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Proposal for a

# REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## on preventing plastic pellet losses to reduce microplastic pollution

{SEC(2023) 346 final} - {SWD(2023) 330 final} - {SWD(2023) 332 final} -
{SWD(2023) 333 final}

# EXPLANATORY MEMORANDUM

## 1. CONTEXT OF THE PROPOSAL

In 2018, the EU Strategy for Plastics in a Circular Economy[1] acknowledged the risks posed by microplastics and advocated innovative solutions targeting different sources. In 2019, the European Commission's group of Chief Scientific Advisers recognised the potential risks posed by microplastics and encouraged precautionary action.[2] In 2020, as a follow-up action of the European Green Deal[3], the Circular Economy Action Plan 2.0[4] committed the Commission to tackling the presence of microplastics in the environment by:

- restricting intentionally added microplastics in products;
- addressing unintentional releases of microplastics by developing inter alia, standardisation, certification and regulatory measures as well as harmonising methods for measuring their releases.

In 2021, in its Action plan: 'Towards zero pollution for Air, Water and Soil'[5], the Commission proposed that, by 2030, the EU should reduce (intentional and unintentional) microplastic releases into the environment by 30%.

On 25 September, the European Commission adopted a Regulation restricting microplastics intentionally added to products.[6] This proposal on preventing plastic pellet losses to the environment and its accompanying Impact Assessment (IA) stems from the Commission's commitments on unintentional releases of microplastics.

### 1.1 Reasons for and objectives of the proposal

**Plastic pellet losses** to the environment are the **3rd source of all unintentional microplastic releases**. Other main sources include paints, tyres, textiles, geotextiles and, to a lesser degree, detergent capsules. Preventing microplastic releases from these sources may require major substitutions or changes to product characteristics. In contrast, plastic pellet losses are due to a lack of awareness and poor handling and therefore can be abated by swift measures to prevent such avoidable pollution. This makes plastic pellets a primary candidate for policy intervention.

Plastic pellets, also referred to as nurdles, nibs, preproduction pellets, and resin pellets, are the industrial raw material used for all plastic production. **Current practices for handling**

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1 Communication from the Commission to the European Parliament, the Council, the European, Economic and Social Committee and the Committee of the Regions A European Strategy for Plastics in a Circular Economy, COM/2018/028 final

2 Scientific opinion on the environmental and health risks of microplastic pollution, April 2019.

3 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee of the Regions, The European Green Deal, COM(2019)640.

4 Communication from the Commission to the European Parliament, the Council, the European, Economic and Social Committee and the Committee of the Regions A new Circular Economy Action Plan For a cleaner and more competitive Europe, COM/2020/98 final

5 Communication from the Commission to the European Parliament, the Council, the European, Economic and Social Committee and the Committee of the Regions Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil', COM/2021/400 final

6 COMMISSION Regulation (EU) amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microplastics – C/2023/6419 final

**pellets lead to losses at all supply chain stages, notably production (virgin or recycled), processing, transport and other logistics and waste management operations**. Once in the environment, they are almost impossible to capture. Their mobility is an aggravating factor. Like all microplastics, plastic pellets that escape from industrial installations or during transport are easily transported through the air and by land surface waters and marine currents and can also be found in soil (including agricultural lands).

**Four types of adverse impacts can be observed from pellet losses: on the environment; on climate; potentially on human health; and on the economy**. Some of these impacts are specifically related to pellets, others are related to microplastics in general. Pellets are known to be eaten by a range of marine and coastal species (e.g. sea turtles, seabirds and shellfish). Once ingested, they can cause physical harm or death. If they cannot pass through the digestive system, they can lead to malnutrition or starvation. Like all microplastics, their potential to act as a carrier for adsorbed toxicants or pathogenic microorganisms is an integral part of the problem. Plastics and microplastics contribute to climate change by being an additional source of both greenhouse gas (GHG) emissions and pressure on ecosystems and biodiversity. Indeed, GHGs are emitted throughout the plastic life cycle, from production to degradation processes, and plastics in the oceans may also interfere with the oceans' capacity to absorb and sequester carbon dioxide. Humans are exposed to microplastics via air and food consumption. There are potential negative economic impacts from microplastics, including plastic pellets, on local activities such as commercial fishing and agriculture (e.g., reduced fishing harvest due to impacts on marine habitats, eco-systems and wildlife) as well as tourism and recreation (e.g. reduced attractiveness or closing of beaches and vulnerable areas like national parks, rivers and lakes).

High volumes of pellets are produced and handled every year, both globally and in the EU (around 57 million tons in the EU in 2021). Estimates show that **between 52 140 tonnes and 184 290 tonnes of pellets were lost to the environment in the EU in 2019. This is equivalent to between 2100 and 7300 trucks full of pellets per year.**

The evidence collected to support the accompanying IA and the inception IA, as well as the public consultation and an additional consultation targeting SMEs, suggest that stakeholders are in favour of all levels of public authorities undertaking action to reduce microplastic pollution. Stakeholders also refer to the industry's voluntary work in this field as a course of action, notably the Operation Clean Sweep® programme (OCS).

This proposal aims to **reduce pellet losses to the environment** and would lead to a 54% to 74% decrease compared to the baseline, equivalent to a 6% reduction in the total amount of unintentional microplastic releases. In line with the Commission's 30% overall reduction target for microplastics released to the environment, it will help **preserving ecosystems and biodiversity, decreasing potential health impacts and benefiting local economic activities**. It also has the potential to improve information on the magnitude of pellet losses throughout the pellet supply chain. Lighter requirements for SMEs will ensure the appropriate mitigation of potential impacts on their operations.

### 1.2 Consistency with existing EU policies

The proposal on preventing pellet losses to the environment supports the objectives of the European Green Deal contributing to resolving the triple crises of climate change, pollution, and biodiversity loss. It will also reinforce overarching strategies such as the Plastics Strategy,

the Circular Economy Action Plan and the Zero Pollution Action Plan. Microplastic pollution originates from:

1. the abandoned, discarded or improper disposal of larger plastic products and their degradation into smaller plastic pieces in the environment;
2. microplastics added intentionally to certain products, such as cosmetics, which ultimately find their way into the environment; and
3. microplastics released unintentionally, mainly due to abrasion during use or to poor handling.

On '**macroplastics**', the Union has already taken a number of regulatory measures to tackle pollution coming from larger plastic products that leak into the environment, including the Single Use Plastics Directive (SUPD)[7], the Waste Framework Directive (WFD)[8], the Packaging and Packaging Waste Directive (PPWD)[9] and the Marine Strategy Framework Directive (MSFD)[10]. These measures contribute to reducing the generation of plastic waste, improving its collection and recycling, and incentivising the use of recycled content in new products, thus reducing the amount of plastic litter in the environment.

Regarding '**unintentionally released microplastics**', beyond plastic pellets, the Commission has examined several other main sources of unintentional release, such as paints, tyres, synthetic textiles, geotextiles and, to a lesser degree, detergent capsules. Measures tackling microplastic releases from tyres have already been included in the EURO 7 Regulation proposal. The preliminary analysis of the other sources revealed uncertainties and data gaps and concluded that other policy instruments may be better suited to tackle them. More information and additional analysis are needed in order to define the most appropriate interventions. For these sources, separate impact assessments may be prepared, where appropriate and necessary, to support possible proposals to tackle microplastic emissions from these sources.

Regarding **industrial emissions**, the Industrial Emissions Directive (IED)[11] is the piece of legislation that regulates and manages emissions from large industrial plants. Plastic pellet losses are not specifically addressed in existing Best Available Technique conclusions. The rules set out in this Regulation should apply without prejudice to the application of the IED.

The proposal on preventing pellet losses to the environment complements the pellet provisions contained in the **REACH restriction on intentionally added microplastics**. This restriction addresses plastic pellets as an avoidable source of releases, by imposing two obligations on economic operators: (1) to provide information on the use and disposal of pellets e.g. via labelling, and (2) to report on estimates of quantities released on an annual

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7 Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment, OJ L 155, 12.6.2019, p. 1–19

8 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312 22.11.2008, p. 3

9 European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste OJ L 365 31.12.1994, p. 10

10 Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy, OJ L 164, 25.6.2008, p. 19–40

11 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), OJ L 334 17.12.2010, p. 17

basis. While increasing information on pellet uses and losses, these obligations are not further specified and a methodology on how to estimate losses is not introduced. The comprehensive obligations and standardised methodology included in this new proposal will help prevent pellet losses at the source and improve the information collected on estimated releases.

The proposal is consistent with the non-binding Recommendation of the Convention for the Protection of the Maritime Environment of the North-East Atlantic (**OSPAR**) on plastic pellets, promoting prevention standards and certification schemes for the entire plastic supply chain.[12] The International Maritime Organisation (**IMO**) is looking at the carriage of plastic pellets by sea in freight containers and is assessing both voluntary and mandatory measures, which would subject pellet-handling operators to stricter requirements.

The proposal aims to pave the way for provisions on microplastics in the context of the ongoing negotiations on a **Global Treaty on Plastic pollution**. The EU and its Member States "stress the need for the future instrument to include measures to reduce unintended release of microplastics. This could include, for example, measures to minimise the risk of leakages of plastic pellets from production, handling and transport".[13]

The proposal contributes to the implementation of the **UN 2030 Agenda for Sustainable Development** guided by the 17 Sustainable Development Goals (SDG), specifically: goal 12 on sustainable consumption and production, goal 14 on the conservation and sustainable use of the oceans, seas and marine resources for sustainable development and goal 15 on life on lands, together with goals 3 on good health, 9 on industry, innovation and infrastructure, and 13 on climate.

