C/2025/5543

24.10.2025

POSITION (EU) NR 6/2025 OF THE COUNCIL AT FIRST READING

with a view to the adoption of a Regulation of the European Parliament and of the Council on preventing plastic pellet losses to reduce microplastic pollution

Adopted by the Council on 22 September 2025

(C/2025/5543)

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 ([1]),

Having regard to the opinion of the Committee of the Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) Microplastics are ubiquitous, persistent and transboundary. They are detrimental to the environment and potentially harmful to human health. The harm caused by microplastics to the environment and potentially to human health can be further increased when harmful chemical additives and other substances of concern added during production and conversion are present. Microplastics are easily carried 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. Their presence in soil has effects on soil properties and triggers 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 ingested by a range of organisms and animals and cause harm to biodiversity and ecosystems. The persistence of plastic pellets in the aquatic environment can be measured over decades, and ingestion of plastic pellets by marine wildlife, in particular seabirds and sea turtles, can 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 the air and food consumption. The growing awareness of microplastics' presence in the food chain can undermine consumer confidence and have economic consequences. There could be negative economic impacts on activities such as commercial fishing and agriculture as well as recreation and tourism in areas affected by the releases.

(2) In its opinion of 30 April 2019 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'.

(3) Plastic pellets are any polymer-containing moulding materials, of primary or secondary origin, or both, regardless of whether they are derived from biomass or intended to biodegrade over time. Plastic pellets are primarily intended to be used in plastic product manufacturing operations via moulding, which encompasses moulding *stricto sensu*, extrusion, foaming, film forming, compression or injection. Alternatively, plastic pellets can be used in product manufacturing operations of non-plastic products, where such pellets are chemically encapsulated in a matrix, such as in lightweight concrete, or physically contained by the product, such as asphalt. Plastic pellets can contain chemical additives and can come in multiple shapes and forms, such as plastic nurdles, granules, flakes, resins, cylinders, beads, powders, micro-powder, microspheres and agglomerates. Their size typically ranges from 2 to 5 millimetres in diameter, though a small portion of plastic pellets are smaller or larger.

([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.
([3]) Position of the European Parliament of 23 April 2024 (not yet published in the Official Journal) and position of the Council at first reading of 22 September 2025 (not yet published in the Official Journal). Position of the European Parliament of … (not yet published in the Official Journal).

(4) Plastic pellet dust is the industrial residue from the handling, grinding or processing of plastic pellets that is not used in plastic product manufacturing operations and therefore does not fall within the scope of the plastic pellets definition in this Regulation. The generation of such dust is difficult to avoid but can be minimised. Such dust should be extracted by means of filters or catchment devices as a health and safety measure at work.

(5) Plastic pellet losses constitute the third largest source of microplastics unintentionally released to the environment in the Union and occur due to poor handling practices at all stages of the plastic pellet supply chain, which includes production including recycling, master batching, compounding, conversion, processing, distribution, transport, including by sea, and other logistic operations, storage, packaging, and the cleaning of plastic pellet containers and tanks. Hence, a supply-chain approach is essential for ensuring that all economic actors involved in the handling of plastic pellets are committed to loss prevention. Since 2015, the European plastic manufacturing industry has progressively adopted the international Operation Clean Sweep® (OCS) programme as a voluntary pledge. Under that programme, each enterprise producing or handling plastic pellets recognises the importance of having zero plastic 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 OCS programme by the plastic industry remains low.

(6) Concerns about the impacts of microplastic pollution on the environment and on human health have been raised 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.

(7) In a bid to tackle plastic pollution, the Commission has in its communication of 16 January 2018 entitled 'A European Strategy for Plastics in a Circular Economy' acknowledged the risks posed by microplastics and called for innovative solutions targeting the different sources of microplastics to be taken. The Commission renewed that commitment in its communications of 11 December 2019 on the European Green Deal, of 11 March 2020 on the new Circular Economy Action Plan and of 12 May 2021 on the Zero Pollution Action Plan. The Zero Pollution Action Plan includes, among its 2030 targets, reducing the amount of microplastics released into the environment by 30 %.

(8) Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) addresses microplastic pollution by imposing a restriction on the placing on the market of microplastics that are intentionally added to products, as considerable microplastic pollution arises from the use of synthetic polymer microparticles on their own or when intentionally added to products, and such pollution poses an unacceptable risk to the environment.

(9) OSPAR Recommendation 2021/06 on the reduction of plastic pellet loss into the marine environment ('OSPAR Recommendation 2021/06') was adopted in June 2021 by the contracting parties to the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention) with the aim of reducing marine litter 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 minimising the risk associated with the transport of plastic pellets by sea are under examination at the International Maritime Organization (IMO) which issued the non-binding circular MEPC.1/Circ 909 on recommendations for the carriage of plastic pellets by sea in freight containers ('MEPC.1/Circ 909'). In this context, the Union and its Member States are to follow closely any future developments at the IMO, and play a leading role in ensuring a high level of environmental protection on this issue, by, for example, setting a high standard of protection.

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

([4]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

(11) While there are Union legal acts concerning the prevention of waste, pollution, marine litter and chemicals, there are no specific Union rules preventing plastic 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 ([5]) lays down basic waste management principles and imposes general obligations on 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.

(12) While the production of polymeric materials on an industrial scale falls under the scope of Directive 2010/75/EU of the European Parliament and of the Council ([6]), other activities like the conversion, transport or storage of plastic 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, established pursuant to Council Directive 96/61/EC ([7]), does not address the specific issue of plastic pellet losses.

(13) Directive 2008/56/EC of the European Parliament and of the Council ([8]) addresses the monitoring and assessment of the impacts of micro-sized litter, including microplastics, in coastal and marine environments. An update of the first guidance on monitoring marine litter has been developed with a view to harmonising methodologies, including in respect of monitoring 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 plastic pellet losses at source.

(14) Commission Regulation (EU) 2023/2055 ([9]), amending Annex XVII to Regulation (EC) No 1907/2006, addresses losses of synthetic polymer microparticles, i.e. plastic pellets, for use at industrial sites as avoidable releases and introduces a reporting requirement for an estimated quantity of microplastics released to the environment on an annual basis. While lacking a methodology to estimate losses, that requirement is intended to increase information on plastic pellet losses and improve the quality of the information collected to assess the risks deriving from these microplastics in the future.

(15) To ensure that plastic pellets are handled safely and responsibly at all stages of the plastic pellet supply chain, so that losses to the environment are prevented and the ambition of zero plastic pellet losses is achieved, it is necessary to establish requirements on the handling of plastic pellets along the entire supply chain, namely in production, including output from recycling, master batching, compounding, conversion, processing, distribution, transport, storage, packaging, and tank and container cleaning at cleaning stations. This Regulation should apply to all entities handling plastic pellets along the entire supply chain, irrespective of their end use.

(16) Handling 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. In this regard, it is important that the Union and its Member States pursue efforts to make the recommendations in MEPC. 1/Circ 909 mandatory at international level. Furthermore, the Union can promote discussion at international level on the obligation for carriers to notify competent authorities when transporting plastic pellets in a country different from the one in which they are established.

([5]) 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, ELI: http://data.europa.eu/eli/dir/2008/98/oj).

([6]) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial and livestock rearing emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

([7]) Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L 257, 10.10.1996, p. 26, ELI: http://data.europa.eu/eli/dir/1996/61/oj).

([8]) 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, ELI: http://data.europa.eu/eli/dir/2008/56/oj).

