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PART 1/3

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Combatting microplastic pollution in the European Union

Accompanying the document

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on preventing plastic pellet losses to reduce microplastic pollution

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Glossary

Term or acronym	*Meaning or definition*
Microplastics	Microplastics are small pieces of plastic, usually smaller than 5mm
Pellets	Plastic pellets, also referred to as nurdles, nibs, preproduction pellets, and resin pellets, are the starting material used for all plastic production worldwide. Pellets are defined within ISO 472:2013 as "a small mass of preformed moulding material, having relatively uniform dimensions in a given lot, used as feedstock in moulding and extrusion operations".
Pellet spill	One-off escape of pellets from primary containment not necessarily resulting in loss to the environment (if contained inside the operating boundary).
Pellet loss	One-off or prolonged escape of pellets to the environment. The escape would therefore result in loss outside the operating boundary into the environment (e.g. water, soil).
Textiles	In the context of this assessment, textiles refer to synthetic clothes made out of chemically produced fibers that can be based on polymers produced by oil distillation, such as polyester, acrylic, polyamide (nylon), acetate, and PPT (polyparaphenylene terephthalamide i.e. Kevlar™).
Paints	Paint means a pigmented or clear coating material, supplied in a liquid paste or powder form, which, when applied to a substrate, forms an opaque film having protective, decorative or specific technical properties and after application dries to a solid, adherent and protective coating. It is a mixture of pigment (absent in the case of vanishes), additives and binder (resin) in a solvent (organic solvent and/or water). Most binders are synthetic polymers such as acrylic, alkyd, polyurethane, epoxy or chlorinated rubber.
Detergent capsules	These are small pouches containing highly concentrated detergent used in washing machines and dishwashers. They are mostly made of dissolvable plastics such as polyvinyl alcohol.
Geotextiles	Geotextiles are a type of geosynthetics used for a variety of civil engineering applications such as building roads, coastal protection, diking, flooding protection, etc. They are primarily made of polymers such as polypropylene or polyester and are mostly manufactured in two different forms woven and nonwoven.
CPR	Construction Product Regulation
DDT	Dichlorodiphenyltrichloroethane
EDC	Endocrine disrupting compounds
EPR	Extended Producer Responsibility
EQSD	EU Directive 2008/105/EC on Environmental Quality Standards
EQS	Environmental Quality Standards
ESPR	Ecodesign for Sustainable Products Regulation
EURO7	European vehicle emissions standards – Euro 7 for cars, vans, lorries and buses
GHG	Greenhouse gases

Term or acronym	*Meaning or definition*
GWD	EU Groundwater Directive 2006/118/EC
GPP	Green Public Procurement
IA	Impact Assessment
IED	Industrial Emissions Directive
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organisation
LCA	Life-cycle Assessment
MARPOL	International Convention for the Prevention of Pollution from Ships
MSFD	EU Marine Strategy Framework Directive
OCS	Operation Clean Sweep
OCS CS	Operation Clean Sweep Certification Scheme
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
PAH	Polycyclic aromatic hydrocarbons
PCB	Polychlorinated biphenyls
PET	Polyethylene terephthalate
PM	Particulate Matter
PVOH/PVA	Polyvinyl alcohol
PVC	Polyvinylchloride
PVOH based products	Different Polyvinyl alcohol-based compositions used as protective films in detergent capsules for laundry & dishwashers
REACH	Regulation (EC) No 1907/2006 on the registration, evaluation, authorisation and restriction of chemicals
SDG	Sustainable Development Goals
SME	Small and medium-sized enterprises. They are defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises. SMEs are enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. In particular, within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million; a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million. Large-sized enterprise means an enterprise that is not a micro, small or medium-sized enterprise.

Term or acronym	*Meaning or definition*
SQAS	Safety & Quality Assessment for Sustainability system
SSD	Sewage Sludge Directive
SUP	Single-use plastics
SWO	Storm water overflows
TPMS	Tyre Pressure Management System
TRWP & TWP	Due to tyre's friction with the road surface, the tyre wear particles (TWP) get contaminated and encrusted as a mixture of road wear, tyre particles and other road dust substances, called Tyre and Road Wear Particle (TRWP)
UWWTD	Urban Wastewater Treatment Directive
Water FD	Water Framework Directive
WEEE	Waste from electrical and electronic equipment
WFD	Waste Framework Directive
WWTP	Wastewater treatment plants

1 INTRODUCTION: POLITICAL AND LEGAL CONTEXT

Microplastics are ubiquitous, persistent, very mobile and virtually impossible to capture once released into the environment. In 2018, the EU Strategy for Plastics in a Circular Economy acknowledged the risks posed by microplastics and advocated innovative solutions targeting different sources. In 2019, the European Commission's group of Chief Scientific Advisers recognised the potential risks posed by these microplastics and encouraged action to reduce and prevent further pollution.[1] In 2020, as a follow-up action of the European Green Deal, the Circular Economy Action Plan 2.0 committed the Commission to tackling the presence of microplastics in the environment by:

- restricting **intentionally added microplastics** in products (e.g. cosmetics, detergents, fertilisers, artificial infill)[2];
- addressing **unintentional releases of microplastics** by developing labelling, standardisation, certification and regulatory measures; harmonising methods for measuring unintentional releases of microplastics; closing the gaps in scientific knowledge related to the risks and occurrence of microplastics in the environment, drinking water and foods.

