



TEXTS ADOPTED

P9_TA(2024)0307

Preventing plastic pellet losses to reduce microplastic pollution

European Parliament legislative resolution of 23 April 2024 on the proposal for a regulation of the European Parliament and of the Council on preventing plastic pellet losses to reduce microplastic pollution (COM(2023)0645 - C9-0378/2023 - 2023/0373(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0645),
- having regard to Article 294(2) and Article 192(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0378/2023),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Italian Chamber of Deputies, asserting that the draft legislative act does not comply with the principle of subsidiarity,
- having regard to the opinion of the European Economic and Social Committee of 14 February 2024¹,
- having regard to the opinion of the Committee of the Regions of 18 April 2024²,
- having regard to Rule 59 of its Rules of Procedure,

¹ OJ C, C/2024/2487, 23.4.2024, ELI:
<http://data.europa.eu/eli/C/2024/2487/oj>.

² OJ C, C/2024/3675, 26.6.2024, ELI:
<http://data.europa.eu/eli/C/2024/3675/oj>.

- having regard to the opinion of the Committee on Industry, Research and Energy,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0148/2024),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Position of the European Parliament adopted at first reading on 23 April 2024 with a view to the adoption of Regulation (EU) 2024/... 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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C , , p. .
² OJ C , , p. .

Whereas:

- (1) Microplastics are ubiquitous, persistent and transboundary. They are detrimental to the environment and ~~potentially~~ harmful to human health, ***particularly due to the presence of harmful chemical additives and other substances of concern added during production and conversion, such as phthalates, bisphenol A, or flame retardants***³. 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

³ ***'Plastic giants polluting through the back door: The case for a regulatory supply-chain approach to pellet pollution', Surfrider Foundation Europe and Rethink Plastic, November 2020.***

agriculture as well as recreation and tourism in areas affected by the releases. **[Am. 1]**

- (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'⁴.
- (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 Scientific opinion on the environmental and health risks of microplastic pollution, April 2019

- (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.

[Am. 2]

- (5) In a bid to tackle plastic pollution, in January 2018, the Commission adopted a Communication entitled ‘European Strategy for Plastics’⁵ 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 Plan⁶ in March 2020 and the Zero Pollution Action Plan⁷ 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) 2023/2055⁸ 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.

⁵ COM(2018) 28 final

⁶ COM(2020)98 final, 2020.

⁷ COM(2021) 400 final

⁸ 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).

- (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 2021/06⁹ 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 chain. Measures for minimizing the risk associated with the transport of plastic pellets by sea are under examination at the International Maritime Organization (**IMO**) ***in light of the significant risk of catastrophic pollution associated with maritime transport of plastic pellets. In this context, the Union should follow closely the developments at the IMO, and play a leading role in ensuring a high-level of environmental protection on this issue.*** [Am. 3]
- (7a) ***Several accidents leading to plastic pellet spills and losses have been registered in the Union with transboundary impacts, highlighting the urgent need for ambitious, holistic measures to significantly reduce the risk of plastic pellet pollution while strengthening response capabilities in relation to plastic pellet spills throughout Union territories and waters.*** [Am. 4]

⁹ OSPAR Recommendation 2021/06 on the reduction of plastic pellet loss into the marine environment

(7b) Nearly 90 % of the world's goods are transported by sea, including plastic pellets. However, poor handling practices or a lack of supervision of certain routine operations, such as cleaning hulls or containers, can lead to such pellets leaking out and spilling into the ocean. Furthermore, many maritime pellet disasters have been reported, making maritime transport a high-risk activity in relation to plastic pellet pollution. The impact of such pellet losses is catastrophic for marine and coastal ecosystems as well as the species that comprise them, and the extreme mobility of plastic pellets makes effective containment and clean-up operations difficult. The handling of such pellets is regulated at international level by the 1972 Convention for Safe Containers, and supplemented by the 2023 Sub-Committee on Carriage of Cargoes and Containers circular on the obligation to report lost containers, but they do not provide the guarantees needed to prevent pollution by plastic pellets. The inclusion of maritime transport in the scope of this Regulation, as well as of provisions relating to the handling of plastic pellets specific to this mode of transport, is therefore essential if the objectives of this Regulation are to be achieved. [Am. 5]

- (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)¹⁰, 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 Council¹¹ 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~~**prevent them from escaping into the environment. [Am. 6]**

¹⁰ 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

¹¹ 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).