([9]) 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, ELI: http://data.europa.eu/eli/reg/2023/2055/oj).

(17) In light of the harmful nature of plastic pellets when lost to the environment and considering the general obligation on economic operators and carriers to avoid plastic pellet losses as set out in this Regulation, it is appropriate to set out specific information requirements in the form of a pictogram and a warning statement. In order to reduce the burden on economic operators and carriers, such requirements should be possible to implement by taking into consideration the already existing obligations under Annex XVII to Regulation (EC) No 1907/2006. Paragraphs 7 and 10 of entry 78 of that Annex set out information requirements for suppliers of synthetic polymer microparticles. For the purposes of this Regulation, suppliers of synthetic polymer microparticles should be understood as any manufacturer, importer, downstream user or distributor placing on the market plastic pellets which are synthetic polymer microparticles. They should provide relevant information on the label, the packaging, the package leaflet or on the safety data sheet. They should be able to provide that relevant information when providing the information as laid down in entry 78, paragraph 10, of Annex XVII to Regulation (EC) No 1907/2006. As the different possible means of providing that relevant information can vary in their effectiveness with regard to contributing to achieving the general obligation of avoiding losses, it is appropriate for the Commission to assess their relative effectiveness in the context of its review of this Regulation.

(18) When plastic pellets are released and dispersed into the marine environment, they can harm living resources and marine life and can interfere with other legitimate uses of the sea, such as fishing and aquaculture. As plastic pellets look like fish egg to birds, they comprise about 70 % of the plastic eaten by seabirds, despite the fact that only 0,05 % of plastic pieces from surface waters are pellets. Such small plastic pieces have been found in the stomachs of 63 of the world's approximately 250 species of seabirds. Furthermore, by weight, plastic pellets are estimated to be the second largest direct source of microplastic marine pollution. It is estimated that billions of individual plastic pellets enter the ocean every year. This is due to both small- and large-scale losses and spills occurring on land and sea during all stages of the supply chain, especially while plastic pellets are in transit. Additionally, plastic pellets can wash up on beaches and coastlines and, as a result, negatively impact tourism and shore-based activities. Several incidents involving seagoing vessels resulted in several tonnes of plastic pellets being released in the marine environment with disastrous consequences for the environment and local communities. For example, the Toconao accident impacting the northern coast of Spain in 2023 caused the loss of six freight containers, amongst which one freight container was holding one thousand 25 kg sacks of plastic pellets. This resulted in millions of plastic pellets being washed up on the Galician Coast.

(19) To address this issue from the perspective of maritime transport, the IMO Marine Environment Protection Committee approved in 2024 MEPC.1/Circ.909. However, since those recommendations are not legally binding, the Union, in line with its obligation under the Treaties to preserve, protect and improve the quality of the environment, and to promote measures at international level to deal with worldwide environmental problems, should introduce binding rules through this Regulation to pioneer worldwide a higher level of environmental protection in this field. Shippers should ensure that plastic pellets are packed in good-quality packaging, that transport information is delivered, in a timely manner, to the operator, agent, and master of the seagoing vessel and that a special stowage request is duly completed. Operators, agents, and masters of seagoing vessels should, on the basis of the transport information received from the shippers, ensure that freight containers containing plastic pellets are properly stowed and secured so as to minimise hazards to the marine environment without impairing the safety of the seagoing vessel and persons on board. Specifically, freight containers containing plastic pellets should be stowed under deck wherever reasonably practicable or inboard in sheltered areas of exposed decks. These requirements complement the overall IMO and Union legal frameworks on the safety of maritime transport and the prevention of pollution from ships, in particular Directive 2002/59/EC of the European Parliament and of the Council ([10]), which established a system to prevent accidents and pollution at sea taking into account the international legal rules.

(20) 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 for preventing the release of plastic 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 good-quality packaging, followed by containment of spilled plastic pellets to make sure they are not lost to the environment, and by cleaning up after a spill or loss event as the final step. Containment and clean-up interventions should be carried out in a manner that minimises environmental damage, in particular in sensitive habitats.

([10]) Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing a Community vessel traffic monitoring and information system and repealing Council Directive 93/75/EEC (OJ L 208, 5.8.2002, p. 10, ELI: http://data.europa.eu/eli/dir/2002/59/oj).

(21) While the aim of this Regulation is to prevent plastic pellet losses by all economic operators, EU carriers and non-EU carriers, the obligations for micro-, small and medium-sized enterprises should be adjusted to mitigate the burden on them. Member States, on the other hand, should not be prevented from introducing or maintaining more stringent protective measures. Such measures, including targeting economic operators handling more than 5 tonnes of plastic pellets, are to be compatible with the Treaties.

(22) In order to ensure the traceability of plastic pellets handled and transported in each Member State and to allow competent authorities to perform compliance checks efficiently, it is necessary for installations handling plastic pellets and carriers transporting them to be registered.

(23) In order to prevent plastic pellet losses, economic operators should establish, implement, and keep up to date at all times a risk management plan, including a risk assessment, identifying potential for spills and losses and documenting in particular existing specific equipment and procedures in place to prevent, contain and clean up plastic pellet losses. The risk management plan should also consider the costs and benefits of additional equipment and procedures to address the identified risks taking into consideration the nature and size of the installation as well as the scale of its operations. Where additives have been added to plastic pellets, economic operators should consider the hazard properties of the plastic pellets concerned, and where such additives are likely to increase the harm to human health or the environment in case of plastic pellet losses, economic operators should consider including this information in the risk management plan.

(24) To enable competent authorities to verify compliance with the risk management plan's requirements, economic operators should provide the competent authority with the risk management plan they have established, together with a self-declaration of conformity or a certificate, as applicable.

(25) Economic operators should be able to determine through a risk-based approach the specific equipment to install or the procedures to implement. Nevertheless, competent authorities, while verifying compliance, should be able to require economic operators to amend the risk management 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.

(26) In order to evaluate the adequacy of the risk management plan designed for each installation, economic operators should keep a record of estimates of the quantity of the plastic pellets lost per year, together with the total quantities handled. To reduce the burden on economic operators, the competent authorities and certifiers should be able to use information on estimates of quantities released in the framework of the reporting requirement under Annex XVII to Regulation (EC) No 1907/2006.

(27) Due to the characteristics of their activity, carriers should not be mandated to establish and implement a risk management 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. Some of these measures should be implemented during loading and unloading operations, which are hotspots for spills and losses. These operations are typically carried out under the responsibility of both the economic operators and the carriers, while the carriers are the only responsible party for the transportation journey.

(28) Non-EU carriers should designate an authorised representative, which should act on behalf of the non-EU carrier and should be able to be addressed by any competent authority. The authorised representative should be explicitly designated by a written mandate of the non-EU carrier with regard to specific obligations under this Regulation. The designation of such representative does not affect the responsibility or liability of the non-EU carrier under this Regulation. The authorised representative should be subject to enforcement proceedings, as far as its mandate is concerned, in the event of non-compliance by the non-EU carrier.

(29) The successful implementation of the actions required to prevent, contain and clean up plastic pellet losses requires the full cooperation and commitment of economic operators', EU carriers' and non-EU carriers' employees. Economic operators, EU carriers and non-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 install, use and maintain the equipment and execute the procedures necessary to ensure compliance with the requirements laid down in this Regulation, including how to monitor and report plastic pellet losses. Where appropriate, economic operators, EU carriers and non-EU carriers should adopt corrective measures including, where necessary, the improvement of equipment and procedures in place. They should also be required to monitor and keep records of annually estimated quantities of losses to help fill persisting knowledge gaps.