## 2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

### 2.1 Legal basis

This initiative is based on Article 192(1) of the Treaty on the Functioning of the European Union (TFEU) as it will increase the level of environmental protection across the EU. While it will also lead to further harmonisation of pellet handling, thus preventing market fragmentation due to different national approaches across Member States, the environmental protection dimension is predominant.

### 2.2 Subsidiarity

A common set of requirements for pellet handling within the Union is essential to ensuring a high level of environmental protection. Like all microplastics, pellets are readily transported from one geographical place to another and can be found in all environments including the most remote places. While pellet losses are usually concentrated at first in one geographical area (petrochemical or polymer industrial areas, logistic platforms like ports, etc.), they are extremely mobile and can then be dispersed by land surface waters and ocean currents, as well as through the air. The transboundary nature of the problem is the most important reason to act at EU level. If Member States act individually, the action would be less cost-effective, and the level of environmental protection would remain suboptimal. There is also a risk that competing different legislation would be established.

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12 Recommendation 2021/06 on the reduction of plastic pellet loss into the marine environment, 2021.

13 The EU submission to UNEP in view of the second session of the Intergovernmental Negotiating Committee on an international legally binding instrument on plastic pollution (INC-2).

### 2.3 Proportionality

The requirements in the proposal do not exceed what is necessary to enable economic operators running installations where plastic pellets are handled in quantities higher than 5 tonnes per year, as well as EU and non-EU carriers, to safely and responsibly handle such pellets. They are based on existing best handling practices, notably the industry Operation Clean Sweep® programme (OCS) and the non-binding Recommendation adopted by the parties to the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR). The proportionality of the requirements is ensured by introducing lighter requirements for SMEs, where necessary, as the result of thorough stakeholder consultation. National competent authorities in charge of verifying industry compliance will be supported by the work of certifiers that will be tasked with certification. This system will provide a high degree of legal certainty and facilitate enforcement activities.

### 2.4 Choice of the instrument

The proposal is a stand-alone legal instrument that would not amend existing legislation. It sets requirements to be implemented by the entire pellet supply chain as well as rules on a compliance system based on third-party certification, self-declaration, and compliance verification by national public authorities. Given that it aims to ensure a high level of environmental protection through changes to economic operators' handling behaviour, a Regulation is considered the most appropriate legal instrument.

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

No ex-post evaluation was carried out as there is no existing regulatory framework at EU level addressing plastic pellet pollution across the entire pellet supply chain.

### 3.1 Stakeholder consultations

The Commission consulted stakeholders via:

1. A public consultation on the originally identified sources with the highest known unintentional releases of microplastics, i.e. plastic pellets, synthetic textiles, tyres, paints, geotextiles and detergent capsules for laundry and dishwashers, from 22 February to 17 May 2022. During the consultation, 410 contributions were made. All stakeholders agreed on **the hazardous nature of microplastic pollution in the Union, its negative impact on the environment and human health, and the need to take action at all levels of authority**. Regarding pellet losses, stakeholders agreed that **improper handling was the major factor**.

2. A second consultation targeting SMEs handling pellets from January to February 2023. During this second consultation, 330 contributions were made. **A majority of the respondents was in favour of making the requirements mandatory if requirements are lighter for smaller companies.** Several requirements were estimated to be too burdensome for micro (less than 10 persons employed) and small (10-49 persons employed) enterprises, as well as firms with capacities below 1000 tonnes per year (average annual tonnage handled by small enterprises). SMEs did not favour the obligation of being externally audited. Among the best handling practices, the mandatory use of specific equipment and packaging (i.e. airtight, puncture-resistant and environmentally sealed) was identified as the most expensive measure. Finally, **respondents identified financial support and a standardised methodology to measure pellet losses as the best ways to support them**.

3. Workshops and bilateral contacts from September 2021 to May 2023 during which environmental NGOs strongly supported **mandatory requirements for pellet handling at the EU level, along with a comprehensive and transparent certification scheme**. The umbrella association of European plastic manufacturers, PlasticsEurope, agreed that the most effective approach to tackling pellet losses is **mandatory external auditing and certification building on OCS and applied to all actors**. Producers considered a legislative proposal requiring certification of an OCS-like pellet loss prevention system would be very quickly implementable by all actors because it would benefit from the existing industry initiative and would reinforce it. The umbrella association of European recyclers, PRE, favoured an **EU-wide legally binding instrument** to enable a level-playing field in the single market among all actors. The umbrella association of European converters, EuPC, pointed to **limited resources** as a barrier to implementing best handling practices.

## 3.2 Impact assessment

### *3.2.1 Problem definition & preferred policy option*

The proposal is based on the Impact Assessment (IA) accompanying the proposal on preventing pellet losses to the environment. The Commission's Regulatory Scrutiny Board (RSB) first issued a negative opinion with comprehensive comments on 18 November 2022. After a significant revision of the initial draft, the RSB provided a positive opinion with reservations on 12 June 2023[14]. Annex I of the Impact Assessment explains how the RSB comments were addressed.

The IA identifies the following problem: **current practices for handling pellets lead to losses at each stage in the supply chain, causing adverse environmental and potential human health impacts**. The following drivers were identified:

- **Market failures** - prices do not reflect negative externalities and imperfect information for market actors. A **lack of specific support and attention for smaller companies**, for whom preventive measures are costly to implement, also explains a suboptimal market outcome.

- **Regulatory failure** - existing relevant regulatory frameworks (governing chemicals, marine litter, water, industrial emissions, waste, packaging and transport activities) do not specifically address the issue of pellet losses and their safe and responsible handling across the entire pellet supply chain.

In the IA, four policy options were assessed to address these problems and drivers:

- Option 1: Mandatory standardised methodology to measure pellet losses
- Option 2: Mandatory requirements to prevent and reduce pellet losses in a new EU law, including three sub-options with lighter requirements for SMEs:

  2a: micro-companies;
  2b: micro- and small companies;
  2c: micro-, small and medium companies;

[14] SEC

- Option 3: Improved packaging for pellet logistics
- Option 4: EU target to reduce pellet losses

Based on a cost-benefit analysis, and a qualitative assessment of the proportionality, coherence, effectiveness and efficiency of the various options considered, a combination of two policy options was proposed as the preferred policy option:

- **Option 1 - Mandatory standardised methodology to measure pellet losses** to address the sub-problem 'Imperfect information' and contribute to improve information on the magnitude of pellet losses throughout the pellet supply chain. It will also facilitate the pellet losses reporting requirement under the REACH restriction.

- **Sub-option 2b - Mandatory requirements in a new EU law with lighter requirements for micro and small companies** to address the drivers 'Prices do not reflect externalities', 'Imperfect information' and 'Regulatory failure'. By focusing on prevention, it will contribute to reducing pellet losses, in an economically proportionate manner, to a level consistent with the Commission's overall reduction target of 30% of microplastic releases by 2030, and also to ensure the appropriate mitigation of impacts on SMEs involved in the pellet supply chain.

Option 3 would entail quite high investment costs for the sector, and its cost effectiveness would be lower than for Option 2. Option 4 would require the establishment of a performant monitoring system first, which would take time. Its implementation would be more challenging, and its costs would be slightly higher than under Options 2 and 2a-c. Sub-option 2b would have a relatively high reduction of pellet losses, and costs would be lower than under Option 2a thanks to lighter requirements for micro- and small enterprises. This option has the highest cost-effectiveness of the (sub)options 2, 2a-c.

### *3.2.2. Impacts of the preferred policy option*

The impacts listed below concern the preferred policy option as a whole and thus encompass provisions from both Option 1 and Sub-option 2b.

- Expected impacts of developing a mandatory standardised measurement methodology

The preferred policy option introduces the development of a standardised methodology to measure pellet losses and mandates its use, once developed, to complement the **reporting requirement on estimates of quantities released, introduced in the REACH restriction**. This restriction does not provide for a methodology to measure pellet losses.

By introducing a standardised methodology, **the preferred policy option entails one-off costs to develop and test the methodology**. The European Committee for Standardisation (CEN) typically takes 3-4 years to complete the process. Either the industry could bear this cost, or the Commission could provide support through a dedicated study. When developing the methodology, CEN will take into account the work carried out by the industry in this field.

It was estimated that the total cost to develop and test the methodology would be between EUR 1 258 000 and EUR 3 174 000. As the methodology will be based on work done by the industry, it is estimated that the lower end of the cost estimation is more likely. The reporting costs incurred by the industry using the methodology are already considered under the

REACH restriction. This applies also to the costs incurred by ECHA to process the information collected.

By providing economic operators with one standardised methodology, instead of several ones that otherwise could be used, **the preferred policy option aims at cost savings**: (1) economic operators do not have to each develop a methodology; (2) reporting to ECHA is simplified; and (3) the quality of the reporting is higher, as one methodology allows for comparability of data and, ultimately, a better understanding of volumes of pellet losses.

**The cost savings are estimated to be higher than the development costs. This approach is fully aligned with the commitment articulated in the** Communication entitled "Better regulation: joining forces to make better laws".[15] While there are no direct reductions of pellet losses under Option 1**, a standardised methodology to measure losses will enable economic operators and public authorities to better tackle pellet losses by improving information, reporting and monitoring of pellet losses.**

- Expected impacts of introducing mandatory requirements to prevent pellet losses and related compliance system

The preferred policy option introduces **mandatory requirements to prevent pellet losses to the environment for the entire pellet supply chain, thus maximising the chances of reducing such losses**.