(9a) This Regulation provides for measures to prevent, contain and clean up plastic pellet pollution occurring following the entry into force of this Regulation, but does not provide for measures to address existing pollution. Cleaning up soil, rivers and streams, and restoring degraded terrestrial, marine, littoral and coastal ecosystems is essential to achieving the 30 % reduction target by 2030, in accordance with the objectives set out in Regulation (EU) 2024/1991 of the European Parliament and of the Council¹², and the objectives of the European Green Deal. The Commission should develop a set of measures to map and clean up those already polluted areas, and implement them either as part of a European strategy for depolluting microplastics, or through support and accompanying measures for Member States. More broadly, the Union should be involved in promoting solutions along the entire value chain, and should include such solutions in the ongoing negotiations on the development of an international Treaty on Plastic Pollution, as well as in the upcoming 81st session of the Marine Environment Protection Committee of the IMO (IMO MEPC). [Am. 7]

¹² **Regulation (EU) 2024/1991 of the European Parliament and of the Council of 24 June 2024 on nature restoration and amending Regulation (EU) 2022/869 (OJ L, 2024/1991, 29.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1991/oj>).**

- (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 Council¹³, 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 2007¹⁴, established pursuant Council Directive 96/61/EC¹⁵ 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 Council¹⁶ 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.

¹³ 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).

¹⁴ https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/pol_bref_0807.pdf

¹⁵ Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L 257, 10.10.1996, p. 26).

¹⁶ 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).

- (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~~**However, that reporting requirement lacks** a methodology to estimate losses, **and only provides annual estimates. While** this requirement will increase information on pellet losses and improve the quality of the information collected to assess the risks deriving from these microplastics in the future, **it is not sufficient to have an overview of the specific nature of the losses and the causes thereof. [Am. 8]**
- (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 **labelling all storage and transport containers containing plastic pellets as well as by** using ~~puncture-proof~~**appropriate** 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. **[Am. 9]**

- (16) While the aim is to ~~prevent~~**achieve zero** plastic pellet losses to the environment for all economic operators, ~~EU carriers and non-EU carriers, obligations for micro-, small and medium-sized enterprises and~~ enterprises **that handle under 1 000 tonnes of plastic pellets annually** should be adjusted to mitigate the burden on them. **[Am. 10]**
- (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 and to achieve zero** 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. **[Am. 11]**

- (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~~**put in place** the specific equipment to install or the ~~procedure~~**procedures** 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. ***Economic operators should be able to be exempted from installing certain types of equipment or from adopting certain measures if they duly justify such exemptions to the competent authorities, taking into account the nature and size of the installation and the scale of its operations. Micro enterprises should consider at least the specific equipment to be installed or the procedures to be executed, taking into account the nature and size of the installation as well as the scale of its operations. [Am. 12]***

- (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 and to achieve zero*** 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. **[Am. 13]**

- (24) **Small**, 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 **mandatory** training programme addressing specific ~~training needs and modalities~~ **issues in relation to prevention, practices, workers protection, clean-up technologies, use and maintenance of equipment, the execution of procedures, as well as the monitoring and reporting of plastic pellet losses**. 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 Council¹⁷ 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. **Small enterprises operating installations where plastic pellets in quantities above 1 000 tonnes have been handled should obtain certification only once. Such certification should be valid for 5 years after which they should notify an update of their risk assessment plan as well as a self-declaration of conformity every 5 years. [Am. 14]**

¹⁷ 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).

- (25) ~~Micro and small-sized enterprises~~**Small**, and medium and large-sized enterprises operating installations where plastic pellets in quantities below 1 000 tonnes have been handled **and micro enterprises** should be required to be subject to a self-declaration of conformity. They should also be given sufficient time to demonstrate their compliance. **[Am. 15]**
- (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 prejudice 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 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) **As** micro, small and medium-sized enterprises (SMEs) ~~in~~**account for an important share of** the pellet supply chain, **they** should comply with the relevant obligations laid down in this Regulation, ~~however they could face~~**while taking into consideration the possible different challenges linked to that compliance and the possible** proportionally higher costs and difficulties when complying with some of the obligations. The Commission **and the competent authorities** should raise awareness among economic operators and carriers regarding the necessity of preventing pellet losses. Additionally, the Commission **and the competent authorities** should develop training materials, **in consultation with all relevant stakeholders**, to assist ~~them~~**economic operators and carriers** in fulfilling their obligations, particularly with respect to the requirements of the risk assessment. **That should be done by taking into account the non-binding Recommendation adopted by the parties to the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)**. 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 **and specialised training to SMEs all personnel handling plastic pellets, as well as financial support and access to finance for micro and small enterprises as well as for installations handling plastic pellets in smaller quantities**. Member States actions should be taken in respect of applicable State aid rules. **[Am. 16]**

- (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 Council¹⁸. ***Pending the adoption of the standardised methodology, economic operators should indicate the methodology used when reporting losses of plastic pellets. [Am. 17]***
- (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.