In 2021, in its Action plan: 'Towards Zero Pollution for Air, Water and Soil', the Commission proposed that, by 2030, the EU should reduce both (intentional and unintentional) microplastic releases into the environment by 30%. This target does not include the contribution of the degradation and fragmentation of macroplastics abandoned, discarded or improperly disposed of into the environment.[3]

Microplastic pollution observed in the environment originates from:

(i) the degradation and fragmentation of larger 'macroplastic' pieces abandoned, discarded or improperly disposed of in the environment;
(ii) microplastics that are added intentionally to certain products, such as cosmetics, and ultimately find their way into the environment; and
(iii) microplastics that are released unintentionally, mainly due to abrasion during use or poor handling.

Although "macroplastics" are likely a large source of microplastics, their degradation and fragmentation are not addressed in this Impact Assessment as these processes can take between a couple of years and up to several centuries so no reliable information is available on the amount of microplastics generated from macroplastics yearly. In addition, the most effective way of tackling the degradation of macroplastics as a source of microplastics is by reducing the improper disposal of macroplastics into the environment. The EU has already introduced an extensive strategy[4] and legislative framework to tackle macroplastic pollution, including the Single Use Plastics Directive

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1 Scientific opinion on the environmental and health risks of microplastic pollution, April 2019.
2 Commission Regulation (EU) …/… amending Annex XVII to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles.
3 Instead, the Zero Pollution Action Plan sets a 50% reduction target for plastic marine litter which will help contribute to a reduction in the releases of microplastics from this source (see also Annex 2 of the Zero pollution action plan).
4 A European Strategy for Plastics in a Circular Economy, 2018.

(SUPD)[5], the Waste Framework Directive (WFD)[6], the Packaging and Packaging Waste Directive (PPWD)[7] and the Marine Strategy Framework Directive (MSFD).[8]

Similarly, **intentionally added microplastics** are not addressed in this IA because the Commission has proposed a draft REACH restriction. This restriction was adopted on 25 September 2023.[9]

On **microplastics unintentionally released**, while several main sources were initially being examined (see Table 1)[10], **this Impact Assessment focuses on plastic pellets**. They also referred to as nurdles, nibs, preproduction pellets, and resin pellets, are the starting material used for all plastic production worldwide[11]. Due to their nature and size, they are regarded as being microplastics. The focus on pellets is due to the conditions being in place for the application of the precautionary principle[12] and for immediate regulatory action tackling this source:

- Contrary to other sources of microplastics unintentionally released, for which an EU legal framework exists or is being negotiated with the European Parliament and the Council, there is no existing or forthcoming EU legislation specifically preventing and reducing pellet losses as a form of pollution occurring along the entire supply chain in the EU. The proposal would remedy a loophole in the current EU legislative framework.
- Sufficient evidence is available documenting the problem and the impacts related to pellet losses, justifying intervention and allowing the design of specific policy measures, while this is not yet the case for most other sources of unintentionally released microplastics.
- Contrary to other sources of microplastics unintentionally released, pellet losses are due to poor handling and therefore largely preventable today in a cost-effective manner. No changes to product or consumer behaviour are required to prevent and reduce pellet losses.
- Techniques to prevent pellet losses are already available to economic operators at an acceptable cost.
- They are the third source of releases and account for 7-10% of microplastics unintentionally released in the EU.
- Preventing and reducing pellet losses now does not impede any future action on other sources later, as there is no interference between the different sources of microplastics.

In contrast, the other sources identified (paints, tyres, synthetic textiles, geotextiles and detergent capsules) were not pursued in this Impact Assessment for several reasons. Measures tackling microplastic releases from tyres had already been included in the EURO 7 Regulation proposal. While the preliminary analysis showed that there is potential to reduce releases from paints, synthetic textiles, geotextiles and, to a lesser extent, detergent capsules, it also highlighted uncertainties and

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5 Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment.
6 Directive 2008/98/EC on waste and repealing certain Directives.
7 Directive 94/62/EC on packaging and packaging waste.
8 Directive 2008/56/EC establishing a framework for community action in the field of marine environmental policy.
9 Commission Regulation (EU) …/… amending Annex XVII to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles.
10 Different approaches were used to estimate the releases from these sources because of the heterogeneity of the available data or data unavailability. For pellets, textiles, detergent capsules and geotextiles, researchers have estimated varying emission levels, as well as a range of possible emissions scenarios. For tyres, a modelling approach was used to estimate the potential microplastic releases. For paints, a confidence interval was used in the estimations.
11 Pellets are defined within ISO 472:2013 as "a small mass of preformed moulding material, having relatively uniform dimensions in a given lot, used as feedstock in moulding and extrusion operations".
12 Communication from the Commission on the precautionary principle, 2000.

data gaps and concluded that other policy instruments may be better suited to tackle them. More information and additional analysis is needed to better understand their patterns and frame the most appropriate interventions. Where appropriate and necessary, separate impact assessments will be prepared, to support possible measures to tackle microplastics releases. Box 1, below, provides an overview of the conclusions for each source not pursued in this impact assessment. Annex 15 contains the preliminary analysis undertaken for each of these sources.