In line with the polluter pays principle, the sector bears the costs of the measures required to comply with the requirements and demonstrate compliance via third-party certification or self-declaration. The public authorities in the Member States are responsible for keeping a public register related to compliance, and in the case of non-compliance, for imposing corrective measures and, where relevant, penalties.

By imposing mandatory requirements based on the work carried out by the industry on pellet loss prevention, containment and clean-up, and by introducing the obligation to demonstrate compliance there are **direct compliance costs for the sector**. **Lighter requirements for the smaller enterprises (micro- and small) are expected to mitigate the impacts on these enterprises**. Overall, the net cost of implementing Sub-option 2b is expected to be EUR 376 - 491 million per year.

Regarding **administrative and enforcement costs for the national competent authorities,** these include the setting up and maintenance of a public register, the compliance verification, complaint-handling mechanisms and access to justice as well as the reporting to the Commission on the implementation of this Regulation every three years. Overall, the costs for the Member States are expected to be EUR 313 000 for the first year and then EUR 125 000 per year for the whole EU. These costs will vary across Member States as they would be higher for larger ones and lower for smaller ones.

Since this option may increase the cost of plastic raw materials, **the general public may be impacted by an increase in the cost of plastic goods**. However, the cost increase, if any, is likely to be limited as the cost of implementing best handling practices is small compared to the turnover of the sector. It is therefore expected that manufacturers will absorb such a slight increase in their production costs leaving consumers unaffected.

[15] Communication from the Commission to the European Parliament, the Council, the European, Economic and Social Committee and the Committee of the Regions *Better regulation: Joining forces to make better laws,*

There is **a significant reduction of pellet losses to the environment, thus reducing microplastic pollution and preserving ecosystems and biodiversity**. It also constitutes **a precautionary measure against potential human health impacts.** The reduction of pellet losses is expected to range from 25 142 tonnes/year to 140 621 tonnes/year. The preferred policy option is thus expected to contribute to around 1/4$^{th}$ of the Commission's 30% reduction target for microplastics.

Other benefits include a **level playing field among economic operators** by guaranteeing that the position of companies applying reduction measures is not weakened by competition from companies that do not apply such measures as in the current voluntary system. For businesses owning the pellets, benefits include an **estimated economic gain** of EUR 25 to 141 million associated with the amount of pellets not lost to the environment.

Reducing pellet losses is expected to have **positive knock-on economic impacts on certain sectors** such as commercial fishing, agriculture, tourism and recreation in areas affected by the releases. There would be fewer pellets lost to the marine environment and, thus, fewer perturbations to marine species, including economically important ones such as oyster and seabass. Similarly, there will be fewer pellets lost to installations' wastewater and in the sewage sludge resulting from the wastewater's treatment, thus fewer pellets lost to the soil after the application of sludge on agricultural land, where this occurs.

The preferred policy option helps create new jobs as implementing best handling practices is expected to require **additional staff** (3 858 full-time equivalent). It also helps **prevent certain costs for society** such as those related to clean up and remediation activities by local communities in areas affected by the releases. These operations are normally challenging as they require technological, human and financial resources.

The preferred policy option is in accordance with the climate neutrality objectives outlined in the European Climate Law, as well as the Union's 2030 and 2050 targets. Its most significant contribution to climate mitigation lies in its ability to prevent the dispersion of plastic pellets into the environment. Preventing plastic pellet pollution at source is expected to result in lower greenhouse gas emissions since less plastic production will be required. Furthermore, there may be positive indirect effects on plankton growth, which, in turn, contributes to carbon sequestration.

- **Regulatory fitness and simplification**

By introducing one measurement methodology and one set of requirements to prevent pellet losses, the preferred policy option helps reduce the risk of legal fragmentation, thus increasing legal certainty and strengthening the functioning of the internal market. This, in turn, is expected to result in some cost savings for businesses and for national competent authorities responsible for the implementation and enforcement of the law.

The preferred policy option contains **a derogation for companies making and handling pellets in quantities lower than 5 tonnes** to avoid costly investments with very limited environmental benefits in terms of pellet loss reduction. In addition, in response to the 2023 consultation targeting SMEs handling pellets, **lighter requirements for the smaller enterprises (micro- and small) are expected to mitigate direct compliance costs on these enterprises** (e.g. enterprises may take into account the nature and size of the installation as well as the scale of its operations, no obligation to invest in more expensive equipment like sewage treatment systems). In addition, the Commission and the Member States should provide technical and financial support to the smaller enterprises (micro- and small), such as SME-specific **guidance and training** materials and tools.

The preferred policy option contains rules on the submission of information, including from certification, made in both the physical and digital environments and is thus considered digital-ready.

The preferred policy option is likely to only have a minor negative impact on the competitiveness of the EU plastics sector, as the estimated costs only represent a very small part of their turnover (about 0.13%).

The administrative costs of the preferred policy option (setting up systems in businesses for administrative procedures to report pellet losses, internal assessments and certification, notifying public authorities of the certification) for businesses are assessed at EUR 44 million. The related adjustment costs (developing and applying the measurement standard, adapting operations and procedures to the new requirements, implementing pellet loss reduction measures) for businesses are assessed at EUR 332 – 447 million. There might be other minor adjustments costs as the increase in the price of pellets could be passed on to the downstream users and, ultimately citizens because of an increase in the price of plastic products.

The proposal reflects the preferred policy option as described above, both regarding the mandatory requirements and the related compliance system. To further mitigate direct compliance costs on SMEs, the proposal contains additional lighter requirements compared to the preferred policy option. These additional lighter requirements are described further, in Section 6.2. In particular, micro- and small enterprises as well as installations handling plastic pellets in quantities below 1000 tonnes per year, will have to provide a self-declaration to demonstrate compliance instead of being certified. These additional measures will lead to a further reduction of the administrative costs entailed by the preferred policy option of EUR 24.6 million (from EUR 44 million down to EUR 19.4 million) and a further reduction in compliance cost of EUR 16.9 million (from EUR 332 – 447 million down to EUR 315 – 430 million). The sum of the additional reduction of costs of EUR 41.5 million would be around 10% of the total net cost as calculated for the preferred policy option (from EUR 376 – 491 million down to 334 – 450 million). For micro and small enterprises, the additional reduction is equivalent to almost 15% of the net cost.

It is difficult to estimate the consequence of these additional lighter requirements on the reduction of pellets losses. It is probable that the additional lighter requirements would lead to an increase in pellet losses. If assumed that pellet losses would increase with 10%, then these additional lighter requirements would lower the reduction in pellet losses by about 2 500 to 14 000 t/year compared to the preferred policy option.

- **Fundamental rights**

The preferred policy option is in accordance with Article 37 of the Charter of Fundamental Rights, according to which the EU must ensure a high level of environmental protection and a quality environment.

## 4. BUDGETARY IMPLICATIONS

The proposal does not require new or significant budgetary allocations to be implemented. Advisory initiatives belonging to the InvestEU Advisory hub can be activated to support SMEs to comply with requirements, also in collaboration with the European Enterprise Network. The Commission will factor in any need for support services and studies.

## 5. OTHER ELEMENTS

### Implementation plans and monitoring, evaluation and reporting arrangements

Every three years, Member States are required to supply the Commission with data on the notifications by certifiers about the certificates issued. In addition, in order to better track performance against the Commission's overall reduction target of 30% by 2030, a commonly validated estimate of total pellet losses is required. An initial estimate has been compiled for the accompanying IA, however further work is needed to expand this in the coming years. This will be enhanced by the standardised measurement methodology and the REACH reporting requirement. Stakeholders largely agree with a system to monitor and report on releases.

## 6 DETAILED EXPLANATION OF THE SPECIFIC PROVISIONS OF THE PROPOSAL

### 6.1. Purpose and scope of the proposal

Article 1 specifies the subject matter of the proposal i.e., obligations for the handling of plastic pellets at all stages of the supply chain to prevent losses. Article 1 also sets the scope i.e. all economic operators involved in the handling of plastic pellets in the Union in quantities above five tonnes per year, and EU carriers and non-EU carriers transporting plastic pellets in the Union.

### 6.2 General obligations and requirements

Regardless of the handling requirements outlined in this Regulation, which must be implemented within 18 months of its entry into force, Article 3 establishes a general obligation for economic operators, EU carriers, and non-EU carriers to prevent losses. This obligation applies from the moment the Regulation enters into force. Furthermore, to enable national competent authorities to efficiently carry out compliance checks, economic operators and EU carriers must inform them about their activities involving the handling of plastic pellets. Article 4 requires all economic operators, EU carriers and non-EU carriers to comply with the requirements set out in this Regulation within 18 months of its entry into force. It also requires them to perform action in the following priority order: prevention to avoid any spills of pellets from primary containment; containment of spilled pellets to make sure they do not become a loss to the environment, and, as a final option, clean up after a spill or loss event.

Article 5 details the requirements to comply with. These are based on the industry Operation Clean Sweep® programme (OCS) and the non-binding Recommendation adopted by the parties to the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)[16]. The requirements are the following:

(1) For economic operators operating installations where plastic pellets are handled, to set up, implement and keep up-to-date a risk assessment plan in accordance with Annex I;

(2) For economic operators operating installations where plastic pellets are handled, to send their risk assessment plan to the competent authorities

[16] Council Decision 98/249/EC of 7 October 1997 on the conclusion of the Convention for the protection of the marine environment of the north-east Atlantic, OJ L 104, 3.4.1998, p. 1–1

together with a self-declaration of conformity issued in accordance with the model form set out in Annex II;

(3) For EU carriers and non-EU carriers, to implement certain actions in accordance with Annex III;

(4) For installations and EU carriers, to train their staff;

(5) For installations and EU carriers, to monitor and keep records of their relevant implementing actions including, where appropriate, adopting corrective actions, and of the estimates of pellet losses as well as to address significant plastic pellet incidents and accidents;

(6) For economic operators that are medium and large enterprises running installations handling plastic pellets in quantities above 1000 tonnes per year, to carry out an annual internal assessment alongside additional measures within the risk assessment plan, in accordance with Annex 1.