¹⁸ 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)

- (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 Union¹⁹. 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')²⁰.

¹⁹ OJ C 326, 26.10.2012, p. 391–407; OJ C 326, 26.10.2012, p. 391–407

²⁰ <https://unece.org/environment-policy/public-participation/aarhus-convention/text>

- (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. ***Member States should endeavour to ensure that the revenue generated from the penalties, or its equivalent financial value, is used to support projects aimed at cleaning up areas polluted by plastic and avoiding plastic pellet pollution.*** [Am. 18]

- (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 the enforcement authorities. The maximum amount of fines should, in case of an infringement committed by a legal person, represent at least ~~4%~~**3%** of the economic annual turnover in the ~~Member State concerned~~**Union**. **[Am. 19]**

(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 Council²¹ does not give private parties a right of compensation as a consequence of environmental damage or of an imminent threat of such damage.

²¹ 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).

(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-Making²². In particular, to ensure equal participation in the preparation of delegated acts, the 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:

²² OJ L 123, 12.5.2016, p. 1.

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, ***with the objective of achieving zero plastic pellet losses.*** [Am. 20]
2. This Regulation applies to the following subjects:
 - (a) economic operators handling plastic pellets in the Union in quantities above 5 tonnes in the previous calendar year;
 - (b) EU carriers and non-EU 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~~ ***regardless of its shape or form, including powders, cylinders, beads and flakes, to which additives might have been added***, that is used as feedstock in plastic product manufacturing ***and plastic recycling*** operations; [Am. 21]

- (aa) ***'plastic pellet dust' means the industrial residue from the handling, grinding or processing of plastic pellets, that is not used as feedstock in plastic product manufacturing operations; [Am. 22]***
- (b) 'spill' means a one-off ***or prolonged*** escape of plastic pellets from primary containment; **[Am. 23]**
- (c) 'loss' means a one-off or prolonged escape of plastic pellets ***at any stage of the supply chain, including*** from ***the*** installation's boundary to the environment or from ~~road vehicles, rail wagons or inland waterway vessels transporting~~***the transport of*** plastic pellets; **[Am. 24]**
- (d) 'installation' means any premises, structure, ~~environment~~***site*** or place within which one or more economic activities involving the handling of plastic pellets are carried out; **[Am. 25]**
- (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 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~~; **[Am. 26]**
- (g) 'non-EU 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~~; **[Am. 27]**
- (h) '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/EC²³;
- (i) 'large-sized enterprise' means an enterprise that is not a micro, small or medium-sized enterprise;
- (j) 'competent authority' means an authority or a body designated by a Member State to carry out its obligations under this Regulation;

²³ Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

- (k) 'certifier' means any of the following:
- (i) a conformity assessment body as defined in Article 2(13) of Regulation (EC) 765/2008 of the European Parliament and of the Council²⁴ 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;
- (l) '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 carriers and non-EU carriers shall ensure that losses are avoided. Where **spills and** losses occur, economic operators, EU carriers and non-EU carriers shall take immediate action to **contain and** clean-up those **spills and** losses. **[Am. 28]**

²⁴ 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).

2. Economic operators and EU 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 and EU 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 **and transport** of plastic pellets, including of any closure of an existing installation, **as applicable**. [Am. 29]
- 3a. ***Without prejudice to Regulation (EC) No 1272/2008 of the European Parliament and of the Council²⁵, economic operators shall, for the purposes of this Regulation, label all storage and transport containers containing plastic pellets in accordance with Annex IVb to this Regulation.*** [Am. 30]
4. Competent authorities shall establish and maintain a public register containing the information they have received in accordance with paragraphs 3 and 42 **and 3. The register shall be publicly available and easily accessible.** [Am. 31]

²⁵ ***Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).***

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, 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 **small**, medium and large-sized enterprises operating installations where plastic pellets in quantities below 1 000 tonnes have been handled in the previous calendar year or that are micro ~~or small-sized~~ enterprises shall notify an update of the risk assessment plan for each installation as well as a renewal of the self-declaration of conformity to the competent authority every ~~5~~**3** years from the last notification.