Table 1: Estimated releases from six main sources of unintentional microplastic releases to the EU environment

Source	Quantity (tonnes/year), 2019*
Paints	231 000 – 863 000
Tyres	360 000 – 540 000
Pellets	52 140 – 184 290
Textiles	1 649 – 61 078
Geotextiles	6 000 – 19 750
Detergent capsules	4 140 – 5 980
TOTAL of the selected six sources	654 929 – 1 674 098 (90-93% of total emissions)
TOTAL of all sources	729 087 – 1 808 198

(*) Estimations based on the supporting study for this Impact Assessment

Box 1: Preliminary assessment of the other main sources of microplastic pollution not pursued in this impact assessment[13]

Paints – Paints are widely used and on average 37% plastic polymer-based, making them a significant source of microplastic releases. While shifting towards mineral paints would help reduce microplastic releases, it is not clear yet if this would lead to an increase of other environmental impacts. The full environmental profile andlife-cycle assessments of polymer and mineral paints are not available yet. Once this information is obtained, requirements on microplastics in paints could be introduced via the Ecodesign for Sustainable Products Regulation (ESPR)[14], where paints is one of the twelve priority products.

Tyres – Tyre abrasion leads to the release of microplastics. These releases are already being targeted in the EURO 7 Regulation proposal[15] and may be addressed by a delegated act under the Tyre Labelling Regulation.[16]

Synthetic textiles – Most apparel is now made out of plastic fibres and releases microplastics. Some key challenges encountered in the course of the assessment are that microplastic releases from synthetic fibres occur throughout the value chain, that most of their production takes place outside of the EU, and that there

[13] More details in Annex 15.

[14] Proposal for a regulation of the European Parliament and of the Council COM/2022/142 final establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC.

[15] Proposal for a regulation of the European Parliament and of the Council COM/2022/586 final on type-approval of motor vehicles and engines and of systems, components and separate technical units intended for such vehicles, with respect to their emissions and battery durability (Euro 7) and repealing Regulations (EC) No 715/2007 and (EC) No 595/2009.

[16] Regulation (EU) 2020/740 on the labelling of tyres with respect to fuel efficiency and other parameters, amending Regulation (EU) 2017/1369 and repealing Regulation (EC) No 1222/2009.

is not sufficient data regarding the profiles of different synthetic fibres and fibre combinations in terms of microplastic releases. Subject to a better understanding of releases from synthetic textiles thanks to a standardised measurement methodology, along with more life-cycle data of alternatives' impacts, relevant measures could be introduced in the framework of the Ecodesign for Sustainable Products Regulation, as announced in the EU Strategy for Sustainable and Circular Textiles. Such an approach will ensure the environmental sustainability challenges of textiles are addressed in a coherent and integrated way.

Detergent capsules – Laundry and dishwasher detergent capsules often rely on a dissolvable plastic film to dispense their product during the wash. However, the complete biodegradation of this film is not guaranteed and may cause microplastic pollution. Subject to scientific evidence pointing towards a need for biodegradability criteria, future action could be taken under the Detergents Regulation.

Geotextiles – Geotextiles are a source of microplastic releases as they are mostly synthetic, used in harsh conditions and not removed at the end of their service life. However, data on their uses and profile in terms of degradation and microplastic releases is scarce. Once more data is available future action could be taken in the framework of the Construction Products Regulation.[17]

In May 2023, five EU Member States and Norway called on the Commission to introduce the necessary measures tackling unintentional microplastic releases, to reach the 30% reduction target in microplastic releases by 2030. According to these countries, tackling microplastics pollution is a cross-border challenge, and therefore national and voluntary measures alone are not sufficient. Measures at EU level are needed.[18]

In March 2022, the United Nations Environmental Assembly launched international negotiations on a Global Treaty on Plastic Pollution , which is expected to target inter alia microplastics. Other international conventions and agreements are looking at the microplastics issue, such as the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) which issued a non-binding recommendation.

In the EU submission to UNEP in view of the second session of the Intergovernmental Negotiating Committee on an international legally binding instrument on plastic pollution (INC-2)[19], the EU and its Member States "stress the need for the future instrument to include measures to reduce unintended release of microplastics. This could include, for example, measures to minimise the risk of leakages of plastic pellets from production, handling and transport".

The EU has committed to implementing the UN 2030 Agenda for Sustainable Development guided by the 17 Sustainable Development Goals (SDG). This initiative would contribute to goal 12 on sustainable consumption and production, goal 14 on the conservation and sustainable use of the oceans, seas and marine resources for sustainable development and goal 15 on life on lands, together with goals 3 (Good health), 9 (Industry, innovation and infrastructure), 13 (Climate).

2 PROBLEM DEFINITION

2.1 What are the problems related to microplastics in general?

Microplastics are ubiquitous, persistent and transboundary. They are detrimental to the

[17] Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC.

[18] Non-paper: Call for ambitious EU measures to reduce and prevent microplastic pollution, May 2023.

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

environment and potentially harmful to human health, and their mobility is an aggravating factor (see an extensive analysis in Annex 7). Microplastics are easily transported through the air and by surface and marine waters. They are found in soils (including agricultural lands), lakes, rivers, estuaries, beaches, lagoons, seas and oceans. They travel across entire continents and are found in the most remote, once pristine regions such as the Antarctic and Mount Everest, or in vulnerable ecosystems like coral reefs and deep seas. Adverse impacts of pellets are described in detail in Section 2.3.

