procedures are not necessarily suitable for new types of device, and placing such devices on the market may be too slow. Specific mechanisms are also required for orphan devices which are only used for small groups of patient and the regulatory costs of which cannot be commercially justified.

4. Preparing periodic safety update reports (PSUR) is arduous and places a particular burden on large operators with hundreds/thousands of products. Reporting taking place once a year is labour-consuming and creates costs. The authorities or notified bodies do not have the resources to read everything.

5. Authorisation for reprocessing and further use currently requires assessment by a notified body, which slows down the process and creates bottlenecks.

6. Notified bodies must ensure that their assessment processes are independent, impartial and transparent. This means that notified bodies may not have interests in any organisation or person that could affect their decisions or assessments. The existing regulation also extends the independence and impartiality requirements to the entire organisation a part of which the notified body is (Section 1.1.2 of Annex VII). In practice, it is an impossible task to identify the services provided by the various units of a global organisation and to take the requirements into account in the operations of the rest of the organisation.

7. Investigations with devices bearing the CE marking used in accordance with their intended use currently also often require a complex and time-consuming authorisation process, which may slow down the commencement and progress of investigations. This may result in innovative research and development projects being delayed or not taking place at all.

8. There are situations, such as exhaustion of funding, change negotiations in the enterprise and project closures and bankruptcies, where it should be made possible to

withdraw an application for authorisation of investigations in the middle of the process. Making a refusal decision, or any decision at all, is not appropriate in such situations.

35. Modifications to applications for authorisation of trials on medicinal products and their assessment process in Regulation (EU) 536/2014 (CTR)

Simplification proposals:

1. *Any assessment being conducted by the reporting Member State (RMS) alone should be agreed between the participating countries separately for each study or, in the event of a pandemic or other corresponding situation, for a specific period of time.*

2. *The RMS should be able to conduct the assessment of applications for substantial modifications alone in certain cases, such as applications for modifications to comply with the conditions specified in Part I of the decision on the trial, or applications for substantial modifications based on detailed trial-specific scientific or regulatory advice provided at the EU level.*

3. *The change of RMS should be enabled by means of an appendix to the Regulation.*

4. *Part I modification application(s) should only apply to an individual country.*

5. *An individual modification application would pertain to matters relating to applications referred to above under 'Opportunity for the RMS to conduct the assessment alone' (compliance with conditions, implementation of advice).*

6. *Document requirements for clinical trials on medicinal products. It should be made possible for an application for the authorisation of a trial to refer to documents of another trial, for example in Part I the documentation on the investigational medicinal product (CTR, Annex I(E) and (G). 'The sponsor shall, where appropriate, refer to any previous applications. If exactly the same documents are used in the application, reference shall also be made to the documents of the previous trials and the same documents should not be resubmitted. If these applications have been submitted by another sponsor, the written agreement concerning the references from that sponsor shall be submitted.'*

7. *Harmonisation of Part I and II assessment schedules. The assessment periods of Part II should therefore be tied to the assessment periods of Part I so that the conclusion on Part II would not be made before the conclusion on Part I.*

8. *EU portal and database on medicinal products. The functioning of the CTIS should be changed, for example, to simplify the addition of non-XEVMPD products and/or for the CTIS to accept free-text fields for these products. Based on the assessor's discretion, free-form fields could be accepted in the XEVMPD or, alternatively, the information could be submitted in the CTIS.*

9. *Cross-border trials. The CTR should be amended to take account of cross-border trials. A country where only individual trial measures are conducted should be able to accept a partial*

application without all of the current requirements set by the CTR, taking subject safety into account.

10. *Facilitating processes in crisis situations. During pandemics and other crisis situations, the delivery of investigational medicinal products directly to subjects should be permitted to ensure the continuity of the investigational medication. The supervision of this activity should be organised but be proportionate to the crisis situation.*

11. *Reducing differences between national requirements.*

Reasoning:

1.–2. Under Article 6 of the Clinical Trials Regulation (CTR), all Member States participating in a trial take part in the assessment of applications for substantial modifications of a trial once the reporting Member State (RMS) has drawn up an assessment report. In the present situation, the RMS must wait for the considerations of the other participating Member States or their technical response on the portal.

3. Trials take place at different times in different countries. This is why the RMS may have to continue the assessment of a trial (modification applications, ad hoc notifications) even if the trial has already ended in the Member State.