[Am. 32]

- 2a. Economic operators that are small enterprises operating installations where plastic pellets in quantities above 1 000 tonnes have been handled in the previous calendar year shall comply with the obligations laid down in paragraph 2 of this Article, unless they hold a valid certificate issued in accordance with Article 5(2a). [Am. 33]***

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

- (a) to change risk assessment plans notified in accordance with paragraphs 1 and 2 to ensure that the losses can effectively be prevented ~~or~~**and**, where appropriate, contained and cleaned up and that Annex I is complied with; **[Am. 34]**
- (b) implement any of the actions listed in Annex I in a timely manner.

4. Competent authorities shall establish, maintain, and update a register containing the risk assessment plans ~~and, self-~~ declarations of conformity notified **and loss notifications provided** in accordance with ~~paragraphs 1 and 2 of this Article~~ **Annex IVa**. The register shall be publicly available on a website. **[Am. 35]**
5. EU carriers and non-EU 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 carriers and non-EU 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 avoid they become a loss;
 - (c) actions to clean-up after a spill or loss.

7. Economic operators, ***EU carriers and non-EU*** and ~~EU~~ carriers shall have the following obligations: **[Am. 36]**

(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, ***including adequate personal protection equipment***, and execute the procedures set out to ensure compliance with this Regulation; **[Am. 37]**

(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~~ ***quantities*** of plastic pellets handled.

[Am. 38]

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 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, **EU** carriers and non-EU carriers shall take corrective actions, ~~as soon as possible~~ **without delay. [Am. 39]**
9. Every year economic operators that are not micro ~~or small-sized~~ enterprises ~~and/or~~ that operate installations where plastic pellets in quantities above 1 000 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~~ **shall** among others cover the following subjects: **[Am. 40]**
 - (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 **an evaluation of** their effectiveness; **[Am. 41]**

- (c) discussions with ***and training programmes involving*** the personnel, inspections of equipment, ***including adequate personal protection equipment***, and procedures in place and revision of any relevant documentation. **[Am. 42]**

The economic operators referred to in the first subparagraph shall maintain records of the assessments and of any actions taken subsequently, and shall make such records available to competent authorities on demand.

[Am. 43]

Article 5

Certification

1. By ... [OP: please insert the date = 24 months after the entry into force of this Regulation], and thereafter every three years, economic operators that are large-sized enterprises shall demonstrate that each installation where plastic pellets in quantities above 1 000 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 ... [OP: please insert the date = 36 months after the entry into force of this Regulation], and thereafter every ~~four~~**three** years, economic operators that are medium-sized enterprises shall demonstrate that each installation where plastic pellets in quantities above 1 000 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. **[Am. 44]**
- 2a. ***By ... [60 months from the entry into force of this Regulation], economic operators that are small enterprises shall demonstrate that each installation where plastic pellets in quantities above 1 000 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. That certificate shall be valid for 5 years. [Am. 45]***
3. Certifiers shall carry out spot-checks ***and inspections of sites, means of transport and immediately surrounding areas*** to ensure that all measures included in the risk assessment plan carried out in accordance with Annex I are duly implemented. **[Am. 46]**

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.

Competent authorities shall establish and maintain and keep up to date a register of certificates. The register shall be publicly available on a website.

Article 6

Environmental management systems

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.

Article 7

Accreditation of certifiers

The accreditation of certifiers referred to in Article 32, point (k)(i) shall include an evaluation of compliance with the following requirements:

[Am. 47]

- (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) the certifier shall have a sufficient number of suitably qualified and experienced personnel responsible for carrying out the conformity assessment tasks;
- (f) the personnel of a certifier shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment tasks;
- (g) where a certifier subcontracts specific tasks connected with certification or has recourse to a subsidiary, it shall take full responsibility for the tasks performed by subcontractors or subsidiaries and shall assess and monitor the qualifications of the subcontractor or the subsidiary and the work carried out by them.

Article 8

Verification of compliance and reporting

1. Competent authorities shall verify compliance of economic operators, EU carriers and non-EU 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 ***unannounced*** environmental inspections and other verification measures, following a risk-based approach. **[Am. 48]**
2. At the latest by ... [OP please insert the date = the first day of the month after ~~four~~***three*** years following the date of entry into force of this Regulation] and every three years 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: **[Am. 49]**

- (a) the number of economic operators per size of enterprise according to Commission Recommendation 2003/361/EC and per economic activity, their installations ***and the quantities of plastic pellets handled by them***, and of the EU carriers and their means of transport allocated to transporting plastic pellets ***and the quantities handled by them***; [Am. 50]
 - (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.