Risks of microplastic pollution were highlighted in a publication revealing that the 5th planetary boundary of novel entities was exceeded.[20] Chemicals at large, including plastics, have been identified as fulfilling the characteristics of a novel entity. The concept of planetary boundaries was defined as the nine "boundaries within which we expect that humanity can operate safely"[21], demonstrating the threat microplastics pose to the environment and potentially to humans.

Microplastic releases to the environment will continue to increase unless action is taken. All global scenarios point to an increase. A 2019 global scenario[22] suggests an exponential increase in microplastic releases to the oceans unless their release is stopped urgently. In Figure 1, the global accumulation of microplastics in the surface ocean is shown under three plastic emission scenarios.

A recent OECD scenarios for 2060[23] also highlight the importance of closing leakage pathways. This scenario estimates that 298 610 tonnes of microplastics leak annually into the environment in the EU-27 (intentional and unintentional).[24] This IA has found a much higher figure for the annual (2019) releases of (only) unintentional microplastics into the European environment: between 0.7 and 1.8 million tonnes. This estimate is considered an update, as it considers all recent relevant research on the sources. It considers in particular the quite recent estimate on paints, which was neglected by many studies before, but is now considered as probably the largest source of unintentional microplastic releases.[25] Annex 14 gives an overview of all sources of unintentional microplastics identified. Annex 15 includes the calculations for the five other sources analysed in the preliminary phase of this impact assessment.

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[20] Persson, L., Carney Almroth, B., Collins, C. et al., 'Outside the Safe Space of the Planetary Boundary for Novel Entities', *Environmental Science and Technology,* Vol. 56, No 3, 2022, pp. 1510–1521, American Chemical Society.

[21] Rockström, J., Steffen, W., Noone, K. et al., 'Planetary boundaries: exploring the safe operating space for humanity', *Ecology and Society*, Vol. 14, No 2, Article 32. The planetary boundaries framework was updated in 2023 suggesting the novel entities boundary is transgressed see 'Earth beyond six of nine planetary boundaries', Science Advances, Vol. 9, Issue 37, Sep 2023.

[22] Ourworldindata.org, "Microplastics in the surface ocean, 1950 to 2050" (https://ourworldindata.org/grapher/microplastics-in-ocean).

[23] OECD (2022), Global Plastics Outlook: Policy Scenarios to 2060, OECD Publishing, Paris, https://doi.org/10.1787/aa1edf33-en.

[24] The European Chemicals Agency ECHA (2020) estimated 176 000 tonnes of microplastics annually due to abrasion and weathering of plastic products and an additional 42 000 tonnes of microplastics deliberately added to products that are subsequently discharged. Opinion of the Committee for Risk Assessment and Opinion of the Committee for Socio-Economic Analysis on an Annex XV dossier proposing restrictions on intentionally-added microplastics.

[25] Paruta et al. (2022) Plastic Paints the Environment, EAEnvironmental Action 2022, ISBN 978-2-8399-3494-7.

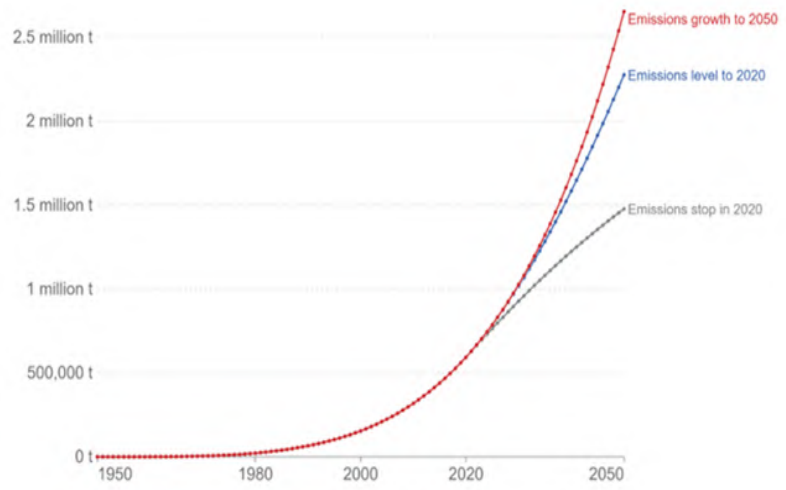


***Figure 1*: Microplastics on the surface ocean 1950 to 2050**[26]

In 2019, the Commission's Group of Chief Scientific Advisors considered that 'although the currently available evidence suggests that microplastic pollution at present does not pose a widespread risk to humans or the environment, there are significant ground for concern and for precautionary measures to be taken'[27] (see Box 2).

Box 2: Recommendations by the European Commission's Group of Chief Scientific Advisors

- Broaden existing policy to prevent and reduce microplastic pollution in both marine and freshwater environments, and in air and soil, and prioritise substance- and context-specific measures for high-volume, high-emission sources;
- Ensure that any new measures are of benefit to society by undertaking cost/benefit and similar analyses;
- Develop a coordinated international response consisting of research collaboration (including filling knowledge gaps on nanoplastic pollution), data sharing and standards development for measurement, monitoring and risk assessment.

Since then, microplastic pollution has been extensively researched, and new evidence has emerged confirming the need for precautionary measures to be taken.