4.–5. In the present situation, only one application for a substantial modification to a trial can be under review at the same time. This slows down the making of modifications required for trials by the period of time taken by the review of a new substantial modification (50 days excluding questions).

6. The document requirements for clinical trials on medicinal products are specified in Annex I and II to the CTR. The same sponsor often conducts several trials on the same tested product or has other fully identical characteristics in its trials, and these are described using the same document in all of the applications concerned. It should be made possible for an application for the authorisation of a trial to refer to documents of another trial, for example in Part I the documentation on the investigational medicinal product (CTR, Annex I(E) and (G)). Reference to documentation that has already been submitted, without having to upload the documents again to the portal, would harmonise and simplify the assessment conducted by the authorities and reduce overlapping work and the efforts of sponsors.

7. At the moment, the assessment of the (national) Part II may be completed when the review of Part I is still ongoing. This has resulted in inability to implement some of the impacts on Part II of modifications made in Part I during the review of the trial application. In these situations, the sponsor has had to submit a Part II modification application, which would have been more consistent and simpler to do as part of the process concerning the previous application. The situation has resulted from the strict deadlines set by the CTR for assessment after the sponsor has answered the questions made (CTR Article 7(2) and (3), Article 14(8) and Article 22(1) and (3)).

8. The CTIS uses the XEVMPD database maintained by the European Medicines Agency (EMA) as the master file for investigational medicinal products (IMP). Academic researchers in particular would sometimes like to use products not included in the database in their research. Adding these as IMPs in the CTIS has been made practically

impossible unless the manufacturer of the product itself is involved in the research and willing to assist in the matter. If the product is used like a medicinal product in a trial, it is classified as an IMP even if it, for other uses, has been classified as, for example, a dietary supplement in Finland. Authorised medicinal products can already be found on the CTIS portal as they have been added to the EMA database.

In practice, these situations necessitate a request to add the product with EMA assistance. Regardless of support provided by the EMA, there have been considerable delays in the submission of applications for several clinical trials on medicinal products, or applications have been regarded as too difficult, whereby the research has not been conducted.

The XEVMPD is undergoing a gradual overhaul. Since the database is also used for purposes other than as the master file for medicinal product information for the CITS (particularly in the monitoring of adverse reactions to authorised medicinal products), the information required by it is, going forward, likely to be larger in quantity than required for the purposes of trials on medicinal products. This is why simpler entry of new IMPs into the portal should also be enabled for academic researchers and others conducting clinical trials on medicinal products that are not aiming to submit an application for marketing authorisation.

9. The existing EU legislation on trials does not recognise cross-border trials across the internal borders of the EU. These refer specifically to situations where subjects participate in a trial conducted in another country, which is when elements such as trial appointments take place in a country other than the subject's country of residence. The investigational medication may be administered in another country, or the subjects may be provided with the medication to take with them. In another situation, the subjects otherwise participate in the trial in their country of residence but may visit another country to participate, for example, in demanding imaging studies that are not available in their own country. In addition, a subject may relocate to another country due to a national emergency such as war. In the present situation, sponsors must submit applications for all of the countries and set up the trial centres required by normal studies, including agreements, appoint the investigators, organise the import of the IMP, etc. Although Article 14 of the CTR on the subsequent addition of a Member State concerned facilitates the submission of the application for authorisation, the other arrangements are almost as extensive and time-consuming as in normal trials conducted within a single country.

10. Those participating in a trial during a pandemic or other crisis situation may have to change from their trial centre to a trial centre in another country. When subjects self-administer their investigational medicinal product, the labelling must be in the subject's own language. To ensure the continuity of investigational medication in these situations, separate dosage instructions provided at the trial centre in accordance with the trial protocol in a language understood by the subject, such as English, should be permitted. Where investigational medicinal products are administered by trial staff, English is accepted in labelling in part of the Member States, such as Finland.

11. The CTR allows the opportunity to lay down national provisions on some aspects of clinical trials on medicinal products. This has resulted in varied approaches that the sponsor must implement in each country in accordance with the requirements of the

Member State. For example, the EMA recommendation paper on decentralised elements in clinical trials contains a separate 16-page appendix providing an overview of national provisions concerning the implementation of such trials in different EU countries. In addition, other country-specific requirements have also been set for certain countries. By clarifying the legislation, it should be ensured that trials could be implemented based on consistent approaches during pandemics and other crisis situations. It should be possible to implement common approaches under a joint authorisation for a clinical trial on medicinal products issued in the EU to Member States participating in the trial.