3a. Every three years, based on the reports of Member States referred to in paragraph 2, the Commission shall produce a synthesis report on compliance and reporting, setting out the qualitative and quantitative information on the implementation of this Regulation contained in the Member States' reports. [Am. 51]

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 carriers and non-EU carriers shall immediately: **[Am. 52]**
 - (a) inform the competent authority in whose territory the incident or accident occurred, ***as well as the competent authority of any territory that is likely to be affected***, and the estimated quantities of losses ***in accordance with the form set out in Annex IVa***; **[Am. 53]**
 - (aa) take measures to contain and clean up such losses in an ecologically sensitive manner***; **[Am. 54]**
 - (b) take ***all possible*** measures to ~~limit~~***minimise*** the health or environmental consequences, and to prevent further incidents or accidents. **[Am. 55]**

2. The competent authority in whose territory the incident or accident occurred shall require, where necessary, that economic operators, EU carriers and non-EU carriers take appropriate complementary measures ***and organise specific training to minimise***~~to limit~~ the health or environmental consequences and to prevent further incidents or accidents. **[Am. 56]**
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. **[Am. 57]**

Article 10

Non-compliance

1. In the event of an infringement of the rules laid down in this Regulation, economic operators, EU carriers and non-EU carriers shall immediately:
 - (a) inform the competent authority;
 - (b) take the 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.
- 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 ~~may~~**shall** suspend the operation of the installation until compliance is restored in accordance with paragraph 1, points (b) and (c). **[Am. 58]**

Article 11

Designation and powers of competent authorities

- 1. Member States shall designate one or more competent authorities for the application and enforcement of this Regulation ***and shall inform the Commission accordingly.*** **[Am. 59]**
- 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. ***By ... [12 months from the entry into force of this Regulation],*** the Commission shall develop ***and fund*** awareness raising and training material, ***which may take the form of guides and courses,*** on the sound implementation of the obligations laid down in this Regulation in consultation with representatives of economic operators, carriers, and certifiers, including micro, small and medium-sized enterprises, ***social partners, civil society representatives and non-governmental organisations*** and in collaboration with competent authorities.
[Am. 60]
2. Member States shall ensure that economic operators and carriers, ~~especially micro, small and medium-sized enterprises,~~ get access to information and assistance regarding compliance with this Regulation. **[Am. 61]**

Without prejudice to applicable State aid rules, the assistance referred to in the first subparagraph for micro, small and medium-sized enterprises may take the form of:

- (a) specialised management and staff training, including the organisation of training programmes;***
- (b) organisational and technical assistance. [Am. 62]***

Without prejudice to applicable state aid rules, the assistance referred to in the first subparagraph ***for micro and small enterprises as well as for installations handling plastic pellets in quantities below the threshold set out in Article 4(2) may also*** may take the form of: **[Am. 63]**

- (a) financial support;
- (b) access to finance, ***including for the purpose of acquiring equipment required to achieve compliance;*** **[Am. 64]**
- ~~(c) specialised management and staff training; [Am. 65]~~
- ~~(d) organisational and technical assistance. [Am. 66]~~

3. Member States shall encourage training programmes for the qualification of certifiers' personnel.

Article 13

Standardised methodology

1. For the purposes of compliance with the obligation referred to in Article 4(7), first subparagraph, point (c), **and Annex IVa**, 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. **[Am. 67]**
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 which it aims to cover, the Commission shall establish the methodology referred to in paragraph 1 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 carrier or non-EU 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), **Article 9(2) and Article 10(2)**. [Am. 68]

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 1 submitting 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 2008/99/EC of the European Parliament and of the Council²⁶, 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 ~~4~~**3** % of the economic operator's annual turnover in the ~~Member State concerned~~**Union** in the business year preceding the fining decision. **[Am. 69]**

²⁶ Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law (OJ L 328, 6.12.2008, p.28).

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 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 carrier and non-EU carrier held responsible.

3a. Member States shall endeavour to ensure that the revenue generated from the penalties referred to in paragraph 1, or its equivalent financial value, is used to support projects aimed at cleaning up areas polluted by plastic before ... [the date of entry into force of this Regulation] and avoiding plastic pellet pollution.

Projects financed by the revenue generated from penalties as referred to in the first subparagraph may contribute to promoting scientific work to study the impact of plastic pellets on human health and the environment, supporting research and development in the area of plastic pellet pollution, implementing awareness programmes, and financing training programmes specifically designed for micro and small enterprises.