(30) Medium-sized and large enterprises typically have a more complex structure due to their size. In cases where they operate installations where plastic pellets are handled in quantities equal to or above a threshold of 1 500 tonnes per year, they should be required to implement, for each installation, extra actions such as carrying out an annual internal assessment and adopting a training programme addressing specific training needs and arrangements for the training programme. The internal assessment could cover subjects, such as the estimated quantities and causes of losses, the preventive, containment and clean-up equipment or procedures implemented to avoid future losses, and their effectiveness, discussions with the personnel, inspections of equipment and procedures in place and revision of any relevant documentation.

(31) Microenterprises and small, medium-sized and large enterprises operating installations where plastic pellets in quantities below a threshold of 1 500 tonnes per year 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.

(32) Enterprises that operate installations where plastic pellets are handled in quantities equal to or above a threshold of 1 500 tonnes per year can be responsible for higher risks of plastic pellet losses. Medium-sized and large enterprises that operate installations where plastic pellets are handled in quantities equal to or above a threshold of 1 500 tonnes per year should demonstrate compliance with the requirements laid down in this Regulation by obtaining, and renewing, a certificate issued by certifiers. In line with a supply-chain approach, while limiting the administrative burden, small enterprises that operate installations where plastic pellets are handled in quantities equal to or above a threshold of 1 500 tonnes per year should demonstrate compliance by obtaining a certificate issued by certifiers with a validity of five years. The certification process is also intended to help small enterprises that operate installations where plastic pellets are handled in quantities equal to or above a threshold of 1 500 tonnes per year to identify the actions needed to be compliant with the requirements laid down in this Regulation. After the expiry period of the certificate, such small enterprises should demonstrate compliance by notifying an update of their risk management plan as well as a self-declaration of conformity to the competent authority every five years from the last notification, unless such small enterprises choose, in a timely manner, to continue to demonstrate compliance by renewing a certificate issued by certifiers.

(33) Certifiers, in particular consultancy services, should not engage in any activity that could conflict with their independence of judgement or integrity in relation to the certification activities for which they are accredited. Certifiers can either be an accredited conformity assessment body, or an environmental verifier licensed to carry out verification and validation in accordance with Regulation (EC) No 1221/2009 of the European Parliament and of the Council ([11]). The certificate should correspond to a unique format in order to ensure homogeneous information.

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

(35) In order to ensure transparency, competent authorities should make certain information publicly available. This includes the notification on installations operated, involvement in the transport of plastic pellets in the Union including significant changes to what was previously notified, the establishment of an authorised representative, risk management plans, self-declarations of conformity, certificates and permits, which should be accessible on an easy-to-find, free and unrestricted website. However, to ensure safety and confidentiality, competent authorities should be able to withhold specific details if their release would jeopardise the safety of the installations concerned, the safety of the local population, or other public interests. The Commission should also publish lists of national websites and authorised representatives of non-EU carriers to ensure wide access to this information while safeguarding business confidentiality.

([11]) 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, ELI: http://data.europa.eu/eli/reg/2009/1221/oj).

(36) In order to be registered with community eco-management and audit scheme (EMAS), economic operators are required to comply with environmental legislation, including this Regulation. Consequently, economic operators which are registered with 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. Such economic operators should therefore be exempted from the obligations of certification and notification to competent authorities when renewing self-declarations and updating the risk management plan. In addition to the exemption provided for operators registered with EMAS and for the purpose of decreasing the burden on other high-integrity systems, it should be possible for economic operators that prepare and implement other environmental management systems for each installation to be exempted from compliance in this Regulation upon meeting certain criteria as laid down in this Regulation.

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

(38) Member States should be able to ensure compliance with this Regulation through permits based on a system of regular inspections of installations to examine the full range of relevant environmental effects, including spills and losses. For installations located in a Member State that decides to enforce and verify compliance through such a system of permits and regular inspections, economic operators should be exempted from obtaining a certificate or submitting a self-declaration of conformity for those installations for which they hold a permit that imposes the conditions necessary for compliance with this Regulation. For installations for which such exemption applies, economic operators should notify the relevant competent authority about the risk management plan and its regular updates. When compliance is ensured through permits, Member States should take the steps necessary to revise the conditions of existing permits and issue new permits such that compliance with this Regulation is ensured in due time.

(39) Directive 2008/98/EC provides that Member States are to require recyclers to obtain a permit, the conditions of which ensure that the production of plastic pellets is conducted without endangering human health or harming the environment, particularly avoiding risks to water, air, soil, plants, or animals.

(40) In order to minimise the effects of any loss, economic operators, EU carriers and non-EU carriers should take the corrective measures necessary to restore compliance with this Regulation. The corrective measures 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 thereof and require that corrective measures be taken to restore compliance.

(41) 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, authorised representatives, shippers, and operators, agents and masters of seagoing vessels transporting plastic pellets, where relevant, 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. Competent authorities should be able to use all facts and circumstances of the case as evidence for the purposes of their inspection.

(42) Micro-, small and medium-sized enterprises account for an important share of the plastic pellet supply chain. When complying with the relevant obligations laid down in this Regulation, they could face specific implementation challenges and proportionally higher costs. The Commission should raise awareness among economic operators and carriers regarding the necessity of preventing plastic pellet losses. Additionally, in consultation with all relevant stakeholders, the Commission should develop training materials, which could take various forms, including guides and courses, to assist economic operators and carriers in fulfilling their obligations, particularly with respect to the requirements of the risk assessment. OSPAR Recommendation 2021/06 should be considered in that regard. Member States should provide access to information and assistance, especially for micro- and small enterprises, regarding compliance with the obligations and the risk assessment requirements. The assistance provided by Member States could include technical support and specialised training for all personnel handling plastic pellets. It

could also include financial support, including for the purposes of certification for small enterprises, as well as access to finance. Member States' actions should be taken in respect of applicable State aid rules.

(43) In order to achieve a common basis for estimating plastic pellet losses, 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 ([12]). 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 that Regulation.

(44) In order to ensure that the objectives of this Regulation are achieved, and its 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, Member States should ensure close cooperation between all designated competent authorities in order to ensure that the duties of those authorities are fulfilled effectively.

(45) In order to ensure compliance, competent authorities should also take the necessary steps, including inspections and hearings based on relevant information, such as 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.

(46) 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 (the 'Charter'). 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 of the European Union (TEU) requires Member States to provide remedies that are sufficient to ensure effective legal protection in the fields covered by Union law. In this respect, Member States should ensure that the public, including natural or legal persons covered by 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 ([13]) ('Aarhus Convention').

(47) Member States should lay down rules on penalties applicable to infringements of national provisions adopted pursuant to this Regulation and should ensure that they are implemented. Member States can lay down rules for administrative as well as criminal penalties. In any case, the imposition of criminal and administrative penalties should not lead to a breach of the right not to be tried or punished twice in criminal proceedings for the same criminal offence (ne bis in idem principle), as interpreted by the Court of Justice of the European Union. For the most serious infringements committed by a legal person, such as those of a high level of gravity due to their nature, extent and repetition, or those that pose a significant risk to human health or the environment, Member States should ensure that their national system of penalties includes administrative financial penalties whose maximum amount should be at least 3 % of the annual Union turnover of that legal person in the financial year preceding the year in which the administrative financial penalty is imposed. For such infringements, without prejudice to the obligations of Member States under Directive 2008/99/EC of the European Parliament and of the Council ([14]), Member States should be allowed to also or alternatively impose criminal penalties, provided that they are effective, proportionate and dissuasive.