FINANCIAL SERVICES

36. EU Sustainable Finance Disclosure Regulation (SFDR) (EU) 2019/2088

Simplification proposals:

The revision should harmonise terminology with other acts. It is also necessary to assess whether some obligations could be removed or combined, particularly if they have proved to be redundant in practice. As regards the SFDR's level 2 regulation, there is a need to examine the delegation of legislative power to ensure the clarity of level 2 regulation. The delegation of legislative power should also be assessed from the perspective of how detailed lower-level regulation should be.

The revision should examine whether, with regard to those subject to CSRD, institution-specific regulation is harmonised as much as possible with CSRD. There is a difference in the concept of 'sustainable investment' between the Taxonomy Regulation and the SFDR. This concept should be harmonised between the acts.

Reasoning:

The work programme of the Commission mentions a revision in Q4/2025. The SFDR delegates the preparation of regulatory technical standards to the European Securities and Markets Authority (ESMA) and their adoption to the Commission. In practice, level 2 regulation has proved both difficult to apply highly detailed and, in some respects, very cumbersome.

The concept-related differences and very minor reporting differences between the various acts place an unnecessary burden on enterprises when, in practice, essentially the same information is reported using slightly different methods or terms.

37. Legislation on financial service providers, such as MiFID (2014/65/EU) and its Article 34

Simplification proposals:

Removal of the notification obligation. The body of financial services legislation should be assessed as a whole with regard to the notification obligation. The assessment should not be limited only to the MiFID.

Reasoning:

Under financial services legislation, the service providers must submit a notification if they provide cross-border services or products. Notifications are also often made and updated in cases where the service provider makes a notification just in case, even though it does not yet intend to provide services or products in the country concerned. Notifications are typically submitted simultaneously for all EEA countries, even though there is actually no cross-border provision to many of them. The EU's retail investment strategy proposal contained an amendment concerning true cross-border activities. The amendment would facilitate the work of financial supervisory authorities. The Council reached an agreement on the proposed amendment, but the consideration of the legislative proposal is still ongoing in the EU. All authorisations of financial service providers are publicly available and notified to the European Securities and Markets Authority (ESMA) (Article 5(3) MiFID), which means customers can check the authorisation of a service provider and its scope. Home Member State legislation and supervision are the primary rule of the MiFID with regard to cross-border activities. Notifications do not deliver added value, but they do place a burden on service providers and their supervisors.

38. Taxonomy Regulation (EU) 2020/852

Simplification proposals:

1. *Sustainable finance: As a general observation, the clarification needs of the EU's sustainable finance should be examined among the various acts in the body of legislation and, for example, with regard to the Directive on corporate sustainability reporting ((EU) 2022/2464) (CSRD). In addition, the various acts contain some similar obligations that also feature slight differences.*

2. *EU Taxonomy Regulation (EU) 2020/852: The Taxonomy Regulation does not obligate enterprises to fulfil the criteria but, instead, to report on compliance with them. Many of the clarification needs of the Taxonomy Regulation relate to the delegated acts adopted under it. The Commission is responsible for the preparation of the delegated acts, whereby their amendment does not require the re-opening of the Taxonomy Regulation itself.*

Reasoning:

1. The EU's Taxonomy Regulation ((EU) 2020/852), Sustainable Finance Disclosure Regulation (SFDR, (EU) 2019/2088), CSRD as well as other EU legislation use similar terms that, however, do not have exactly the same meaning. For example, there is a difference between the SFDR and the Taxonomy Regulation as regards the concept of 'sustainable investment'. The clarification and harmonisation of different acts containing similar obligations would promote the usability of the acts and reduce overlapping reporting.