Stakeholder views (see Annex 2) largely refer to the hazardous nature of microplastic pollution in the EU and its negative impact on the environment (79% of all respondents completely or somewhat agreed) and on human health (81% of all respondents completely or somewhat agreed). Regarding the harmful economic effects of microplastics, 58% of EU citizens completely or somewhat agreed with the statement, including half of the business organisations and two-thirds of the NGOs. All stakeholders agreed action to reduce microplastics should be undertaken by all levels of public authorities (EU, national, regional and local levels). Regarding pellets, stakeholders mostly agreed that there is improper handling in current pellet-related activities. As to the type of action, 95% of all respondents supported international action, 87% of them called on the EU to set up a comprehensive legislative system for pellet-handling companies, and 71% of them supported voluntary measures.

[26] Microplastics in the surface ocean, 1950 to 2050, Our World In Data.
[27] Scientific opinion on the environmental and health risks of microplastic pollution, April 2019.

2.2 What are the problems related to plastic pellets?

Current practices for handling pellets lead to losses at each stage in the supply chain, causing adverse environmental and potential human health impacts.

The problem of pellet losses has been known about since the 1980s with the US Environmental Protection Agency (EPA) and the Center for Marine Conservation (now known as the Ocean Conservancy) "detecting plastic pellets in US waterways from the Atlantic to the Pacific".[28]

Plastic industrial raw materials come in different forms, including pellets, flakes, powders and in liquid forms, all referred to collectively as "pre-production plastic pellets".[29] The umbrella term of "pellets" will be used in this IA. In Europe, approximately 80 % of all plastic industrial raw materials produced are in the form of round to oval granules of approximately 2 mm to 5 mm in diameter.[30] A relevant part of the remaining 20% is even smaller than 2 mm, such as powders, and a minor part can be slightly bigger.

The pellet supply chain

Pellets can reach the environment through losses occurring at every stage in the supply chain: production (virgin or recycled), processing (compounding, masterbatch making, converting, etc.), distribution, other logistic operations (storage and tank cleaning), waste management, etc. Therefore, tackling pellet losses clearly requires a supply chain approach.

The pellet supply chain is complex, involving several operators as outlined in Box 3. Virgin pellets are manufactured at large installations and then stored in silos. They are mostly filled directly into tankers, or packed for transport to conversion sites, where final plastic products are made. Transport occurs by road, rail, air and cargo ship. Distribution methods vary from small bags (20- 25 kg) to silo trucks (up to 35 t) and large maritime containers. Not all bags are sealed, airtight and puncture-resistant to prevent damage and tears. Losses can also occur at recycling facilities, where plastic waste is recycled back into pellets in order to be reintroduced into the plastic manufacturing cycle.[31]

Box 3: Companies handling pellets

- Producers who create virgin plastic pellets from oil, gas and other raw materials;
- Recyclers who collect, sort, clean and process plastic waste into recycled plastic flake or pellets;
- Traders/brokers who purchase the plastic material and store it or otherwise handle it before selling it to converters or exporting;
- Intermediary facilities that handle the plastic material between the producer and the processor, such as storage and repacking facilities;

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[28] Document Display | NEPIS | US EPA; Plastics Industry Association (2016) Operation Clean Sweep Celebrates 25 Years

[29] The Convention for the Protection of the Marine Environment of the North- East Atlantic (OSPAR) Commission, OSPAR Background document on pre-production plastic pellets, 2018. Technically, according to ISO 472:2013, a pellet is a "small mass of preformed moulding material, having relatively uniform dimensions in a given lot, used as feedstock in moulding and extrusion operations".

[30] Plastics Europe, 'Operation Clean Sweep® Progress Report 2017', 2018 (https://www.opcleansweep.eu/application/files/8316/3456/6233/PlasticsEurope_OCS_progress_report-2017.pdf).

[31] Hann, S., Sherrington, C., Jamieson, O., Hickmann, M., Kershaw, P., Bapasola, A., Cole, G. (2018). Investigating options for reducing releases in the aquatic environment of microplastics emitted by (but not intentionally added in) products, Eunomia.

- Processors who transform the plastic pellets by either mixing them with other materials to alter their physical properties or by transforming them directly into manufactured goods (the former are called compounders and the latter converters). In this IA, we refer to all of them as "converters";
- Distributors who sell (a small portion of) the plastic pellets to sectors such as construction;
- Logistic companies (including importers, transport and cleaning stations); and
- Waste management companies.

Producers: in Europe, there are close to 100 large polymer-producing companies that are members of the trade association "Plastics Europe".[32] These companies produce some 54.8 million tonnes of virgin pellets per year and represent 90% of the total EU production. In 2021, circa 138 000 people worked for plastic manufacturers in the EU27. The number of individual enterprises was around 2 300. In 2021, plastic manufacturers created a turnover of EUR 117 billion.

Processors / converters: their situation is significantly different as Figure 2 shows: the trade association "European Plastic Converters" (EuPC) totals about 51 national and European industry associations, representing 90% of the total EU processing, equivalent to ca 48 000 individual companies, out of which 66% are micro-companies (some 31 400 micro-enterprises handling an average tonnage below 100 tonnes and representing an average turnover of EUR 300 000 annually, equivalent to 4% of the total turnover of the industry).[33] Converters employ 1.3 million people and have an annual turnover of EUR 269 billion.[34]

Recyclers: in 2021, there were some 730 plastic recycling companies in the EU. They have more than 20 000 employees and create a turnover of EUR 8.5 billion annually. In 2021, they produced 7.6 million tonnes of recycled pellets, while the installed capacity is roughly 11 million tonnes. About 165 organisations are members of the trade association "Plastics Recyclers Europe" (PRE) regrouping both national industry associations and individual, mostly large, companies.[35] These companies represent 80% of the EU market installed capacity.