By ... [60 months from the entry into force of this Regulation], and every year thereafter, the Commission shall report to the European Parliament and to the Council on how the revenue generated from penalties in the previous year has been used and how such use has contributed to the reduction of plastic pellet pollution, including information on the beneficiaries and the level of expenditure concerning the objectives set out in the first and second subparagraphs.
[Am. 70]

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 from the relevant natural or legal persons and, where appropriate, from the relevant competent authorities responsible for the infringement.
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 5 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 a 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~~**IVb** in order to take account of the technical progress and scientific developments. **[Am. 71]**

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 **3, 4, 5, 8 and 94**~~and 5~~; **[Am. 72]**
- (b) relevant international standards;
- (c) the specificities of the sectors of activity;
- (d) the specific needs of micro, small and medium-sized enterprises.

Article 17a

Review

The Commission shall monitor the application of this Regulation and relevant developments at the IMO. By ... [8 years from the entry into force of this Regulation], the Commission shall publish a comprehensive report on the overall application of this Regulation and its effectiveness and shall submit, where appropriate, a legislative proposal to amend this Regulation.
[Am. 73]

Article 17b

Traceability

By ... [24 months from the entry into force of this Regulation], the Commission shall publish a report on the possibility of introducing chemical traceability of plastic pellets. That report shall at least consider:

- (a) the technical feasibility of introducing a unique and differentiable, chemical signature which is not harmful to the environment or human health;***
- (b) setting up a Union database of all chemical signatures.***

Where appropriate, the report referred to in the first paragraph shall be accompanied by a legislative proposal. [Am. 74]

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 ...,

For the European Parliament

The President

For the Council

The President

ANNEX I

RISK ASSESSMENT PLAN FOR INSTALLATIONS

The risk assessment plan referred to in Article 4(1) shall contain the following elements:

- (1) the site plan;
- (1a) *the number of tonnes of plastic pellets handled per year;***
[Am. 75]
- (2) the locations where pellet spills and losses may originate from within the installation's boundaries, specifying high- and low-risk locations;
- (3) the handling operations during which pellet spills and losses may originate from within the installation's boundaries, specifying high- and low-risk operations;
- (3a) *information relating to the chemical nature of each polymer contained in plastic pellets on site, including information on physico-chemical properties and hazard proprieties;***
[Am. 76]
- (4) the estimation of the quantities of spills and losses in the identified locations and operations;
- (5) drawing up of the list of the activities over which the installation might have authority to exercise control, including suppliers, sub-contractors and off-site storage facilities;
- (6) the definition of one specific role of a member of staff responsible for recording, investigating and follow-up on spills and losses, including reporting to competent authorities as in Article 4 (7) and Article 9 (1);
- (7) description of equipment in place to prevent, contain and clean up spills and losses.

Economic operators shall ~~consider~~ **put in place** at least the

following, taking into account the nature and size of the installation as well as the scale of its operations: **[Am. 77]**

- (a) For prevention: vacuum seals on hoses and pipework; tear- and impact-resistant, ***waterproof, sealed and labelled*** packaging that can withstand degradation in ***rough*** aquatic environments; equipment to create secure connection points with secondary barriers in place; loading systems designed to ensure transfer lines can be completely emptied after loading and unloading; ***shock-resistant, waterproof, sealed and labelled*** containers or external silos to store pellets; automated transport systems for pellets, ***filters to prevent the spread of pellet dust in the air and on site***; **[Am. 78]**
- (b) For containment: ***spill trays and*** catchment devices placed along the exterior edge of loading and unloading areas; ***in-ground retention tanks with steel grating below spill hotspots such as transfer points***; industrial vacuum cleaners and hand tools for immediate cleaning; ~~internal and external~~ ***indoor and outdoor*** drain covers ***on all drains with a mesh size smaller than the smallest plastic pellets handled on site***, storm water drainage or filtration systems to manage reasonably foreseeable flood or storm events; a sewage treatment system; **[Am. 79]**
- (c) For clean-up: industrial vacuum cleaners for internal and external usage; dedicated appropriate containers for recovered pellets that are covered ***shock-resistant, waterproof, sealed***, labelled and secured to prevent further spills and losses; hand tools (e.g., brooms, dustpan and brush, buckets, repair tapes); reinforced collection bags. **[Am. 80]**

Exemptions in relation to the installation of certain types of equipment referred to in this point shall be possible for economic operators that are able to justify such exemptions to the competent authorities, taking into account the nature and size of the installation as well as the scale of its

operations.