(48) Where appropriate, Member States should support the financing of projects aimed at: cleaning up areas polluted by plastic pellets using environmentally sustainable practices; collecting, processing and providing information on incidents and accidents that cause losses and related responses; improving knowledge of the impacts of plastic pellet losses on human health and the environment; and promoting awareness-raising programmes, especially for the most affected areas such as industrial zones and ports.

([12]) 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, ELI: http://data.europa.eu/eli/reg/2012/1025/oj).

([13]) OJ L 124, 17.5.2005, p. 4, ELI: http://data.europa.eu/eli/convention/2005/370/oj.

([14]) 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, ELI: http://data.europa.eu/eli/dir/2008/99/oj).

(49) 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. Such rules on compensation contribute to the pursuit of the objectives of preserving, protecting and improving the quality of the environment and the protection of human health as laid down in Article 191 of the Treaty on the Functioning of the European Union (TFEU). 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 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 ([15]) does not give private parties a right of compensation as a consequence of environmental damage or of an imminent threat of such damage.

(50) It is therefore appropriate for this Regulation to address the right to compensation for damage suffered by individuals and to ensure that individuals can defend their rights against damage to health caused by infringements of this Regulation and thereby ensure a more efficient enforcement of this Regulation. Procedures relating to claims for compensation should be designed and applied in such a way that they do not render the exercise of the right to compensation for damage impossible or excessively difficult.

(51) The impact of this Regulation on the procedural autonomy of the Member States should be limited to what is necessary to ensure the objective of protecting human health through a safe environment pursued by it and should not affect other national procedural rules establishing the right to seek compensation for infringements of this Regulation. Such national rules should, however, not hamper the effective functioning of the mechanism for seeking compensation required by this Regulation.

(52) To ensure that individuals can defend their rights against damage 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 or 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 effectiveness. However, experience shows that, while there is overwhelming epidemiologic evidence on the negative health impacts of pollution on the population, it is not straightforward to make a direct link between a specific loss of plastic pellets and specific impacts on human health or the environment, and such impacts are generally also not immediate.

(53) 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 in respect of amendments to the Annexes to this Regulation. 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 ([16]). 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.

(54) 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. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([17]).

(55) In order to provide economic operators, EU carriers, non-EU carriers, shippers, and operators, agents and masters of seagoing vessels with sufficient time to adapt to the requirements laid down in this Regulation, its application should be deferred.

([15]) 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, ELI: http://data.europa.eu/eli/dir/2004/35/oj).

([16]) OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

([17]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

(56) Since the objective of this Regulation, namely preventing plastic pellet losses, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down obligations for the handling of plastic pellets to prevent losses at all stages of the plastic pellet supply chain, with the aim of achieving zero plastic pellet losses.

2. This Regulation applies to the following natural and legal persons:

(a) economic operators handling plastic pellets in the Union in quantities equal to or above a threshold of 5 tonnes in the previous calendar year;

(b) economic operators operating installations in the Union for the cleaning of plastic pellet containers and tanks;

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

(d) shippers and operators, agents and masters of seagoing vessels transporting plastic pellets in freight containers leaving or calling at a port of a Member State.

Article 2

Definitions

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

(1) 'plastic pellets' means a mass of polymer-containing material, regardless of its shape, form, or size, that is produced for moulding in plastic product manufacturing operations, irrespective of its actual use;

(2) 'spill' means a one-off or prolonged escape of plastic pellets within an installation's boundaries or within road vehicles, rail wagons, or inland waterway vessels transporting plastic pellets from primary containment;

(3) 'loss' means a one-off or prolonged escape of plastic pellets to the environment at any stage of the supply chain, either from the installation's boundary or from road vehicles, rail wagons, inland waterway vessels or seagoing vessels leaving or calling at a port of a Member State, transporting plastic pellets;

(4) 'installation' means any premises, structure, location, site or place within which one or more economic activities involving the handling of plastic pellets are carried out;

(5) '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;

(6) '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;

(7) '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;

(8) 'shipper' means any natural or legal person by whom or in whose name or on whose behalf a contract of carriage of goods has been concluded with any natural or legal person engaged in the transport of plastic pellets as part of its economic activity by using seagoing vessels;

(9) 'operator' means the owner or manager of a seagoing vessel;

(10) 'agent' means any person mandated or authorised to supply information on behalf of the operator;

(11) '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/EC ([18]);

(12) 'large enterprise' means an enterprise that is not a micro-, small or medium-sized enterprise;

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

(14) 'authorised representative' means a natural or legal person established in the Union who has been designated by a written mandate from a non-EU carrier pursuant to Article 4, to act on its behalf in relation to specific tasks with regard to the obligations laid down in Article 3(2) and (3), Article 5(6), third subparagraph, and Article 15(1);

(15) 'certifier' means any of the following natural or legal persons:

(a) a conformity assessment body as defined in Article 2, point (13), of Regulation (EC) No 765/2008 of the European Parliament and of the Council ([19]);

(b) a natural or legal person which has obtained a license to carry out verification and validation in accordance with Regulation (EC) No 1221/2009;

(16) '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;

(17) 'permit' means a written authorisation, issued by the relevant competent authority, to operate an installation.

Article 3

General obligations

1. Economic operators, EU carriers and non-EU carriers shall ensure that losses are avoided. Where losses occur, economic operators, EU carriers and non-EU carriers shall take immediate action to contain and clean up those losses in accordance with environmentally sustainable practices.

2. Economic operators shall notify the competent authorities of the Member State about each installation located in that Member State which they operate or control, or, where applicable, for which they have been delegated decisive economic power over its technical functioning. For each installation notified, they shall specify whether the installation handles plastic pellets in quantities below, or equal to or above, a threshold of 1 500 tonnes per year. Before the transport of plastic pellets in the Union for the first time, EU carriers or authorised representatives referred to in Article 4, as applicable, shall notify the competent authorities of the Member State in which the EU carrier or the authorised representative is established about their involvement in the transport of plastic pellets within the Union and the means of transport used.

3. Economic operators, EU carriers and authorised representatives shall notify the competent authorities referred to in paragraph 2 of any significant change in what was previously notified in accordance with paragraph 2 regarding the concerned installations and activities related to handling and transporting plastic pellets, including any closure of an existing installation, cessation of transport activities or where they are no longer subject to this Regulation, and any changes in the quantities of plastic pellets handled that are relevant for the application of the obligations associated with the thresholds.

([18]) Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

([19]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30, ELI: http://data.europa.eu/eli/reg/2008/765/oj).

Article 4

Authorised representatives of non-EU carriers

1. Non-EU carriers shall designate in writing an authorised representative in at least one Member State where the non-EU carrier is engaged in the transport of plastic pellets.

2. Non-EU carriers shall mandate in writing the authorised representative to act on their behalf for the purpose of ensuring compliance with Article 3(2) and (3), Article 5(6), third subparagraph, and Article 15(1) of this Regulation. Such authorised representative may be addressed in addition to the non-EU carriers or instead of them. The authorised representative's mandate shall be valid only when accepted in writing by the authorised representative. The designation of an authorised representative shall be without prejudice to legal actions which could be initiated against the non-EU carriers.

3. The non-EU carrier shall simultaneously inform the competent authorities of the Member State referred to in paragraph 1 and the Commission of the designation of an authorised representative and its mandate before the first transport of plastic pellets in the Union.