(7) For economic operators that are medium and large enterprises running installations handling plastic pellets in quantities above 1000 tonnes per year, to be certified in accordance with the model form set out in Annex 3.

To further mitigate impacts on SMEs, the proposal contains additional lighter requirements for their installations to those already contained in the preferred policy option. These requirements take the following form for micro-and small enterprises as well as installations handling plastic pellets in quantities below 1000 tonnes per year:

– No obligation of third-party certification but self-declaration of conformity, as well as a longer validity of the self-declaration (five years);

– No obligation to carry out internal assessments;

– No obligation to review compliance assessments at formal management meetings; and

– No obligation to establish an awareness and training programme.

Article 4 requires all economic operators, EU carriers and non-EU carriers to comply with the requirements set out in this Regulation within 18 months of its entry into force. It also requires them to perform action in the following priority order: prevention to avoid any spills of pellets from primary containment; containment of spilled pellets to make sure they do not become a loss to the environment, and, as a final option, clean up after a spill or loss event.

Economic operators that are medium-sized enterprises running installations handling plastic pellets in quantities above 1000 tonnes per year, will be subject to the following lighter requirement:

– Certification with a longer transitional period than for large enterprises before first certification (36 months instead of 24) and a longer validity of the certificate (four years instead of three).

Similarly, specific requirements apply to carriers and non-EU carriers transporting plastic pellets in light of the specificities of their pellet-related activities.

### 6.3 Compliance system

Article 5 details obligations regarding certifications to be carried out, at the site level, to facilitate national competent authorities' compliance checks. Certifications (resulting in certificates of conformity as described in Article 5 are phased in over a certain period. Annex II provides for the format of the certificate of conformity. Certifiers must be any natural or legal person, or any association or group of such persons, who have obtained a licence to carry out verification and validation in accordance with the EMAS Regulation, or officially accredited bodies, with no conflicts of interest, and with the required expertise, equipment and infrastructure. Article 7 defines provisions for the certifiers to fulfil in order to be accredited by the Member States. When assessing conformity, certifiers must use spot-checks. Once the certifiers have issued a certificate, they are required to notify the competent authority thereof, who must keep a corresponding register. Such register must be publicly available on a website for transparency purposes.

According to Article 6, economic operators that are registered to the Community eco-management and audit scheme ('EMAS') will be deemed compliant and therefore exempted from the obligation of obtaining a certificate and of notifying the renewals of the risk assessment plan and self-declaration of conformity pursuant to this Regulation.

Where applicable, economic operators are required to notify the competent authority of their self-declarations of conformity. Competent authorities must keep a corresponding register, which must be publicly available on a website for transparency purposes.

### 6.4 Enforcement provisions

Article 8 sets out that the national competent authorities are in charge of verifying economic operators', carriers' and non-EU carriers' compliance with the requirements and rules of the Regulation. They are expected to perform environmental inspections or other checks, taking into account information sent by certifiers and economic operators (self-declarations, risk assessment plans) as well as addressing complaints filed by natural or legal persons or organisations according to Article 14. Article 8 also sets out reporting obligations for Member States, namely the submission every three years of a report to the Commission on the implementation of this Regulation.

Article 4 entitles national competent authorities to require economic operators to implement further measures in case those established in the plans and implemented are not considered sufficient. Article 9 empowers them to impose on economic operators, EU carriers and non-EU carriers any appropriate follow-up measures in case of severe incidents and accidents. Article 10 sets out that, in case of non-compliance leading to an immediate danger to human health or significant adverse effects upon the environment, competent authorities should be able to order the suspension of operations. Powers to investigate and enforce are defined in Article 11. Regarding infringements, Article 15 defines a series of obligations for Member States to respect when defining their penalty regime.

Article 16 on compensation aims at securing that, where damage to health has occurred, fully or partially as a result of a violation of this Regulation, the public concerned is able to claim and obtain compensation for that damage from the natural or legal persons responsible for the violation and, where relevant from relevant competent authorities.

Article 17 sets out the exercise of the delegation. The rules of adoption of delegated acts are set out in Article 18.

### 6.5 Assistance to SMEs

Article 12 ensures initiatives are taken to help SMEs in the pellet supply chain implement the Regulation. In particular, the Commission is required to set up awareness raising and training material on the sound implementation of the requirements laid down in this Regulation. Member States should ensure these enterprises get access to information and assistance regarding compliance with the Regulation. Without prejudice to applicable state aid rules, Member States' assistance may take the form of: financial support; access to finance; specialised management and staff training; and organisational and technical assistance.

### 6.6 Standardised methodology

While observable, plastic pellet losses are not routinely measured. The REACH reporting requirement on estimates of pellet lost on a yearly basis will contribute to increased information on pellet losses. However, it does not provide for any methodology to measure pellet losses. Article 13 requires the Commission to request European standardisation organisations to establish a standard to estimate quantities of pellets lost to the environment.

2023/0373 (COD)

Proposal for a

# REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## on preventing plastic pellet losses to reduce microplastic pollution

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[17],

Having regard to the opinion of the Committee of the Regions[18],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Microplastics are ubiquitous, persistent and transboundary. They are detrimental to the environment and potentially harmful to human health. Microplastics are easily transported through the air and by land surface waters and ocean currents, and their mobility is an aggravating factor. They are found in soil (including agricultural lands), lakes, rivers, estuaries, beaches, lagoons, seas, oceans and in remote, once pristine regions, and their presence in soil may have effects on soil properties and trigger soil alterations which negatively impact the growth of some plants. Impacts of microplastics on the marine environment have been extensively documented. Once in the marine environment, microplastics are nearly impossible to collect, and are known to be eaten by a range of organisms and animals and cause harm to biodiversity and ecosystems. The persistence of a plastic pellet in the aquatic environment may be measured over decades or more, and ingestion of plastic pellets by marine wildlife, notably seabirds and sea turtles, may cause physical harm or death. Microplastics also contribute to climate change as an additional source both of greenhouse gas emissions and of pressure on ecosystems. Microplastics' potential to act as a carrier for adsorbed toxicants or pathogenic microorganisms is an integral part of the problem. Humans are exposed to microplastics via air and food consumption. The growing awareness of microplastics' presence in the food chain can undermine consumer confidence and bear economic consequences. There may be negative economic impacts on activities such as commercial fishing and agriculture as well as recreation and tourism in areas affected by the releases.

[17] OJ C , , p. .
[18] OJ C , , p. .

(2) In their opinion entitled 'Environmental and health risks of microplastic pollution', the Commission's Group of Chief Scientific Advisors considered that 'there are significant grounds for concern and for precautionary measures to be taken'[19].

(3) Plastic pellet losses constitute the third largest source of microplastics unintentionally released to the environment in the Union and are due to poor handling practices at all stages of the supply chain, including production, processing, distribution, transport, including by sea, and other logistic operations. Hence, a supply chain approach is essential for ensuring the commitment of all economic actors involved in plastic pellet handling towards loss prevention. Since 2015, the European plastic manufacturing industry has progressively adopted the international Operation Clean Sweep® programme (OCS) as a voluntary pledge. Under this programme, each company making or handling pellets recognises the importance of making zero pellet losses and commits to adopting best practices. While such practices are generally well understood by OCS signatories, they have not been comprehensively implemented. The uptake of the programme by the plastic industry remains low.

(4) The impacts of microplastic pollution on the environment and possibly on human health have raised concerns in most parts of the world. Some Member States have adopted or proposed dedicated measures. However, a patchwork of national restrictions could potentially hamper the functioning of the internal market.

(5) In a bid to tackle plastic pollution, in January 2018, the Commission adopted a Communication entitled 'European Strategy for Plastics'[20] where it acknowledged the risks posed by microplastics and called for innovative solutions targeting the different sources of microplastics to be taken. This commitment was renewed with the adoption of the European Green Deal in December 2019, the new Circular Economy Action Plan[21] in March 2020 and the Zero Pollution Action Plan[22] in May 2021. The latter includes, among its 2030 targets, reducing the amount of microplastics released into the environment by 30%.

(6) Commission Regulation (EU) 2023/2055[23] addresses microplastic pollution by imposing a restriction on the placing on the market of microplastics that are intentionally added to products (the 'restriction'), as there is considerable microplastic pollution arising from the use of synthetic polymer microparticles on their own or intentionally present in products, and pollution poses an unacceptable risk to the environment.

(7) In 2021, the parties to the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) adopted the non-binding Recommendation 2021/06[24] to reduce the loss of plastic pellets into the marine environment by promoting the timely development and implementation of effective and consistent pellet loss prevention standards and certification schemes for the entire plastic supply

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19 Scientific opinion on the environmental and health risks of microplastic pollution, April 2019

20 COM(2018) 28 final

21 COM(2020)98 final, 2020.

22 COM(2021) 400 final

23 Commission Regulation (EU) 2023/2055 of 25 September 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles (OJ L 238, 27.9.2023, p. 67).