Economic operators that are micro-enterprises shall consider at least the elements set out in this point, taking into account the nature and size of the installation as well as the scale of its operations. [Am. 81]

- (8) description of procedures in place to prevent, contain and clean up spills and losses.

Economic operators shall ~~consider~~ **put in place** at least the following **measures** taking into account the nature and size of the installation as well as the scale of its operations: **[Am. 82]**

- (a) for prevention: limits on the volumes of pellets transported in certain packaging (e.g., pellets must be packaged and sealed in 25kg sacks ~~tear-~~ **and impact-resistant packaging that can withstand degradation in aquatic environments**, and loaded no more than ~~1 tonne~~ **1 tonne** per pallet); regular inspection and maintenance of packaging, containers and storage facilities; use of spill trays under transfer points and during loading and unloading; clear protocols for opening, loading, closing and sealing containers at the start and end of loading; physical testing and monitoring of the effectiveness of prevention procedures; **[Am. 83]**
- (b) for containment: regular inspection, cleaning and maintenance of catchment devices; regular inspection, cleaning and maintenance of drain covers, storm water drainage or filtration systems; regular inspection and cleaning of vehicles leaving and/or entering a site, outgoing water facilities and fences on the ~~perimeter of the facility~~ **installation's boundaries** that are in public areas when applicable; immediate replacement or repair of leaking packaging; checks for broken and discarded packaging or containers for residual pellets before disposal or repair; **regular inspection, cleaning and** maintenance of sewage

treatment system. **[Am. 84]**

- (c) for clean-up: spilled plastic pellets are cleaned up immediately to prevent losses to the environment, at the latest upon termination of the operation, and collected in a designated ***waterproof, sealed and labelled*** container. If possible, spilled plastic pellets are reused as raw material to reduce wastage. If spilled plastic pellets cannot be reused as raw materials, they are retrieved and disposed of in accordance with waste legislation; ***along with damaged containers.*** **[Am. 85]**

Exemptions in relation to taking the measures referred to in this point shall be possible for economic operators that are able to justify such exemptions to the competent authorities, taking into account the nature and size of the installation as well as the scale of its operations.

Economic operators that are micro enterprises shall consider at least the elements set out in this point, taking into account the nature and size of the installation as well as the scale of its operations. **[Am. 86]**

- (9) in addition to elements described in points (1) to (8), economic operators that are ~~medium or large-sized enterprises and operate installations where plastic pellets in quantities above 1 000 tonnes have been handled in the previous calendar year~~ ***not micro-enterprises*** shall also take the following actions: **[Am. 87]**

- (a) describe the elements that should be reviewed at formal management meetings at least once a year including the estimated quantity and causes of any losses; preventive, mitigating and clean up equipment and procedures implemented and their effectiveness.
- (b) establish an awareness and training programme, based on the employees' specific roles and responsibilities, on prevention, containment and clean-up, the installation, use and

maintenance of equipment, the execution procedures, as well as the monitoring and reporting of pellet losses;

- (c) set the procedures for informing drivers, suppliers and subcontractors about the relevant procedures to prevent, contain and clean up spills and losses.

ANNEX II

FORM FOR SELF-DECLARATION OF CONFORMITY

.....

..... (name and address of the economic operator).

Declares under its sole responsibility that the handling of plastic pellets in the installation located in

..... (address) with registration number (if available) meet all requirements of Regulation (EU) No [...] of the European Parliament and of the Council of [...] on preventing plastic pellets losses to reduce microplastic pollution.

By signing this declaration, I declare that the risk assessment attached, carried out on the (date) has been implemented.

Done at ... on .../.../20....

Signature

ANNEX III

ACTIONS FOR EU CARRIERS AND NON-EU CARRIERS

Measures to be taken and equipment to be put in place by EU carriers and non-EU carriers:

- (1) For prevention: verification during and after loading and unloading, that pellets are properly removed from the outside of the transport equipment before leaving the loading/unloading site; ~~clear communication on~~, **visible labelling concerning safe stowage and storage** requirements; prevention of any leakage, including during the transport journey, e.g., by technical suitability of the transport means and containers, supplemented, if necessary, with appropriate ~~sealing~~**waterproof, sealed tear- and impact-resistant packaging that can withstand degradation in aquatic environments; spill trays and catchment devices**; ensuring that protective covers on e.g. forklifts/hydraulic equipment are used to prevent the piercing of packaging; regularly cleaning **and checking whether** the loading compartments ~~and the~~, containers **and trailers are in good condition to contain** ~~and~~ to minimise the loss of spilled pellets; visual checking of openings and integrity of the loading compartments prior and, to the extent possible, during the journey, including in the multimodal terminals, rail terminals, inland and seaports.