Transporters: the "European Chemical Transport Association" (ECTA) represents approximately 100 transport companies active in the transport of chemical products, with about half handling also pellets.[36] Most of these ECTA members are not SMEs. They cover about 30% of the total pellet transport in Europe. Beyond ECTA members, ca. 13 000 transporter providers are mainly micro and small enterprises.

Other logistic operators: the "European Federation of Tank Cleaning Organizations" (EFTCO) declares that around 440 tank cleaning stations in Europe deal with tanks containing pellets. Also, there would be at least 850 storage or warehouse providers in Europe storing pellets. These companies are mainly micro and small enterprises.

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[32] Plastics Europe, 'Membership' (https://plasticseurope.org/about-us/membership/).
[33] European Plastic Converters (EuPC), 'Organisation' (https://www.plasticsconverters.eu/).
[34] Eurostat (2021 figures) for EU-27 (Statistics | Eurostat (europa.eu))
[35] Plastics Recyclers Europe, 'Plastics Recycling Industry in Europe: Mapping of Installed Plastics Recycling Capacities 2021 Data', 2023 (https://www.residuosprofesional.com/wp-content/uploads/2023/03/Plastics-Recycling-Industry-in-Europe-2023.pdf).
[36] European Chemical Transport Association, 'List of ECTA and ECTA RC* Members 2023' (https://www.ecta.com/organization/list-of-members/).

More information on the share of SMEs[37] in the pellet supply chain is presented in Annex 12.

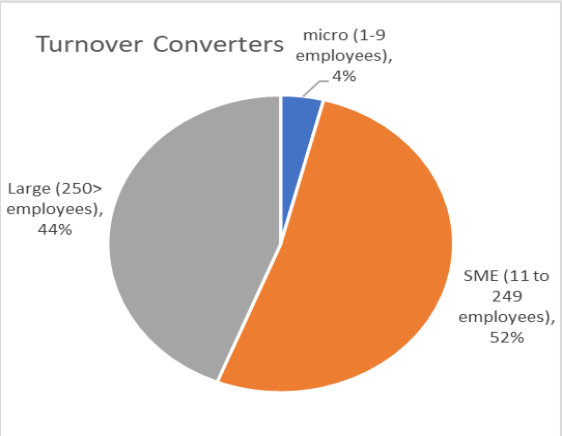


Figure 2: Breakdown of plastic processors

Pellet losses

Pellet losses can be the result of:

1) chronic, ongoing pellet incidents during routine operations. These losses usually occur as a result of lack of awareness and improper training, poor handling and housekeeping practices and due to the absence of pellet loss preventive and mitigating measures. They typically happen during both bulk and packed loading and unloading operations at special installations and during transport and logistic operations. The industry corroborates this presumption by adding process and mixing points as other pellet loss hotspots.[38]
2) acute, one-off, pellet incidents. These usually occur as a result of accidents during transport or major equipment failures in the absence of pellet loss preventive and mitigating measures.





[37] SMEs are defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises. In particular, within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million; a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.

[38] Plastics Europe, 'Operation Clean Sweep® Progress Report 2019', 2020 (https://plasticseurope.org/knowledge-hub/operation-clean-sweep-progress-report-2019/).

Figure 3: pellets lost in the environment & pellets ingested by fishes

(Credits last picture: Sri Lanka Marine Environment Protection Authority)

Chronic pellet incidents have been reported at production sites in the Netherlands[39], Belgium[40], Spain[41], Denmark[42] and Sweden.[43] Logistics platforms like ports are hotspots for pellet losses: the ports of Rotterdam, Antwerp and Tarragona have been reported to be heavily polluted locations by several organisations active in the monitoring of pellet losses.[44] An important part of chronic pellet incidents also happens during the transport of pellets across land (e.g. road and rail), such as in Belgium[45], or during maritime transport.[46]

Acute pellet incidents have happened in industrial facilities in Italy[47] and during the transport of pellets across land, e.g. in France[48] and during maritime transport, e.g. in the Netherlands[49] or in Denmark.[50] Acute pellet incidents where entire containers are lost at sea result in large quantities of pellets being released directly into the marine environment.[51] Some big incidents with unknown origin have also to be mentioned, such as in the Loire-Atlantique coastline of France[52], among several others in Europe and worldwide.[53] Chronic and acute pellet incidents are presented in Annex 8.