24 OSPAR Recommendation 2021/06 on the reduction of plastic pellet loss into the marine environment

chain. Measures for minimizing the risk associated with the transport of plastic pellets by sea are under examination at the International Maritime Organization.

(8) In the Union submission to United Nations Environment Programme in view of the second session of the Intergovernmental Negotiating Committee on an international legally binding instrument on plastic pollution (INC-2)[25], the Union and its Member States stressed the need for the future instrument to include measures to reduce unintentional releases of microplastics.

(9) Despite Union legislation concerning the prevention of waste, pollution, marine litter and chemicals, there are no specific Union rules preventing pellet losses as a source of microplastic pollution along the entire supply chain. Directive 2008/98/EC of the European Parliament and of the Council[26] lays down basic waste management principles and imposes general obligations for Member States to take measures to prevent waste generation. Those general obligations should be complemented by addressing specific aspects and requirements for the careful handling of plastic pellets in order to avoid them becoming waste.

(10) While the production of polymeric materials on an industrial scale fall under the scope of Directive 2010/75/EU of the European Parliament and of the Council[27], other activities like the conversion, transport or storage of pellets, usually operated by small and medium-sized enterprises, are not covered by that Directive. Moreover, the Reference Document on Best Available Techniques in the Production of Polymers of August 2007[28], established pursuant Council Directive 96/61/EC[29] concerning integrated pollution prevention and control, does not address the specific issue of pellet losses.

(11) Directive 2008/56/EC of the European Parliament and of the Council[30] addresses the monitoring and assessment of the impacts of microlitter, including microplastics, in coastal and marine environments. An update of the first guidance on monitoring marine litter is under development in view of harmonised methodologies including to monitor the presence and distribution of plastic pellets along the coastline. However, Directive 2008/56/EC does not include specific requirements concerning the prevention or reduction of pellet losses at source.

(12) Commission Regulation (EU) 2023/2055 addresses losses of synthetic polymer microparticles for use at industrial sites i.e. plastic pellets as avoidable releases. For these releases, a reporting requirement for an estimated quantity of microplastics released to the environment on an annual basis is introduced. While lacking a methodology to estimate losses, this requirement will increase information on pellet

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25 UNEP, The EU's Pre-session Submission ahead of Second Session of Intergovernmental Negotiating Committee to develop an international legally binding instrument on plastic pollution, 2023

26 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

27 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p.17).

28 https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/pol_bref_0807.pdf

29 Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L 257, 10.10.1996, p. 26).

30 Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p.19).

losses and improve the quality of the information collected to assess the risks deriving from these microplastics in the future.

(13) To ensure that plastic pellets are handled safely and responsibly at all stages of the supply chain, so that losses to the environment are prevented, it is necessary to establish requirements on the handling of plastic pellets along the entire supply chain: production, master batching and compounding, conversion, waste management, including recycling, distribution, repacking, transport, storage and tank cleaning at cleaning stations.

(14) Such requirements should take into account internationally recommended good handling practices as well as existing requirements on the handling of plastic pellets established by the industry in the Union.

(15) Economic operators, EU carriers and non-EU carriers should implement the requirements on the handling of plastic pellets by following a priority order of action with the paramount goal of preventing the release of pellets in the environment as the top priority. Therefore, preventing spills of plastic pellets from primary containment during routine handling, thus reducing the risk of spills to the lowest possible level, should be the first step, including by avoiding any unnecessary handling (for instance by reducing the transfer points) and by using puncture-proof packaging, followed by containment of spilled pellets to make sure they do not become a loss to the environment, and eventually by clean up after a spill or loss event as the final step.

(16) While the aim is to prevent plastic pellet losses to the environment for all economic operators, EU carriers and non-EU carriers, obligations for micro-, small and medium-sized enterprises should be adjusted to mitigate the burden on them.

(17) The registration of installations handling plastic pellets and of carriers transporting them is necessary for the traceability of plastic pellets handled and transported in each Member State and to allow competent authorities to perform compliance checks efficiently.

(18) In order to prevent plastic pellet losses, economic operators should establish, implement, and update at all times a risk assessment plan identifying potential for spills and losses and documenting in particular specific equipment and procedures in place to prevent, contain and clean up pellet losses, taking into consideration the installation size and the scale of operations.

(19) To enable competent authorities to verify compliance with the risk assessment plan's requirements, economic operators should provide the competent authority with the risk assessment plan they have conducted, together with a self-declaration of conformity.

(20) Economic operators should be able to choose the specific equipment to install or the procedure to execute. Nevertheless, competent authorities, while verifying compliance, should be able to require economic operators to amend the risk assessment plan including by taking, in a given timeframe, any of the actions listed in this Regulation to ensure adequate implementation of the requirements of this Regulation.

(21) In order to evaluate the adequacy of the risk assessment plan carried out for each installation, economic operators should keep record of an estimate of the quantity of the pellets released to the environment per year, together with the total volume handled. To reduce burden on economic operators, the information on estimates of quantities released may be used in the framework of the reporting requirement under Commission Regulation (EU) 2023/2055.

(22) Due to the characteristics of their activity, carriers should not be mandated to conduct a risk assessment plan. Instead, they should be required to undertake tangible measures aimed at preventing, containing, and addressing spills and losses. These measures should be subject to verification by competent authorities, primarily during the transportation process.

(23) The successful implementation of the actions required to prevent plastic pellet losses requires the full cooperation and commitment of economic operators', EU carriers' and non-EU carriers' employees. Economic operators and EU carriers should be required to train their staff according to their employees' specific roles and responsibilities in order to ensure they are aware of and are able to use the equipment and execute the procedures necessary to ensure compliance with the requirements laid down in this Regulation. Economic operators and EU carriers should also be required to monitor and keep records of the relevant actions to implement the requirements set out in this Regulation, for instance, the placement of new catchment devices. Where appropriate, they should adopt corrective actions including, where necessary, the improvement of equipment and procedures in place.

(24) Medium and large-sized enterprises that operate installations where plastic pellets are handled in quantities above 1 000 tonnes may bring higher risks of pellet losses to the environment. For this reason, these enterprises should be required to implement, for each installation, extra actions like carrying out an annual internal assessment, and adopting a training programme addressing specific training needs and modalities. In addition, for these enterprises, compliance with the requirements laid down in this Regulation should be demonstrated by obtaining, and renewing, a certificate issued by certifiers. These certifiers can either be an accredited conformity assessment body, or an environmental verifier licenced to carry out verification and validation in accordance with Regulation (EC) No 1221/2009 of the European Parliament and of the Council[31] on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS). The certificate should correspond to a unique format in order to ensure homogeneous information.

(25) Micro and small-sized enterprises, and medium and large-sized enterprises operating installations where plastic pellets in quantities below 1 000 tonnes have been handled should be required to be subject to a self-declaration of conformity. They should also be given sufficient time to demonstrate their compliance.

(26) To enable competent authorities to more efficiently verify compliance under this Regulation, certifiers should notify competent authorities about the outcome of their assessments. Certificates should not prejudge the assessment on compliance by competent authorities.

(27) In order to be EMAS registered, economic operators are required to comply with environmental legislation, including this Regulation. Consequently, economic operators which are registered to EMAS should be considered compliant with the requirements laid down in this Regulation provided that an environmental verifier has verified that requirements laid down in this Regulation have been included in their environmental management system and implemented. These economic operators

[31] Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1).

should therefore be exempted from the obligations of certification and notification to competent authorities when renewing self-declarations and risk assessments.

(28) Competent authorities should verify economic operators', EU carriers' and non-EU carriers' compliance with the obligations arising from this Regulation using, if appropriate, the findings provided as part of the certification or as self-declarations, based on either environmental inspections or other verification measures, on a risk-based approach. Inspections should, where possible, be coordinated with those required under other Union legislation. Competent authorities should provide the Commission with information on the implementation of this Regulation.

(29) In order to minimise the effects of any loss, the economic operator, EU carrier and non-EU carrier should take the measures necessary to restore compliance. The corrective action required should be proportionate to the infringement detected and its expected harmful effects on the environment. Where competent authorities detect an infringement of this Regulation, they should notify the economic operator, the EU carrier or the non-EU carrier about the infringement detected and require that corrective measures are taken to restore compliance.

(30) Competent authorities should have a minimum set of inspection and enforcement powers in order to ensure compliance with this Regulation, to cooperate with each other more quickly and more efficiently, and to deter economic operators, EU carriers and non-EU carriers from infringing this Regulation. Those powers should be sufficient to tackle the enforcement challenges and to prevent non-compliant economic operators from exploiting gaps in the enforcement system by relocating to Member States whose competent authorities are not equipped to tackle unlawful practices.

(31) Competent authorities should be able to use all facts and circumstances of the case as evidence for the purpose of their inspection.

(32) Micro, small and medium-sized enterprises (SMEs) in the pellet supply chain should comply with the relevant obligations laid down in this Regulation, however they could face proportionally higher costs and difficulties when complying with some of the obligations. The Commission should raise awareness among economic operators and carriers regarding the necessity of preventing pellet losses. Additionally, the Commission should develop training materials to assist them in fulfilling their obligations, particularly with respect to the requirements of the risk assessment. Member States should provide access to information and assistance regarding compliance with obligations and the risk assessment requirements. Regarding the assistance of Member States, this could include technical and financial support as well as specialised training to SMEs. Member States actions should be taken in respect of applicable State aid rules.

(33) In order to facilitate common grounds to estimate the losses of plastic pellets to the environment, it is necessary to have a standardised methodology set in a harmonised standard that is adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council[32].

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[32] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12–33*)*

(34) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements set out in this Regulation.