Article 5

Obligations regarding the handling of plastic pellets

1. Economic operators shall take the following actions:

(a) establish a risk management 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 management plan; and

(c) notify the risk management plan 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 management 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-sized or large enterprises operating installations where plastic pellets in quantities below a threshold of 1 500 tonnes have been handled in the previous calendar year or that are microenterprises shall notify an update of the risk management plan for each installation as well as a renewal of the self-declaration of conformity to the competent authority of the Member State where the installation is located every 5 years from the last notification.

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

(a) change risk management plans notified in accordance with paragraphs 1 and 2 to ensure that the losses can effectively be prevented and, where appropriate, contained and cleaned up and that requirements set out in Annex I are complied with; and

(b) implement any of the actions listed in Annex I in a timely manner.

4. EU carriers and non-EU carriers shall ensure that the actions set out in Annex III are implemented.

5. When economic operators implement the actions set out in the risk management plan and the EU carriers and non-EU carriers implement the actions laid down in Annex III, they shall do so in the following order of priority:

(a) actions to prevent spills;

(b) actions to contain spills to avoid them becoming a loss;

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

6. Economic operators, EU carriers and non-EU carriers shall have the following obligations:

(a) ensure that their staff are 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; and

(b) keep records of annually estimated quantities of losses and of the total quantities 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 18(3) economic operators, EU carriers and non-EU carriers shall estimate the quantities of losses referred to in point (b) of the first subparagraph of this paragraph, in accordance with the standardised methodology referred to in Article 18.

Authorised representatives shall provide evidence of the compliance by non-EU carriers with the obligation laid down in point (a) of the first subparagraph. Economic operators and EU carriers and authorised representatives shall retain records referred to in point (b) of the first subparagraph for a period of five years and make them available to competent authorities on demand, and, where applicable, to certifiers for the purposes of Article 6.

7. 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 measures without delay.

8. Every year economic operators that are medium-sized or large enterprises operating installations where plastic pellets in quantities equal to or above a threshold of 1 500 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 management plan laid down in Annex I or with the conditions under which the permit referred to in Article 7(1), point (a), was granted.

The economic operators referred to in the first subparagraph of this paragraph shall retain records of the internal assessments for a period of five years and shall make them available to competent authorities on demand, and to certifiers for the purposes of Article 6.

Article 6

Certification

1. By … [24 months from the date of entry into force of this Regulation], and every three years thereafter, economic operators that are large enterprises shall demonstrate that the handling process at each installation where plastic pellets in quantities equal to or above a threshold of 1 500 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 … [36 months from the date of entry into force of this Regulation], and every four years thereafter, economic operators that are medium-sized enterprises shall demonstrate that the handling process at each installation where plastic pellets in quantities equal to or above a threshold of 1 500 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. By … [60 months from the date of entry into force of this Regulation], economic operators that are small enterprises shall demonstrate that the handling process at each installation where plastic pellets in quantities equal to or above a threshold of 1 500 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.

The economic operators referred to in the first subparagraph of this paragraph shall comply with Article 5(2) after the expiry period of the certificate unless they choose to renew it in accordance with the first subparagraph of this paragraph.

4. Certifiers shall carry out spot checks, including, if accessible, at immediately surrounding areas, to ensure that the risk management plan is adequate to prevent plastic pellet losses and that all measures included therein are duly implemented.

5. Certificates shall meet the following requirements:

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

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

(c) they certify conformity of the installation covered by the certificate with the requirements set out in Annex I;

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

(a) certificates issued;

(b) certificates suspended or withdrawn;

(c) changes in certificates.

Article 7

Compliance through permits

1. Member States may exempt economic operators from the obligations laid down in Article 5(1), point (c), and Article 5(2) as well as from the obligation to obtain a certificate pursuant to Article 6(1), (2) and (3) in respect of each installation, provided that:

(a) the operation of the installation is subject to a permit;

(b) the economic operator has notified the authority competent for the issuance of permits about its risk management plan as well as its updates every 3 years for large, 4 years for medium-sized, and 5 years for micro- and small enterprises;

(c) the permit has been granted or reviewed and, if necessary, updated on the basis of verification of the economic operator's compliance with the requirements set out in Annex I following the notification of a risk management plan and subsequent updates, as referred to in point (b); and

(d) the installation is subject to regular inspections by competent authorities, including site visits, examining the full range of relevant environmental effects, including those of spills and losses, with the periodicity referred to in Article 5(2) and the periodicity equivalent to that resulting from the application of Article 6(1), (2) and (3).

2. The Member State shall notify the exemption of the economic operators and national rules on permits to the Commission.

Article 8

Compliance through environmental management systems

1. Economic operators which are registered with the Community eco-management and audit scheme (EMAS) in accordance with Regulation (EC) No 1221/2009 shall be exempt from compliance with the obligations laid down in Article 5(2) and in Article 6(1), (2) and (3) of this Regulation provided that the environmental verifier as defined in Article 2(20) of Regulation (EC) No 1221/2009 has checked that requirements set out in Annex I to this Regulation have been included in the environmental management system of the economic operator and have been implemented.

2. Member States may exempt economic operators from compliance with Article 5(2) and Article 6(1), (2) and (3) if they have prepared and implemented an environmental management system (EMS) for each installation, and provided that:

(a) an accredited certifier has conducted a conformity assessment to verify, including through spot checks, that the EMS and the way it is implemented are compliant with the requirements set out in Annex I;

(b) the economic operator notifies the competent authorities about the conformity assessment of the EMS referred to in point (a), including information about the economic operator, the installation for which compliance is verified, the date on which spot checks are carried out, and the period for which the conformity assessment is valid; and

(c) the regular conformity assessments of the EMS include, at least every three years, an evaluation of its implementation in accordance with the requirements set out in Annex I.

Article 9

Accreditation of certifiers

The accreditation of certifiers referred to in Article 2, point (15)(a), shall include an evaluation of compliance with the following requirements:

(a) the certifier shall be established under the law of a Member State and shall have legal personality;

(b) the certifier shall be a third-party body independent of the economic operator;

(c) the certifier, its senior 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;

(d) the certifier and its personnel shall operate in a non-discriminatory manner and 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, especially as regards persons or groups of persons with an interest in the results of those activities. The impartiality of the certifiers, their senior management and the personnel responsible for carrying out the certification and tasks shall be guaranteed;

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

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

(g) without prejudice to the powers of the competent authorities under Article 16(3), point (b), the personnel of a certifier shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment tasks;

(h) 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. Only the tasks that fall within the scope of accreditation of the certifier may be performed by subcontractors or subsidiaries. Certifiers shall ensure that the activities of their subcontractors or subsidiaries do not affect the confidentiality, objectivity or impartiality of their certification activities.

Article 10

Obligation to provide information

Without prejudice to Regulation (EC) No 1272/2008 of the European Parliament and of the Council [20] and Regulation (EC) No 1907/2006, any manufacturer, importer, downstream user or distributor placing on the market plastic pellets which are synthetic polymer microparticles under entry 78, paragraph 7, of Annex XVII to Regulation (EC) No 1907/2006 shall provide the information as referred to in Annex V to this Regulation on the label, the packaging, the package leaflet, or on the safety data sheet. The information shall be clearly visible, legible and indelible. The text information shall be provided in the official languages of the Member States where the plastic pellets are placed on the market, unless the Member States concerned provide otherwise. The manufacturer, importer, downstream user or distributor may provide that information when carrying out the obligations pursuant to entry 78, paragraph 7, of Annex XVII to Regulation (EC) No 1907/2006.