[Am. 88]

- (1a) Additional measures to be taken and equipment specifically applicable to maritime and inland waterway transport:**

- (a) provide a clear indication of the containers containing plastic pellets;**
- (b) store plastic pellets in containers in good condition and avoid protrusions that could tear bags and boxes and store containers in the hold and not on deck;**

(c) contain, clean up and avoid losses of plastic pellets into water when cleaning the boarding area, deck, hold or in a shipping container. [Am. 89]

(2) For containment and clean-up: ***replace or*** where possible, repair damaged packaging (e.g. by using booms, barriers and tape) and contain the remaining pellets in the ***container or*** loading compartment; collect the spilled pellets in closed ***waterproof*** containers ~~or bags~~ ***labelled and sealed*** for proper disposal; in case of transport of pellets in bulk tanks, ***deploy appropriate spill trays and catchment devices before*** opening the bottom manhole/cone of the silo tank only after entering the cleaning bay; replace the container liner only in suitable and non-public areas, where any spillage can be contained; ***immediately*** notify the authorities such as international and national emergency, or environmental authorities, as appropriate, from the Member State where the event occurred. **[Am. 90]**

(3) Equipment on board: at least one portable lightning apparatus ***lighting device***, hand tools (e.g. brooms, dustpan and brush, buckets, repair tapes, etc.); closed collection containers/reinforced collection bags. **[Am. 91]**

(3a) Training: establish an awareness and training programme, based on the employees' specific roles and responsibilities, on prevention, containment and clean-up of plastic pellet losses, the installation, use and maintenance of equipment, the execution procedures, as well as the monitoring and reporting of plastic pellet losses. [Am. 92]

ANNEX IV

FORM OF THE CERTIFICATE OF CONFORMITY

.....

..... (name).

with registration number

.....

accredited for the scope

. (NACE Code)

declares, after having verified the installation of the economic operator

..... (name) located in with

registration number (if available)

.....

that the installation meets all requirements laid down in Annex I of
Regulation (EU) No [...] of the European Parliament and of the Council of
[...] on preventing plastic pellets losses to reduce microplastic pollution.

By signing this declaration, I declare that:

- the verification has been carried out in full compliance with the requirements of Regulation (EU) No [...], including spot-checks performed in (dates),
- the outcome of the verification confirms that there is no evidence of non-compliance with the applicable legal requirements of Regulation (EU) No [...].

Done at ... on .../.../20....

Signature

ANNEX IVa

FORM FOR LOSS TRACKING

Place of Incident: [Text Box]

Pellet Loss Tracking Form

Date of Incident: [date]

Time of Incident: [time]

Location of Loss:

[] Production Area

[] Storage Area

[] Manufacturing Area

[] Transportation

Description of Pellet Loss:

[Text Box]

Estimated Quantity of Lost Pellets:

[Text Box]

[Text Box - estimated quantity of lost pellets based on the standardised methodology referred to in Article 13]

Cause of Loss:

[] Equipment Malfunction

[] Human Error

[] Environmental or Weather Factors (Specify): [Text Box]

[] Other (Specify): [Text Box]

Immediate Actions Taken:

[Text Box]

Clean-up Measures:

[] Sweeping

[] Vacuuming

[] Absorbent Materials

[] Containment

[] Disposal

Environmental Impact Assessment:

[] Soil Contamination

[] Water Contamination

[] Air Quality Contamination

[] Wildlife Impact

Witness Information (if applicable):

Name: [Text Box]

Contact Number: [Text Box]

Email Address: [Text Box]

Reporting Person:

Name: [Text Box]

Position: [Text Box]

Contact Number: [Text Box]

Email Address: [Text Box]

Attachments (e.g., photos, reports):

[File Upload]

Additional comments: [Text Box] [Am. 93]

ANNEX IVb

LABELLING FOR PLASTIC PELLETS

<i>Pictogram</i>	
<i>Signal Word</i>	<i>Danger</i>
<i>Hazard Statement</i>	<i>Harmful to the environment</i>
<i>Precautionary Statement - Prevention</i>	<i>Avoid release to the environment</i>
<i>Precautionary Statement - Response</i>	<i>Collect spillage</i>
<i>Precautionary Statement - Disposal</i>	<i>Reuse as raw material, recycle or dispose of contents..</i>
	<i>... in accordance with local/ regional/national/international law (to be specified).</i>

[Am. 94]