(35) In order to ensure that the objectives of this Regulation are achieved, and the requirements are enforced effectively, Member States should designate their own competent authorities responsible for the application and enforcement of this Regulation. In cases where there is more than one designated competent authority in their territory, in order to ensure effective exercise of the duties of the competent authorities, Member States should ensure close cooperation between all designated competent authorities.

(36) In order to ensure compliance, competent authorities should also take the necessary steps, including inspections and hearings when in possession of and based on relevant information, including substantiated complaints submitted by third parties. Third parties submitting a complaint should be able to demonstrate a sufficient interest or maintain the impairment of a right.

(37) Member States should ensure that any measures taken by their competent authorities under this Regulation are subject to effective judicial remedies in accordance with Article 47 of the Charter of Fundamental Rights of the European Union[33]. According to settled case law of the Court of Justice of the European Union, it is for the courts of the Member States to ensure judicial protection of a person's rights under Union law. Furthermore, Article 19(1) of the Treaty on European Union requires Member States to provide remedies that are sufficient to ensure effective judicial protection in the fields covered by Union law. In this respect, Member States should ensure that the public, including natural or legal persons in accordance with this Regulation, has access to justice in line with the obligations that Member States have agreed to as parties to the UN Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters of 25 June 1998 (the 'Aarhus Convention')[34].

(38) In order to ensure that economic operators are effectively dissuaded from non-compliance with the requirements laid down in this Regulation, Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are implemented. The penalties provided should be effective, proportionate and dissuasive. To facilitate a more consistent application of penalties, it is necessary to establish common criteria for determining the types and levels of penalties to be imposed in case of infringement. Those criteria should include, inter alia, the nature and gravity of the infringement as well as the economic benefits derived from the infringement in order to ensure that those responsible are deprived of those benefits.

(39) When setting penalties and measures for infringements, the Member States should foresee that, based on the gravity of the infringement, the level of fines should effectively deprive the non-compliant economic operator, EU carriers and non-EU carriers from the economic benefit derived from non-compliance with the obligations deriving from this Regulation, including in cases of repeated infringements. The gravity of the infringement should be the leading criterion for the measures taken by

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33 *OJ C 326, 26.10.2012, p. 391–407: OJ C 326, 26.10.2012, p. 391–407*

34 https://unece.org/environment-policy/public-participation/aarhus-convention/text

the enforcement authorities. The maximum amount of fines should, in case of an infringement committed by a legal person, represent at least 4% of the economic annual turnover in the Member State concerned.

(40) Where damage to human health has occurred as a result of an infringement of this Regulation, Member States should ensure that the individuals affected are able to claim and obtain compensation for that damage from the relevant natural or legal persons and, where appropriate, from the relevant competent authorities responsible for the infringement. Such rules on compensation contribute to pursuing the objectives of preserving, protecting and improving the quality of the environment and protecting human health as laid down in Article 191 of the Treaty on the Functioning of the European Union. They also underpin the right to life, integrity of the person and health care laid down in Articles 2, 3 and 35 of the Charter of Fundamental Rights of the European Union and the right to an effective remedy as laid down in Article 47 of the Charter. Moreover, Directive 2004/35/EC of the European Parliament and of the Council[35] does not give private parties a right of compensation as a consequence of environmental damage or of an imminent threat of such damage.

(41) To ensure that individuals can defend their rights against damages to health caused by infringements of this Regulation and thereby ensure its more efficient enforcement, non-governmental organisations promoting the protection of human health or the environment, including those promoting the protection of consumers and meeting any requirements under national law, as members of the public concerned, should be empowered to engage in proceedings, as the Member States so determine, either on behalf or in support of any victim, without prejudice to national rules of procedure concerning representation and defence before the courts. Member States usually enjoy procedural autonomy to ensure an effective remedy against violations of Union law, subject to the respect of the principles of equivalence and effectivity. However, experience shows that while there is overwhelming epidemiologic evidence on the negative health impacts of pollution on the population, in particular as regards air, it is difficult for the victims under the procedural rules on the burden of proof generally applicable in the Member States to demonstrate a causality link between the suffered harm and the violation. Therefore, it is necessary to adapt the burden of proof applicable to such situations. When an individual can provide sufficiently robust evidence to give rise to a presumption that the violation of this Regulation is at the origins of the damage caused to the health of an individual, or has significantly contributed to it, it should be for the defendant to rebut that presumption in order to escape his liability.

(42) In order to take into account technical progress and scientific developments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[36]. In particular, to ensure equal participation in the preparation of delegated acts, the

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35 Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L 143, 30.4.2004, p.56).

36 OJ L 123, 12.5.2016, p. 1.

European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(43) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission in respect of reporting of information on the implementation of this Regulation.

(44) In order to provide economic operators, EU carriers, and non-EU carriers with sufficient time to adapt to the requirements laid down in this Regulation, its application should be deferred.

HAVE ADOPTED THIS REGULATION:

**Article 1**

**Subject matter and scope**

1. This Regulation lays down obligations for the handling of plastic pellets at all stages of the supply chain to prevent losses.

2. This Regulation applies to the following subjects:

(a) economic operators handling plastic pellets in the Union in quantities above 3 tonnes in the previous calendar year;

(b) EU land carriers and non-EU land carriers transporting plastic pellets in the Union.

(c) EU maritime carriers and non-EU maritime carriers transporting plastic pellets in the Union.

**Article 2**

**Definitions**

For the purposes of this Regulation, the following definitions apply:

(a) ‘plastic pellet’ means a small mass of preformed polymer-containing moulding material, having relatively uniform dimensions in a given lot, that is used as feedstock in plastic product manufacturing operations;

(b) ‘spill’ means a one-off escape of plastic pellets from primary containment;

(c) ‘loss’ means a one-off or prolonged escape of plastic pellets from installation’s boundary to the environment or from road vehicles, rail wagons or inland waterway vessels transporting plastic pellets;

(d) ‘installation’ means any premises, structure, environment or place within which one or more economic activities involving the handling of plastic pellets are carried out;

(e) ‘economic operator’ means any natural or legal person who operates or controls in whole or in part the installation, or, where this is provided for in national law, to whom decisive economic power over the technical functioning of the installation has been delegated;

(f) ‘EU land carrier’ means any natural or legal person established in a Member State, engaged in the transport of plastic pellets as part of its economic activity by using road vehicles, rail wagons or inland waterway vessels;

(g) ‘non-EU land carrier’ means any natural or legal person established in a third country, engaged in the transport of plastic pellets as part of its economic activity in the Union by using road vehicles, rail wagons or inland waterway vessels;

(h) ‘EU maritime carrier’ means any natural or legal person established in a Member State, engaged in the transport of plastic pellets as part of its economic activity by using marine vessels operating within the territorial waters and Exclusive Economic Zone of the EU Member State.

(i) ‘non-EU maritime carrier’ means any natural or legal person established in a third country, engaged in the transport of plastic pellets as part of its economic activity by using marine vessels operating within the territorial waters and Exclusive Economic Zone of the EU Member State.

(j) ‘micro, small or medium-sized enterprise’ means a micro, small or medium-sized enterprise within the meaning of the Annex to Commission Recommendation 2003/361/EC37[37];

(k) ‘large-sized enterprise’ means an enterprise that is not a micro, small or medium-sized enterprise;

(l) ‘competent authority’ means an authority or a body designated by a Member State to carry out its obligations under this Regulation;

(m) ‘certifier’ means any of the following:

[37] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

(i) a conformity assessment body as defined in Article 2(13) of Regulation (EC) 765/2008 of the European Parliament and of the Council[38] or any other association or group of such bodies, which has obtained accreditation in accordance with this Regulation;

(ii) an environmental verifier, as defined in Article 2(20), point (b), of Regulation (EC) No 1221/2009;

(p) 'conformity assessment' means the process demonstrating whether an installation fulfils the applicable rules of this Regulation and of the delegated acts adopted on the basis thereof;

**Article 3**

**General obligations**

1. Economic operators, EU land carriers, non-EU land carriers, EU maritime carriers, and non-EU maritime carriers shall ensure that losses are avoided. Where losses occur, economic operators, EU carriers, non-EU carriers, EU maritime carriers, and non-EU maritime carriers shall take immediate action to clean-up those losses.

2. Economic operators, EU land, non-EU land, EU maritime, and non-EU maritime carriers shall notify the competent authority, in the manner determined by the latter, of each installation they operate and of when engaging in the transport of plastic pellets, as applicable.

3. Economic operators, EU land and non-EU land, EU maritime, and non-EU maritime carriers shall notify the competent authorities of the Member State in which they are established of any significant change in their installations and activities related to handling of plastic pellets, including any closure of an existing installation.

4. Competent authorities shall establish and maintain a public register containing the information they have received in accordance with paragraphs 3 and 4.

5. The competent authority bears the responsibility to ensure that activities falling under its scope or under its control do not result in harm which may impact the lives of the current and *future* generations negatively. In case of evident damage to future generations the competent authority shall act accordingly per Article 9 and 15(3) to prevent further irreversible damage in the long term.

[38] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

6. Competent authorities shall report to the Commission all action undertaken in reference to the obligations set in this regulation. The timeframe for reporting shall be at the minimum as set out in paragraphs (a) and (b) of this article:

   (a) Within the first 12 months of the entry of the regulation a report shall be conducted at 6 and 12 months, respectively;

   (b) After the lapse of the timeframe specified in paragraph (a) of this article, reporting by the competent authorities shall be conducted annually;

   (c) Reports shall be made publicly available under the provisions of Article 4(4) of this Regulation.