2. For example, the delegated act adopted under Article 8 of the Regulation has been regarded in part difficult to apply and in part inappropriate. Particularly over the past year, concerns and application problems have emerged among stakeholders with regard to the green asset ratio (GAR), the metric for credit institutions for

taxonomy alignment. Many taxonomy-related reporting needs can likely be addressed by amending the delegated act. The delegated acts concerning the technical assessment criteria of the taxonomy are often difficult to apply and, for example, it has been found with regard to a few functions that they refer to criteria that do not exist. There is a need to correct delegated acts, and the work is currently underway in the EU. A key issue is whether the technical assessment criteria could be simplified in a significant manner without compromising the objectives concerning the environment, so that application would be easier for enterprises. If the Taxonomy Regulation itself was re-opened, the relationship of the reporting obligations with the CSRD and the SFDR would need to be assessed. Would it be more beneficial for enterprises if the CSRD also included the reporting obligations of the Taxonomy Regulation (Article 8) and the SFRD included the Taxonomy Regulation's reporting obligations concerning financial products (Articles 5–7)? The Taxonomy Regulation supplements the documents regulated by the said acts. However, it should be noted in this regard that, if this were to happen, the reporting obligations concerning enterprises and financial products might diverge over time, since they would be part of separate bodies of law.

TRANSPORT

39. Regulations (EC) No 715/2007 (Euro 5/6), (EC) No 595/2009 (Euro VI) and Regulation (EU) 2024/1257 (Euro 7)

Simplification proposals:

We wish to make a general reference to the Union legislation on emission standards, including Regulations (EC) No 715/2007 (Euro 5/6), (EC) No 595/2009 (Euro VI) and Regulation (EU) 2024/1257 (Euro 7), as well as the implementing and delegated powers conferred on the European Commission under these acts. We request that the European Commission identify appropriate means to simplify and streamline the existing type-approval requirements and procedures. Such simplification should facilitate the placing on the market of solutions that are better suited to low ambient temperatures and arctic operating conditions.

Reasoning:

There is a particular need to ensure that issues arising from the freezing of AdBlue (in -11 °C) can be effectively addressed. To this end, it is essential to allow for the practical and flexible introduction of more frost-resistant reagents and to enable the necessary vehicle modifications required to use them. This should apply both to new vehicles and to those already in service. Improved regulatory flexibility in this area would support the deployment of technically viable solutions in harsh climatic conditions and reduce operational disruptions linked to reagent freezing. Such a regulatory adjustment would also promote a more level playing field for economic operators across EU Member States and contribute to the achievement of the Union's environmental objectives.

40. Commission Implementing Regulation (EU) 2023/2599 (administration of shipping companies)

Simplification proposals:

Developing the THETIS-MRV system so that it contains information on changes of ownership, on the transfer of a ship under the responsibility of another administering authority and on the date of the change would enable the abandonment of separate lists of ships.

Reasoning:

According to Commission Implementing Regulation (EU) 2023/2599, when a shipowner operates as a shipowner in accordance with the Emissions Trading System (ETS) Directive, it must provide the administering authority with a list of the ships in respect of which it has assumed responsibility for ETS obligations. In practice, this list of ships is also accessible by the administering authority in the THETIS-MRV system, whereby a separate list of ships is redundant.

For the administering authority, it is essential to receive information about any changes of the shipping company responsible for ETS concerning the ship. The development of the system would enable the separate lists of ships to be abandoned.

41. ReFuelEU Aviation Regulation 2023/2405/EU

Simplification proposals:

With regard to new actors entering the scope of application of the ReFuelEU Aviation Regulation, a waiting period of one year (at least 6 months) should be applied before the obligations of the Regulation enter into force, that is, the years should be counted using the so-called n−2 rule.

Reasoning:

This rule was applied to begin with when the actors in-scope of the Regulation in 2024 were determined based on data for 2022. However, the n−1 rule has now been adopted, that is, for example, the actors in-scope of the Regulation on 1 January 2025 were determined based on data for 2024. Practice has shown that it may be difficult for new actors falling within the scope of application of the Regulation to fulfil their obligations and that they may not necessarily be on an equal footing with other actors in terms of, for example, opportunities to request exemptions from refuelling obligations for specific routes.

As a rule, the scope of application of the Regulation covers aircraft operators (in most cases airlines) that operated at least 500 commercial passenger air transport flights or 52 commercial all-cargo air transport flights departing from Union airports in the previous reporting period. Under the Regulation, 'Union airport' means an airport where passenger traffic was higher than 800,000 passengers or where the freight traffic was higher than 100,000 tonnes in the previous reporting period, and which is not situated in an outermost region (Article 349 TFEU).