Existing monitoring programs in Europe show the presence of plastic pellets in the marine environment. In addition to those implemented in the context of the Marine Strategy Framework Directive, which requires all Member States[54] to monitor and assess microlitter on beaches[55], there are programs like the Port of Antwerp's collaboration with PlasticsEurope.[56] However, plastic pellets have been observed, since the 1970s, all over the world, in marine environments that are not close to petrochemical or polymer industries. NGOs such as SOS Mal de Seine and Fidra have documented this using different observation protocols. This demonstrates that while pellet losses can be

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39 Westerschelde-plastic-nurdles-versie-definitief-21-11-2021-2.pdf (plasticsoupfoundation.org)

40 Ecaussinnes (Belgium): Surfrider Foundation tackles industial plastic granules

41 New report out exposes alarming impacts of plastic pellets across Europe - Good Karma Projects

42 Tackling sources of Marine Plastic Pollution through effective corporate engagement: a Danish Case Study

43 The unaccountability case of plastic pellet pollution - ScienceDirect

44 Plastic Giants polluting through the backdoor. New report out exposes alarming impacts of plastic pellets across Europe - Good Karma Projects

45 Ecaussinnes (Belgium): Surfrider Foundation tackles industial plastic granules

46 Sources, fate and effects of Microplastics in the marine environment: a global assessement

47 Nurdle pollution hotspot identified in Italy (nurdlehunt.org.uk)

48 Morbihan. A truck loses its cargo, 28 tons of plastic pellets on the road (ouest-france.fr)

49 24 million plastic pellets from MSC Zoe on northern Dutch coastline – The Northern Times

50 Plastic pellets spill pollutes Danish, Norwegian, Swedish coastlines – KIMO (kimointernational.org)

51 In 2021, the container ship MV X-Press Pearl caught fire and sank losing approximately 1680 tonnes of plastic pellets in a single event (some 84 billion pellets). In Europe, in 2020, the MV Trans Carrier lost more than 10 tonnes of plastic pellets in the German Bight. Plastic pellets spill pollutes Danish, Norwegian, Swedish coastlines – KIMO (kimointernational.org) 24 million plastic pellets from MSC Zoe on northern Dutch coastline – The Northern Times

52 Les plages de la côte Atlantique polluées par une marée de granulés plastiques, l'Etat porte plainte (lemonde.fr). In less than an hour, volunteers collected more than 80,000 pellets from the Tréguennec in Finistère beach.

53 Nurdle Map (nurdlehunt.org.uk)

54 Commission Decision (EU) 2017/848 of 17 May 2017 laying down criteria and methodological standards on good environmental status of marine waters and specifications and standardised methods for monitoring and assessment, and repealing Decision 2010/477/EU

55 In 2016, pain started the MSFD subprogram on microplastics on beaches, and pellets were detected with an average concentration of 47.8 pellets/kg or 419.2 pellets/m2. Currently, the MSFD Technical Group on Litter is developing a protocol for monitoring pellets on beaches.

56 Plastics Europe, 'Port of Antwerp Activity report 2021', 2021 (https://plasticseurope.org/knowledge-hub/port-of-antwerp-activity-report-2021/).

concentrated in one geographical area, they are also extremely mobile and can be dispersed by surface water and sea currents, as well as through the air.

Pellet pathways

Spilled pellets can reach the environment and become losses through several pathways (Figure 4).

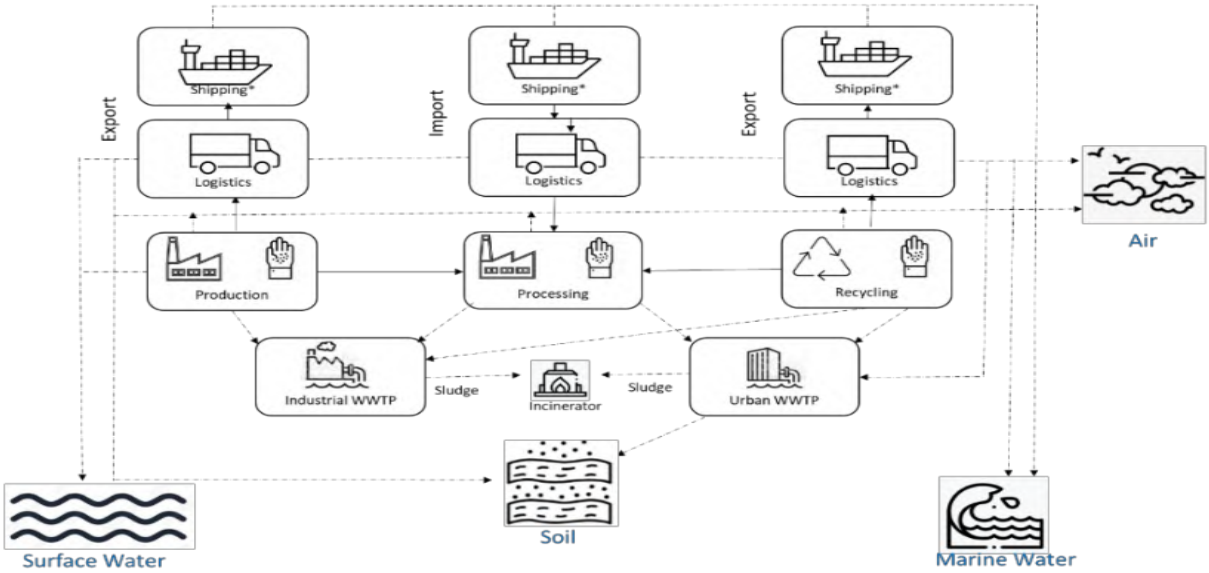


Figure 4: Pellet pathways (solid lines are pellet movements; dotted lines are loss pathways)

From **production, processing and recycling installations**, spilled pellets can either reach industrial or urban wastewater treatment facilities (via wet cleaning pushing pellets to drains[57]) or can enter the environment directly (air, soil, surface and marine waters, but also via overflows making pellets bypass the wastewater treatment facilities). In industrial wastewater treatment facilities, pellets are captured in sludge and incinerated. However, the effluent may still contain some pellets (particularly, flakes and powders). In urban wastewater treatment facilities, pellets are captured in sludge (between 95-99%, depending on the treatment efficiency). On average, half of sludge, which has captured pellets, in the EU is spread on agricultural lands as fertiliser.