**Article 4**

**Obligations regarding the handling of plastic pellets**

1. Economic operators shall take the following actions:

   (a) establish a risk assessment plan for each installation in accordance with Annex I taking into account the nature and size of the installation as well as the scale of its operations;

   (b) install the equipment and execute the procedures described in the risk assessment plan referred to in point (a);

   (c) notify the risk assessment plan referred to in point (a) to the competent authority of the Member State where the installation is located together with a self-declaration of conformity issued in accordance with the model form set out in Annex II. Economic operators shall keep the risk assessment plan up-to-date (according to standards specified in Article/anex/regulations), taking into account in particular the weaknesses identified through their experience in handling plastic pellets, and shall make it available to competent authorities on demand.

2. Economic operators that are medium and large-sized enterprises operating installations where plastic pellets in quantities below 1000 tonnes have been handled in the previous calendar year shall notify the competent authority of an updated risk assessment plan for each installation and update their self-declaration every 2 years. Micro and small-sized enterprises regardless of production levels, shall update their self-declaration every 5 years.

3. Competent authorities may require economic operators to take the following actions:

   (a) to change risk assessment plans in accordance with paragraphs 1 and 2 to ensure that the losses can effectively be prevented or, where appropriate, contained and cleaned up, and that Annex I is complied with;

(b) implement any of the actions listed in Annex I promptly.

4. Competent authorities shall establish, maintain, and update a register containing the risk assessment plans and self-declarations of conformity notified in accordance with paragraphs 1 and 2 of this Article. The register shall be publicly available on a Website.

5. EU land carriers, non-EU land carriers, EU maritime carriers, and non-EU maritime carriers shall ensure that the actions set out in Annex III are implemented during loading and unloading operations, transport journeys, cleaning, and maintenance operations.

6. When economic operators implement the actions set out in the risk assessment plan established in accordance with Annex I and the EU land carriers, non-EU land carriers, EU maritime carriers, and non-EU maritime carriers implement the actions laid down in Annex III, they shall take action, in the following priority order:

(a) actions to prevent spills

(b) actions to contain spills to prevent environmental impact and material losses;

(c) actions to clean-up after a spill or loss.

7. Economic operators and EU land and maritime carriers shall have the following obligations:

(a) ensure that their staff is trained according to their specific roles and responsibilities and that they are aware of and are able to use the relevant equipment and execute the procedures set out to ensure compliance with this Regulation;

(b) keep records of the actions taken to comply with the obligations set out in this Article;

(c) keep records of annually estimated quantities of losses and of the total volume of plastic pellets handled.

As from six months after the publication of the relevant harmonised standard in the *Official Journal of the European Union* or from the date of application of the implementing act referred to in Article 13(2) of this Regulation economic operators shall estimate the quantities of losses referred to in the first subparagraph, point (c) in accordance with the standardised methodology referred to in Article 13.

Economic operators and EU land and maritime carriers shall retain records referred to in points (b) and (c) of this paragraph for a period of five years and make them available to competent authorities and, where applicable, to certifiers on demand.

8. Where an action taken for the prevention, containment and clean-up of spills and losses fails, economic operators, land and maritime carriers, and non-EU land and maritime carriers shall take corrective actions, as soon as possible.

9. Every year economic operators that are not micro or small-sized enterprises and that operate installations where plastic pellets in quantities above 1000 tonnes have been handled in the previous calendar year shall, for each installation, carry out an internal assessment on the state of compliance of the installation with the requirements of the risk assessment plan laid down in Annex I. The internal assessment may among others cover the following subjects:

   (a) the estimated quantities and causes of losses;

   (b) the preventive, containment and clean up equipment and/or procedures implemented to avoid future losses, and their effectiveness;

   (c) discussions with the personnel, inspections of equipment and procedures in place and revision of any relevant documentation.

## Article 5

## Certification

1. By 24 months after the entry into force of this Regulation, and thereafter every one year, economic operators that are large-sized enterprises shall demonstrate that each installation where plastic pellets in quantities above 1000 tonnes have been handled in the previous calendar year is compliant with the requirements set out in Annex I, by obtaining a certificate issued by a certifier.

2. By 24 months after the entry into force of this Regulation, and thereafter every two years, economic operators that are medium sized enterprises shall demonstrate that each installation where plastic pellets in quantities above 1000 tonnes have been handled in the previous calendar year is compliant with the requirements set out in Annex I, by obtaining a certificate issued by a certifier.

3. Certifiers shall carry out annual spot-checks to ensure that all measures included in the risk assessment plan carried out in accordance with Annex I are duly implemented.

4. Certificates shall meet the following requirements:

   (a) be issued in accordance with the model form set out in Annex IV and in electronic form;

   (b) specify the economic operator, the installation covered by the certificate, the date of the spot-checks carried out, and the period of validity;

   (c) certify conformity of the installation covered by the certificate with the requirements laid down in Annex I;

5. Without undue delay, certifiers shall notify the competent authority of the following:

   (a) certificates issued;

   (b) certificates suspended or withdrawn;

   (c) changes in certificates.

6. Competent authorities shall establish and maintain and keep up to date a register of certificates. The register shall be publicly available on a relevant website provided by the Commission.

**Article 6**

**Environmental management systems**

1. Economic operators which are registered to the Community eco-management and audit scheme in accordance with Regulation (EC) No 1221/2009 are exempt from compliance with the notification obligation laid down in Article 4(2) and the obligations laid down in Article 5(1) and (2) of this Regulation provided that the environmental verifier as defined in Article 2(20) of Regulation (EC) No 1221/2009 has checked that requirements laid down in Annex I have been included in the environmental management system of the economic operator and have been implemented

2. Where Article 6(1) applies, the environmental verifier, as defined in Article 2(20) of Regulation (EC) No 1221/2009, shall report to the national competent authorities all information regarding the economic operator's compliance with the obligations under Article 4(2), Article 5(1) and (2).

**Article 7**

**Accreditation of certifiers**

The accreditation of certifiers referred to in Article 2, point (k)(l) shall include an evaluation of compliance with the following requirements:

   (a) the certifier shall be independent of the economic operator;

   (b) the certifier, its top-level management and the personnel responsible for the conformity assessment shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to the certification activities;

   (c) the certifier and its personnel shall carry out their activities with the highest degree of professional integrity and the requisite technical competence and shall be free

from all pressures and inducements, including financial, which might influence their judgement or the results of their certification activities;

(d) the certifier shall have the expertise, equipment and infrastructure required to perform the conformity assessment in relation to which it has been accredited;

(e) appropriate expertise training for the certifiers shall be provided by authorities appointed by the Commission body, Member States may provide additional advice through their ministerial staff.

(f) certifiers shall be accredited to a financial support of 10% of their yearly operating costs for the duration of first 3 years of their activity from the European Union Budget. To qualify, certifiers will be obliged to provide the Commission with yearly financial reports of which content's details will be published by the Commission within [*OP please insert the date = the first day of the month- 4 months after following the date of entry into force of this Regulation*].

(g) certifiers shall be eligible for a renewal of the financial support scheme as laid out in Article 7(f) of this Regulation, provided they meet the requirements laid out in Article 3(6) of this Regulation. The Commission reserves the right to deny financial support in case the certifier fails to sufficiently comply with the obligations set out in Article 3(6) of this Regulation.

(h) certifiers shall have a sufficient number of suitably qualified and experienced personnel responsible for carrying out the conformity assessment tasks;

(i) the personnel of a certifier shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment tasks;

(j) certifiers shall not subcontract or delegate any of its responsibilities and tasks to any organisation, association, group or legal or natural person.

**Article 8**

**Verification of compliance and reporting**

1. Competent authorities shall verify compliance of economic operators, EU land carriers, non-EU land carriers, EU maritime carriers and non-EU maritime carriers with the obligations laid down in this Regulation, taking into account the information provided in self-declarations of conformity referred to Article 4(1) and (2) and provided by certifiers in accordance with Article 5(5). The competent authorities shall carry out environmental inspections and other verification measures, following a risk-based approach.

2. At the latest by … [*OP please insert the date = the first day of the month after years following the date of entry into force of this Regulation*] and every year thereafter Member States shall, submit a report to the Commission containing qualitative and quantitative information on the implementation of this Regulation during the previous calendar year. The information shall include:

(a) the number of economic operators per size of enterprise according to Commission Recommendation 2003/361/EC and per economic activity, their installations, and of the EU land and maritime carriers and their means of transport allocated to transporting plastic pellets;

(b) the number of risk assessment plans, self-declarations notified pursuant to Article 4(1) and 4(2) and certificates notified pursuant to Article 5(5);

(c) the number and results of environmental inspections and other verification measures carried under paragraph 1 of this Article as well as the number of incidents and accidents reported in accordance with Article 9(1) and the measures taken in case of non-compliance with the obligations set out in this Regulation.

3. The Commission shall lay down by means of implementing acts a format for the reports referred to in paragraph 2. The Commission reserves its right to update the content of the implementing acts through directives. Introduction of new content shall always take place in accordance with the Regulation (EU) No 182/2011.

**Article 9**

**Incidents and accidents**

1. Without prejudice to Directive 2004/35/EC, in the event of an incidental or accidental loss significantly affecting human health or the environment, economic operators, EU land carriers, non-EU land carriers EU maritime carriers, and non-EU maritime carriers shall immediately:

(a) inform the competent authority in whose territory the incident or accident occurred and the estimated quantities of losses;

(b) take measures to limit the health or environmental consequences and to prevent further incidents or accidents.