In practice, this therefore means that, if an airline or airport exceeds the thresholds set for the coverage of the Regulation right at the end of the previous year, the obligations

enter fully into force at the beginning of the following year. With regard to Finland, included in the scope of application of the Regulation from the beginning of 2025 were the Rovaniemi Airport (with 800,000 passengers exceeded around two weeks before the end of the year) as well as three new aircraft operators: Scanwings, Fly 7 Finland Oy and the Ukrainian Skyline Express Airlines.

The ReFuelEU Aviation Regulation allows requests for exemptions from the refuelling obligation for specific routes, but the requests must be made at least three months before the date of application of the exemption. In practice, this may turn out to be impossible for new aircraft operators. The Commission published a list of aircraft operators in-scope of the Regulation on 8 July 2025. An airline wishing to request an exemption from the beginning of 1 January 2025 should have done so on 30 September 2024 at the latest. In the list of airports, Rovaniemi is still shown with a preliminary status even through the passenger number data has been known since the start of the year. The Commission has, however, stated that the lists on its website are not legally binding and that all actors should be prepared for changes in advance. In practice this is, however, impossible.

The current schedule under the Regulation causes problems and additional work for all in-scope actors (aviation fuel suppliers, aircraft operators, airport managing bodies) as well as for the authorities.

In addition, in the same way as for maritime transport, the EU ETS Directive and the Commission's verification Regulation (EU) 2018/2067 determine the practices for ETS and for emissions verification and accreditation at the EU level. The verifier must be accredited by a national accreditation body of an EEA country, and there is no need to seek accreditation separately in all operating countries. However, Finnish legislation requires, in addition, that the aviation verifiers are approved separately by the Finnish Transport and Communications Agency (Traficom). This increases the administrative burden and costs for both the verifiers and for Traficom, even though in practice Traficom is only tasked with checking the verifier's valid accreditation certificate.

OTHER

42. Directive 2014/24/EU on public procurement; Directive 2014/25/EU on procurement by entities operating in the water, energy, transport and postal services sectors (Utilities Directive) and Directive 2014/23/EU on the award of concession contracts

Simplification proposals:

1. *Three directives should be merged into a single directive and overlapping provisions should be dismantled and rules clarified. Sector-specific provisions should be included in their own chapters.*
2. *The procedures for the companies' meeting suitability obligations should be simplified and clarified (a more advanced and clearer digital solution to replace the ESPD form)*

3. *The number of procurement procedures should be reduced to three (3 + direct procurement) and simplified.*
4. *The procurement directives should be maintained as "how to buy" regulation (possible content requirements in the sector-specific regulations).*
5. *The use of advanced digital solutions should be promoted in the offerings for public procurement.*

Reasoning:

The companies would like to participate in public procurement more than at the moment. The directives are complex and include many overlapping provisions. Directives affect a large number of companies in almost all sectors. In principle, their rules apply to all competitive tendering of public authorities and certain other contracting entities in procurement of goods and services and public works contracts (including concessions contracts) when the value of contracts exceeds the EU thresholds and the procurement has not exceptionally been excluded from the scope of the application of procurement directives.

43. Consumer protection regulation

Simplification proposals:

The B2C obligations laid down in several different EU acts (both general and specific regulation) should be examined as a whole. In addition, the mutual order of priority of EU acts should be set out clearly. Consistency in wordings should also receive particular attention when the same thing is actually meant. For example, it might be necessary to re-examine the necessity of the information provision requirements of the Electronic Commerce Directive (2000/31/EC, Articles 5 and 6), the Services Directive (2006/123/EC, Article 22) and the Portability Regulation ((EU) 2017/1128) to the extent that they currently apply to B2C relationships. In addition, it might be appropriate to examine the extensive list of information concerning distance and off-premises contracts to be provided under Article 6 of the Consumer Rights Directive (2011/83/EU), in particular from the perspective of whether some of the advance information would belong more naturally as part of contractual terms, for example.

Reasoning:

It is common in the consumer protection sector that multiple different EU acts, all of which contain lists often differing from each other concerning which information the trader must provide the consumer with at the various stages of a transaction. Here a key problem is the cumulation of B2C information provision obligations. Information obligations have been increased in recent years, and it has been proposed that they continue to be added, on the one hand, to the EU's general consumer protection instruments and, on the other, to legislation such finance, digital, data and environmental acts.