Article11

Public access to information

1. Competent authorities shall make available to the public, including systematically via the internet, on a website which is easy to find, free of charge and without restricting access to registered users, while ensuring that confidential business information is safeguarded, the following:

(a) the information they have received in accordance with Article 3(2) and (3) and Article 4;

(b) the risk management plans they have received in accordance with Article 5(1) and (2);

(c) the self-declarations of conformity they have received in accordance with Article 5(1) and (2);

(d) the certificates issued pursuant to Article 6 and notifications they have received in accordance with paragraph 6 of that Article;

(e) the content of the decision granting a permit, including a copy of the permit and any subsequent updates or a link to other existing publicly accessible registers or websites, established at Member State level, that provide access to such permits and their subsequent updates; and

(f) the content of the conformity assessment of the EMS they have received in accordance with Article 8(2), point (b).

2. Competent authorities, when making the risk management plans referred to in paragraph 1, point (b), of this Article, available to the public, shall not publicly disclose the information referred to in Annex I, paragraph 1, point (b). Competent authorities may omit parts of other information referred to in paragraph 1, points (a) and (b), of this Article, if its disclosure would adversely affect the safety of the installations concerned or safety of the local population, or any of the interests listed in Article 4(2), points (a) to (h), of Directive 2003/4/EC of the European Parliament and of the Council [21]. Competent authorities may require economic operators to identify the parts of the information they consider are not to be publicly disclosed.

3. The Commission shall publish the list of national websites as referred to in paragraph 1 on its website, provided that the necessary information is submitted by Member States.

4. The Commission shall make a list of designated authorised representatives of non-EU carriers based on the information submitted to it pursuant to Article 4(3) and shall make that list available to the public, including systematically via the internet, on a website which is easy to find, free of charge and without restricting access to registered users, while ensuring that confidential business information is safeguarded.

[20] 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

[21] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26, ELI: http://data.europa.eu/eli/dir/2003/4/oj).

Article 12

Obligations regarding the transport of plastic pellets by sea in freight containers

1. Shippers shall ensure that:

(a) plastic pellets are packed in good-quality packaging that is strong enough to withstand the shocks and loadings normally encountered during transport and is constructed and closed so as to prevent any loss of contents which could be caused by vibration or acceleration forces under normal transport conditions;

(b) transport information identifying the freight containers containing plastic pellets is delivered to the operator, agent and master of the seagoing vessel as an addition to the cargo information required by Regulation VI/2 of the International Convention for the Safety of Life at Sea (SOLAS), before plastic pellets are taken on board; and

(c) cargo information referred to in point (b) of this paragraph is accompanied by a special stowage request requiring stowage of the freight containers containing plastic pellets in accordance with paragraph 3.

2. Operators and masters of seagoing vessels and, where relevant, agents shall ensure that they are in possession of the list or manifest or appropriate loading plan in accordance with the cargo information received from the shipper referred to in paragraph 1, point (b).

3. Operators and masters of seagoing vessels shall ensure that freight containers containing plastic pellets are stowed under deck, wherever reasonably practicable, or inboard in sheltered areas of exposed decks. In both cases, such containers shall be secured to minimise hazards to the marine environment without impairing the safety of the seagoing vessel and persons on board.

Article 13

Verification of compliance and reporting

1. Competent authorities shall verify compliance of economic operators, EU carriers, non-EU carriers and authorised representatives, shippers, and operators, agents and masters of seagoing vessels with the obligations laid down in this Regulation, taking into account, where applicable, the information provided in self-declarations of conformity referred to in Article 5(1) and (2) and collected by certifiers and competent authorities in accordance with Article 6(6) and Article 7(1) in accordance with exemptions granted pursuant to Article 8. The competent authorities shall carry out environmental inspections, including without prior notice, and other verification measures, following a risk-based approach.

2. By … [the first day of the month after four years from 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 three consecutive calendar years. The information shall include:

(a) the number of economic operators per size of enterprise under Commission Recommendation 2003/361/EC and per economic activity, their installations, and the number of EU carriers and non-EU carriers and the means of transport used by those carriers for transporting plastic pellets;

(b) the number of risk management plans and self-declarations notified pursuant to Article 5(1) and 5(2), respectively, the number of certificates notified pursuant to Article 6(6) and the number of economic operators that are registered with EMAS or have implemented an EMS meeting the conditions in Article 8(2);

(c) the number of permits granted meeting the conditions pursuant to Article 7; and

(d) the number and results of environmental inspections and other verification measures carried out under paragraph 1 of this Article, as well as the number of incidents and accidents reported in accordance with Article 14(1) and the measures taken in the event of non-compliance with the obligations set out in this Regulation.

3. The Commission shall by means of implementing acts lay down a format for the reports referred to in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 24(2).

4. No later than three months after the reporting date referred to in paragraph 2, the Commission shall make publicly available a Union-wide overview of the application of this Regulation, based on the data submitted pursuant to that paragraph.

Article 14

Incidents and accidents

1. Without prejudice to Directive 2004/35/EC, in the event of an incident or accident that causes a loss affecting human health or the environment, economic operators, EU carriers and non-EU carriers shall:

(a) immediately inform emergency services, where relevant;

(b) immediately take all possible measures to minimise the human health or environmental consequences;

(c) without delay and no later than 30 days after the incident or accident that causes a loss affecting human health or the environment, provide the following information to the competent authorities in whose territories the incident or accident occurred:

(i) the estimated quantities of the loss;

(ii) the causes of the loss; and

(iii) the measures taken pursuant to point (b); and

(d) take measures 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 carriers and non-EU carriers take appropriate complementary measures to minimise the human health or environmental consequences and to prevent further incidents or accidents, including by organising specific training.

3. In the event of any incident or accident 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 15

Non-compliance

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

(a) inform the competent authority;

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

(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 shall, or, where that infringement leads to a significant loss, the competent authority may, suspend the operation of the installation or part of it, and immobilise or prevent the movement of road vehicles, rail wagons or inland waterway vessels until compliance is restored in accordance with paragraph 1, points (b) and (c).

Article 16

Designation and powers of competent authorities

1. Member States shall designate one or more competent authorities for the application and enforcement of this Regulation. Member States shall inform the Commission, without delay after … [date of entry into force of this Regulation], of the names, addresses, and contact details of the competent authorities, and also inform it of any subsequent changes to that information.

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 of competent authorities as referred to in paragraph 2 shall include at least the following:

(a) the power to access 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 purpose 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; and

(d) the power to access installations.

4. Competent authorities may use any information, document, finding, statement or intelligence as evidence for the purposes 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 17

Information and assistance regarding compliance

1. By … [12 months from the date of entry into force of this Regulation], the Commission shall develop and make available to the public, including via the internet, on a website which is easy to find, free of charge and without restricting access to registered users, awareness-raising and training material on the appropriate 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, and relevant environmental non-governmental organisations and in collaboration with competent authorities. Where appropriate, the Commission shall also consult representatives of authorised representatives, shippers, and operators, agents and masters of seagoing vessels.

2. Member States shall ensure that economic operators, EU carriers and non-EU carriers, authorised representatives, shippers, and operators, agents and masters of seagoing vessels get access to information regarding compliance with this Regulation and that they, especially micro- and small- enterprises, get assistance in that regard.

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

(a) financial support, including for the purposes of certification for small enterprises;

(b) access to finance;

(c) specialised management and staff training; and

(d) organisational and technical assistance.