2. The competent authority in whose territory the incident or accident occurred shall require, where necessary, that economic operators, EU land carriers, non-EU land carriers, EU maritime carriers, and non-EU maritime carriers take appropriate complementary measures to limit the health or environmental consequences and to prevent further incidents or accidents.

3. In the event of any incident or accident significantly affecting human health or the environment in another Member State, the competent authority in whose territory the accident or incident occurred shall immediately inform the competent authority of that other Member State.

**Article 10**

**Non-compliance**

1. In the event of an infringement of the rules laid down in this Regulation, economic operators, EU land carriers, non-EU land carriers, EU maritime carriers, and non-EU maritime carriers shall immediately:

   (a) inform the competent authority. This shall include an assessment of the damage to environment done by the infringement;

   (b) take all measures necessary to ensure that compliance is restored within the shortest possible time;

   (c) comply with any complementary measures determined by the competent authority as necessary to restore compliance;

   (d) recover the damage done and take measures to restore the area affected to a state before the damage took place in the shortest possible time.

2. Where the infringement of the rules laid down in this Regulation poses an immediate danger to human health or threatens to cause an immediate significant adverse effect upon the environment, the competent authority must suspend the operation of the installation until compliance is restored in accordance with paragraph 1, points (b) and (c).

**Article 11**

**Designation and powers of competent authorities**

1. Member States shall designate one or more competent authorities in consultation with the European Environment Agency for the application and enforcement of this Regulation. The competent authority or authorities shall:

   (a) implement and enforce the Regulation in a timely manner;

   (b) where necessary, coordinate enforcement actions between the European Commission, and national competent authorities, and between national competent authorities;

(c) regularly organise communication and cooperation between national competent authorities and stakeholders.

2. Member States shall confer on their competent authorities the powers of inspection and enforcement necessary to ensure compliance with this Regulation.

3. The powers referred to in paragraph 2 shall include at least the following:

(a) the power of access to any relevant documents, data or information related to an infringement of this Regulation, in any form or format and irrespective of their storage medium or the place where they are stored, and the power to take or obtain copies thereof;

(b) the power to require any natural or legal person to provide any relevant information, data or documents, in any form or format and irrespective of their storage medium or the place where they are stored, for the purposes of establishing whether an infringement of this Regulation has occurred or is occurring and the details of such infringement;

(c) the power to start an inspection on their own initiative to bring about the cessation or prohibition of infringements of this Regulation;

(d) the power of access to installations.

4. Competent authorities may use any information, document, finding, statement or intelligence as evidence for the purpose of their environmental inspections and other verification measures, irrespective of the format or medium on which they are stored.

5. Where there is more than one competent authority in their territory, Member States shall ensure that appropriate communication and coordination mechanisms are established.

**Article 12**

**Assistance relating to compliance**

1. The Commission shall develop awareness raising and training material on the sound implementation of the obligations laid down in this Regulation in consultation with representatives of economic operators, land and maritime carriers and certifiers, including micro, small and medium-sized enterprises and in collaboration with competent authorities.

2. Member States shall ensure that micro- and small-sized enterprises receive access to information, funding, and assistance regarding compliance with this Regulation.

Without prejudice to applicable state aid rules, the assistance referred to in the first subparagraph may take the form of:

(a) financial support from the European Union budget;

(b) access to finance from the European Union budget;

(c) specialised training for management and staff;

(d) organisational and technical assistance.

3. Member States shall ensure that medium and large-sized enterprises receive access to information and assistance regarding compliance with this Regulation.

Without prejudice to applicable state aid rules, the assistance referred to in the first subparagraph may take the form of:

(a) specialised training for management and staff;

(b) organisational and technical assistance.

4. Member States shall require training programmes for the qualification of certifiers' personnel as provided for in article 12(1) of this Regulation.

**Article 13**

**Standardised methodology**

1. To ensure compliance with the obligation referred to in Article 4(7), first subparagraph, point (c), a methodology to estimate quantities of losses shall be developed in harmonised standards in accordance with the procedures established by Regulation (EU) No.1025/2012.

2. Where no European standardisation organisation accepts the request to draft a harmonised standard or where the Commission considers that the proposed standard does not satisfy the requirements as stated in Article 13(1) of this Regulation, the Commission shall establish the methodology by means of an Implementing act.

**Article 14**

**Complaint-handling and access to justice**

1. Natural or legal persons or organisations regarded under national law as having a sufficient interest or those who consider that their rights were impaired shall be entitled to submit substantiated complaints to competent authorities when they deem, on the basis of

objective circumstances, that an economic operator, EU land, and maritime carrier or non-EU land, and maritime carrier is failing to comply with the provisions of this Regulation.

For the purposes of the first subparagraph, non-governmental entities or organisations promoting human health, environmental or consumer protection and meeting any requirements under national law shall be deemed to have a sufficient interest.

2. Competent authorities shall assess the substantiated complaint referred to in paragraph 1 and, where necessary, take the necessary steps, including inspections and hearings of the person or organisation, with a view to verifying those complaints. If the complaint is found to be grounded, the competent authorities shall take the necessary actions in accordance with Article 4(3).

3. Competent authorities shall, as soon as possible, inform the person or organisation referred to in paragraph 1 that submitted the complaint of its decision to accede to or refuse the request for action put forward in the complaint and shall provide the reasons for it.

4. Member States shall ensure that a person or organisation referred to in paragraph 1submitting a substantiated complaint shall have access to a court or other independent and impartial public body competent to review the procedural and substantive legality of any decision on that complaint as well as of the competent authority's decisions, acts or failure to act under this Regulation, without prejudice to any provisions of national law which require that administrative review procedures be exhausted prior to recourse to judicial proceedings. Those review procedures shall be fair, equitable, timely and free of charge or not prohibitively expensive, and shall provide adequate and effective remedies, including injunctive relief where necessary.

5. Member States shall ensure that practical information is made available to the public on access to the administrative and judicial review procedures referred to in this Article.

## Article 15

## Penalties

1. Without prejudice to the obligations of Member States under Directive 2021/0422/COD of the European Parliament and of the Council, Member States shall lay down rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are applied. The penalties provided shall be effective, proportionate, and dissuasive.

2. The penalties referred to in paragraph 1 shall include fines proportionate to the turnover of the legal person or to the income of the natural person having committed the infringement. The level of the fines shall be calculated in such a way as to make sure that they effectively

deprive the person responsible for the infringements of the economic benefits derived from those infringements. The level of the fines shall be gradually increased for repeated infringements. In the case of an infringement committed by a legal person, the maximum amount of such fines shall be at least 5% of the economic operator's annual turnover in the Member State concerned in the business year preceding the fining decision.

3. Member States shall ensure that the penalties established pursuant to this Article take due account of the following, as applicable:

(a) the nature, gravity and extent of the infringement;

(b) the intentional or negligent character of the infringement;

(c) the population or the environment affected by the infringement, bearing in mind the immediate and long-term impact of the infringement on the objective of achieving a high level of protection of human health and the environment;

(d) the financial situation of the economic operator, EU land carrier , non-EU land carrier, EU maritime carriers, and non-EU maritime carriers held responsible.

**Article 16**

**Compensation**

1. Member States shall ensure that, where damage to human health has occurred as a result of a infringement of this Regulation, the individuals affected have the right to claim and obtain compensation for that damage in line with Directive 2021/0422/COD

(a) from the relevant natural or legal persons;

(b) from the competent authorities in case of negligence.

2. Member States shall ensure that, as part of the public concerned, non-governmental organisations promoting the protection of human health or the environment and meeting any requirements under national law are allowed to represent the individuals affected and bring collective actions for compensation. Member States shall ensure that a claim for an infringement leading to a damage cannot be pursued twice, by the individuals affected and by the non-governmental organisations referred to in this Paragraph.

3. Member States shall ensure that national rules and procedures relating to claims for compensation are designed and applied in such a way that they do not render impossible or excessively difficult the exercise of the right to compensation for damage caused by an infringement pursuant to paragraph 1.

4. Where the claim for compensation referred to in paragraph 1 is supported by evidence from which a causal link may be presumed between the damage and the infringement, Member States shall ensure that the onus is on the person responsible for the infringement to prove that the infringement did not cause or contribute to the Damage.

5. Member States shall ensure that the limitation periods for bringing claims for compensation referred to in paragraph 1 are not shorter than 10 years. Such periods shall not begin to run before the infringement has ceased and the person claiming the compensation knows or can reasonably be expected to know that he or she suffered damage from an infringement pursuant to paragraph 1.

**Article 17**

**Amendments to Annexes**

The Commission is empowered to adopt delegated acts in accordance with Article 19 to amend Annexes I to IV. in order to take account of the technical progress and scientific developments.

When adopting delegated acts referred to in the first paragraph, the Commission shall take into account:

(a) the experience gained from the implementation of obligations set out in Articles 4 and 5;

(b) relevant international standards;

(c) the specificities of the sectors of activity;

(d) the specific needs of micro, small and medium-sized enterprises.

**Article 18**

**Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 17 shall be conferred on the Commission for a period of 5 years from … [*OP please insert the date = the first day of the month following the date of entry into force of this Regulation*]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods

of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 17 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 17 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

**Article 19**

**Entry into force and application**

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

This Regulation shall apply [*OP: please insert the date = 18 months after the entry into force of this Regulation*]. However, Article 3(1) shall apply from [*OP: please insert the date the date of the entry into force of this Regulation*].

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

Done at Brussels,

*For the European Parliament*
*The President*

*For the Council*
*The President*