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

Article 18

Standards

1. For the purposes of compliance with the obligation referred to in Article 5(6), point (b), 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. The Commission shall submit the request for the development of harmonised standards to one or more European standardisation organisations by… [12 months from the date of entry into force of this Regulation].

3. 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 of this Article by means of an implementing act. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24(3).

Article 19

Complaint-handling and access to justice

1. Natural or legal persons regarded under national law as having sufficient interest or those that consider that their rights were impaired shall be entitled to submit substantiated complaints to competent authorities where they deem, on the basis of objective circumstances, that an economic operator, EU carrier, non-EU carrier, or a shipper, or an operator, agent or master of a seagoing vessel is failing to comply with this Regulation.

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

2. Competent authorities shall assess substantiated complaints as referred to in paragraph 1 of this Article and, where appropriate, take the steps necessary to verify such complaints, including inspections and hearings of the person or organisation. Where the complaint is found to be grounded, the competent authorities shall take the necessary actions in accordance with Article 5(3), Article 14(2) and Article 15(2).

3. Competent authorities shall, as soon as possible, inform the persons referred to in paragraph 1 that submitted the complaint of their 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 referred to in paragraph 1 has access to a court or another independent and impartial public body competent to review the procedural and substantive legality 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 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 20

Penalties

1. Without prejudice to the obligations of Member States under Directive (EU) 2024/1203 of the European Parliament and of the Council ([22]), Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

2. The penalties referred to in paragraph 1 shall include administrative financial penalties that effectively deprive those that committed the infringement of the economic benefits derived from their infringements.

3. For the most serious infringements committed by a legal person, the maximum level of the administrative financial penalties referred to in paragraph 2 shall be at least 3 % of its annual Union turnover in the financial year preceding the year in which the administrative financial penalty is imposed.

4. Member States may also, or alternatively, impose criminal penalties, provided that they are equivalently effective, proportionate and dissuasive to the administrative financial penalties referred to in this Article.

5. 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 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;

(c) the repetitive or one-off character of the infringement.

6. Member States shall without undue delay notify the Commission of the rules and measures referred to in paragraph 1 and of any subsequent amendments affecting them.

Article 21

Compensation

1. Member States shall ensure that, where damage to human health has occurred as a result of an infringement of this Regulation, the individuals affected have the right to claim and obtain compensation for that damage from the natural or legal persons responsible for the infringement.

2. 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.

3. Member States may establish limitation periods for bringing claims for compensation referred to in paragraph 1. Such periods shall not begin to run before the infringement has ceased and the person entitled to claim the compensation knows or can reasonably be expected to know that he or she suffered damage from an infringement pursuant to paragraph 1.

Article 22

Amendments to Annexes

1. The Commission is empowered to adopt delegated acts in accordance with Article 23 to amend:

(a) the technical requirements laid down in paragraphs 2, 3, 4 and 5 of Annex I;

(b) points (1), (2) and (3) of Annex III to add or remove equipment requirements or procedures or to specify the technical features of the existing equipment and procedures; and

(c) the details of the forms laid down in Annexes II and IV.

([22]) Directive (EU) 2024/1203 of the European Parliament and of the Council of 11 April 2024 on the protection of the environment through criminal law and replacing Directives 2008/99/EC and 2009/123/EC (OJ L, 2024/1203, 30.4.2024, ELI: http://data.europa.eu/eli/dir/2024/1203/oj).

2. The Commission shall adopt the delegated acts referred to in paragraph 1 of this Article on the basis of:

(a) the experience gained from the implementation of Articles 3, 5, 6, 7, 8, 13 and 14;

(b) the information made available by economic operators on the annually estimated quantities of plastic pellet losses, as reported pursuant to Annex XVII to Regulation (EC) No 1907/2006;

(c) relevant international standards;

(d) the specificities of the sectors of activity;

(e) the specific needs of micro-, small and medium-sized enterprises; or

(f) technical progress and scientific developments.

Article 23

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 22(1) shall be conferred on the Commission for a period of five years from … [24 months from 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 22(1) 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 22(1) 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 24

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 25

Evaluation and review

1. By … [eight years from the date of entry into force of this Regulation], the Commission shall conduct an evaluation of the implementation of this Regulation in light of the objectives that it pursues. The Commission shall present a report on the main findings of the evaluation to the European Parliament and to the Council. The report shall include at least:

(a) the experience gathered from the implementation of this Regulation;

(b) the information reported by Member States pursuant to Article 13(2);

(c) the information made available by economic operators on the annually estimated quantities of plastic pellet losses, as reported pursuant to Annex XVII to Regulation (EC) No 1907/2006;

(d) the contribution of this Regulation to the overall target of reducing microplastic pollution by 30 % by 2030;

(e) an assessment of whether further actions need to be taken with regard to additional sources of unintentional releases of microplastics with a view to achieving the Union objective of reducing microplastic pollution;

(f) the latest data and scientific findings;

(g) an assessment of the latest data and scientific findings on chemical traceability of plastic pellets and of the relevance of introducing a unique chemical signature;

(h) the interaction of this Regulation with relevant international initiatives addressing plastic pellet losses, in particular with regard to maritime transport;

(i) an assessment of the impact on the implementation of this Regulation of excluding from certain obligations under this Regulation economic operators handling plastic pellets below certain thresholds, and the relevance of establishing a threshold for carriers;

(j) an assessment of the effect that the exemptions granted pursuant to Article 7 had in achieving the objective of preventing spills and losses;

(k) an assessment of the compliance by carriers, in particular non-EU carriers, with the obligations under this Regulation;

(l) an assessment of the relative effectiveness of the different means of providing information as referred to in Article 10.

2. Where appropriate, the report shall be accompanied by a legislative proposal to the European Parliament and Council.

3. In the event of the adoption by the International Maritime Organization (IMO) of measures for the safe transport of plastic pellets by ships and for the prevention of marine pollution caused by plastic pellets transported by ships, the Commission shall assess those measures, including the need to ensure alignment with those measures, and shall, if appropriate, adopt a legislative proposal.

Article 26

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*.

It shall apply from … [24 months from the date of entry into force of this Regulation]. However, Article 3(1), Article 5(6), second subparagraph, Article 16, Article 17(1) and Article 18(2) and (3) shall apply from … [the date of entry into force of this Regulation].

By way of derogation from the second paragraph of this Article, Article 1(2), point (d), Article 12, Article 13(1), Article 17(2) and (3) and Article 19 shall apply, as far as shippers and operators, agents and masters of seagoing vessels are concerned, from … [36 months from the date of 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 *For the Council*

The President *The President*

ANNEX I

Risk management plan for installations

1. The risk management plan referred to in Article 5(1) shall contain the following elements:

   (a) the site plan;

   (b) the number of tonnes of plastic pellets handled per year;

   (c) the locations within the installation's boundaries where spills could occur, specifying high- and low-risk locations;

   (d) the locations within the installation's boundaries from which losses could originate and the locations in the immediately surrounding areas which could be affected by losses, specifying, in both cases, high- and low-risk locations;

   (e) the handling operations during which pellet spills and losses could occur, specifying high- and low-risk operations;

   (f) the annual estimation of the quantities of spills in the identified locations and of losses from those locations;

   (g) the list of the activities during which plastic pellet spills or losses could occur and over which the installation could have the authority to exercise control, including activities involving suppliers, (sub-)contractors and off-site storage facilities;

   (h) the definition of one specific role of a member of staff responsible for recording, investigating and following up on spills and losses, including reporting to competent authorities as laid down in Article 5(6) and Article 14(1);

   (i) a description of the packaging and equipment put in place to prevent, contain and clean up spills and losses; and

   (j) a description of the procedures put in place to prevent, contain and clean up spills and losses.

2. With respect to point (i) of paragraph 1, the packaging and equipment put in place to prevent, contain and clean up spills and losses shall be adequate for and proportionate to the nature and size of the installation and shall include:

   (a) for prevention: for installations where packaging takes place, packaging that is strong enough to withstand the shocks, loadings and weather conditions normally encountered during transport; the strength of the packaging material used and the construction of the packaging shall be appropriate to the capacity of the packaging and its intended use; the packaging shall be sift-proof or provided with a suitable liner, and it shall be securely constructed and closed so as to prevent any loss of contents which could be caused by vibration or acceleration forces under normal transport conditions;

   (b) for containment: at high-risk spill locations, catchment devices (e.g. spill trays and in-ground retention tanks with steel grating) placed to ensure spills on the floor can easily be contained and cleaned, and plastic pellet retaining drain covers or suitable alternatives to protect underground drainage systems;

   (c) for clean-up: at spill and loss locations, vacuum cleaners with sufficient capacity for internal and external usage, sufficient cleaning tools (e.g. brooms, dustpans and brushes, buckets, repair tapes) and disposal bins for collected plastic pellets and empty bags.

3. With respect to point (j) of paragraph 1, the procedures put in place to prevent, contain and clean up spills and losses shall be adequate for and proportionate to the nature and size of the installation and shall include:

   (a) informing third parties accessing the installation to load, unload or otherwise handle plastic pellets about the relevant procedures to prevent, contain and clean up spills and losses;

(b) handling the packaging of plastic pellets in such a way as to prevent the piercing of packaging; at high-risk spill locations, ensuring that there are regular inspections, cleaning and maintenance of catchment devices and storage facilities as well as of packaging and containers; if the packaging and containers are leaking or sifting, ensuring that they are not used further;

(c) containing spills and cleaning them up as soon as possible, and at the latest at the end of the operation;

(d) ensuring that the outside of the road vehicle, rail wagon or inland waterway vessel is free from plastic pellets when leaving the installation and ensuring that loading and unloading ramps of road vehicles and rail wagons are closed when leaving the loading or unloading place.

4. In addition to paragraph 2 and on the basis of the nature and size of the installation as well as the scale of its operations, economic operators shall consider including in the risk management plan the description of at least the following equipment:

(a) for prevention: for installations where packaging takes place: packaging that can withstand degradation in aquatic environments; vacuum seals on hoses and pipework; protective covers on forklifts, hydraulic equipment, or other loading and unloading equipment to prevent the piercing of packaging; 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; sealed containers or external silos to store pellets; protection to prevent overfilling of silos; automated transport systems for pellets; plastic pellet dust extraction equipment with appropriate plastic pellet dust filters or catchment devices; for the cleaning of plastic pellet containers or silos, the use of filters or catchment devices for rinse water and air cleaning;

(b) for containment: secondary catchment devices placed between areas where plastic pellets are handled and the boundary of the installation, around the installation and at points of connection, where plastic pellets are transferred; drain covers on all floor drains inside buildings and drains located on external surfaces (e.g. concrete plinths, asphalt roads and paved footpaths) with, where appropriate, 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; closed containers for spilled plastic pellets and for empty packaging; zones to repair or manage damaged packaging; a floor or underground at loading and unloading areas which does not hinder the cleaning of spills;

(c) for clean-up: industrial vacuum cleaners; dedicated containers for recovered plastic pellets that are covered, labelled and secured to prevent further spills and losses, including for plastic pellets found in the locations in the immediately surrounding areas of the installation; reinforced collection bags.

5. In addition to paragraph 3 and on the basis of the nature and size of the installation as well as the scale of its operations, economic operators shall consider including in the risk management plan a description of at least the following procedures:

(a) for prevention: limits on the quantities of plastic pellets transported in certain packaging; 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; reception and departure procedures for EU carriers and non-EU carriers; plastic pellet dust prevention procedures and measures;

(b) for containment: regular inspection, cleaning and maintenance of drain covers, storm water drainage or filtration systems; regular inspection and cleaning of vehicles leaving or entering a site, outgoing water facilities and fences on the perimeter of the facility that are in public areas when applicable; immediate replacement or repair of leaking packaging or containers; maintenance of the sewage treatment system;

(c) for clean-up: once the spilled plastic pellets have been cleaned up, if possible, they shall be reused as raw material to reduce wastage; if spilled plastic pellets cannot be reused as raw materials, they shall be retrieved and disposed of in accordance with waste legislation.

6. Economic operators that are medium-sized or large enterprises and operate installations where plastic pellets in quantities equal to or above a threshold of 1 500 tonnes have been handled in the previous calendar year shall include in their risk management plan also the following:

   (a) elements that are to 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) 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 of procedures, as well as the monitoring and reporting of plastic pellet losses;

   (c) 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) …… meets all the requirements of Regulation (EU) [… of the European Parliament and of the Council of …] (*) on preventing plastic pellet losses to reduce microplastic pollution.

By signing this declaration, I declare that the measures set out in the risk assessment attached, which was carried out on the …….. (date), have been implemented.

Done at … on …/…/20…

Signature

(*) OJ: please insert in the text the number and date of this Regulation.

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 plastic pellets are properly removed from the outside of the transport means and freight containers before leaving the installation, and that loading and unloading ramps of the transport means are closed when leaving the installation; clear communication on requirements concerning safe stowage; visually checking the integrity of packaging of plastic pellets prior to the journey; ensuring that protective covers on, for example, forklifts/hydraulic equipment are used to prevent the piercing of packaging; prevention of any leakage during the transport journey, for example, by ensuring that the transport means are technically suitable and that freight containers are supplemented, if necessary, with appropriate sealing; regularly cleaning the loading compartments, the freight containers and trailers to minimise the loss of spilled plastic pellets; visually checking the openings and integrity of the loading compartments, freight containers and trailers to contain and minimise plastic pellet losses prior to and, to the extent possible, during the journey, including in the multimodal terminals, rail terminals, inland ports and seaports.

(2) for containment and clean-up: where possible, repair damaged packaging during transport and contain the remaining plastic pellets in the loading compartment; collect the spilled plastic pellets in closed containers or bags for proper disposal; where plastic pellets are transported in bulk tanks, open 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; notify the appropriate authorities, such as international and national emergency authorities or environmental authorities of the Member State where the loss occurred.

(3) equipment on board: at least one portable lighting device, hand tools (e.g. brooms, dustpans and brushes, buckets, repair tapes, etc.); closed collection containers/reinforced collection bags.

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 the requirements laid down in Annex I of Regulation (EU) […of the European Parliament and of the Council of …] (+) on preventing plastic pellet losses to reduce microplastic pollution.

By signing this declaration, I declare that:

— the verification has been carried out in compliance with the requirements of Regulation (EU) […] (++), including spot checks performed on …… (dates),

— the outcome of the verification confirms that there is no evidence of non-compliance with the requirements of Regulation (EU) […] (++).

Done at … on …/…/20…

Signature and stamp or digital signature

(+) OJ: please insert in the text the number and date of this Regulation.
(++) OJ: please insert in the text the number of this Regulation.

ANNEX V

Information to be provided pursuant to Article 10

Harmful to the environment – avoid losses