Pellets lost during **logistic and shipping operations** often reach the environment directly. Therefore, the main pellet loss pathways are water-related, i.e. urban, rain and storm water for losses occurring in terrestrial areas and marine water for losses at installations close to ports or occurring in the sea.

Scale of the problem

While observable, these losses are not routinely measured, or indeed readily measurable at any specific step. There is no harmonized methodology for measuring pellet losses and not many measurements have been made at different steps of the supply chain, nor are any systemic monitoring and reporting data available within the Member States or the industry to calculate pellet losses. Hence, it is impossible to establish exact figures on pellet losses at each step because it depends on the installation size, actors involved, handling practices, etc., and all these aspects are very heterogeneous in the EU. Nevertheless, efforts to quantify the amount of pellets entering the

[57] In case of dry cleaning, pellets go to waste management (mostly for incineration) except for recyclers who collect and put them back in the recycling process.

environment typically apply a 'loss rate' as well as a number of handling steps to the total pellet volume handled. Robust empirical evidence to inform a 'loss rate' or a number of handling steps is scarce. However, the greater the number of steps at which pellets are handled, the greater the opportunities for loss. The major handling steps occur at production plants (of both virgin and recycled pellets), processing installations and during logistic operations, i.e. all loading and unloading operations to transport pellets from one installation to another, including warehouse installations, where pellets are stored and/or re-packed, and cleaning installations.

Several studies use the figures for pellet losses of 0.01%-0.04%.[58] However, all these studies refer to the same estimate from just one processor and is based on measurement in the effluent, so it does not measure losses at other steps of the supply chain or emissions happening otherwise, i.e. direct emissions to air, water and soil. Given the high uncertainty and potential double counting, rates in the range of 0.001% and 0.1% have been suggested by some studies.[59] The Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)[60] found an even bigger range in various publications; loss estimates show a variation from 0.0003% to 1% of total plastic demand, making it difficult to estimate the exact magnitude of the problem. The reason for such a large variation is that the actors involved in the supply chain range from micro-enterprises to large companies and the level of awareness and measures in place to prevent pellet losses vary considerably. Similarly, the number of handling steps in a typical supply chain is influenced by the size of the operation.

To take into account these uncertainties, a range of loss rates has been used to calculate the losses occurring at four major steps: production, processing, recycling and logistics (including distribution), starting from the most often cited loss rates. It is estimated that losses happen at a higher rate at processing and recycling installations because of relatively small installations and a large number of handling steps (0.02%-0.06% of the total volume processed or recycled) than at production ones (0.01%-0.03% of the total volume produced), and at an even higher rate during transport and logistic operations because pellets more often reach the environment directly at these steps, but with a higher uncertainty (0.03%-0.12%). These rates count for the major handling steps in the production, processing, recycling and transport/logistic phases. These figures can be improved once the reporting obligation under REACH (possibly complemented with a harmonised methodology under this initiative) is in place.

Chronic losses in reference year

High volumes of pellets are produced and handled every year, both globally and in the EU. In 2019, about 65.3 million tons of pellets (57.9 million tonnes of virgin, 6.5 million tonnes of recycled, and 0.9 million tonnes of bio-based) were produced in the EU.[61] In the same year, 12.7 million tonnes of pellets were imported to the EU to be converted into final plastic products at a converting site in the EU, while 14.9 million tonnes of pellets were exported.

This IA has found that the amount of pellets lost to the environment in the EU in 2019 can be estimated to be between 52 140 tonnes and 184 290 tonnes (logistics 27 870 – 111 480 tonnes, converters 15 600 – 46 800 tonnes, producers 7222 – 21 665 tonnes and recyclers 1448 – 4345

[58] Sea-based sources of microplastics to the Norwegian marine environment. Norwegian Environment Agency (Miljødirektoratet) (2021). (according to Sundt et al. (2014)

[59] Peano et al., 'Plastic Leak Project', 2020 (https://quantis.com/who-we-guide/our-impact/sustainability-initiatives/plastic-leak-project/).

[60] OSPAR, 'Assessment document of land-based inputs of microplastics in the marine environment', 2017 (https://www.ospar.org/documents?v=38018 Page 22).

[61] Based on data from Eurostat and industry.

tonnes), equivalent to 0.08% to 0.28% of total pellet volumes in the EU. The methodology used to calculate these losses is presented in detail in Annex 8.

2.3 The impacts of pellet losses

Four types of adverse impacts can be observed from pellets finding their way into the environment: on the environment; on climate; on human health; and on the economy.

These impacts are summarised below and explained in more detail in Annex 7. Most of these impacts are related to microplastics in general, due to a lack of research specifically assessing the impact of pellets. However, as a subset of microplastics, it is assumed that most of the impacts of pellets are comparable to those of microplastics. Indeed, approximately 80 % of all plastic raw materials produced are approximately 2 mm to 5 mm in diameter, therefore well within the usual size of microplastics (up to 5mm). Of the remaining 20%, a significant portion is smaller than 2 mm, such as powders, and a minor part can be slightly bigger. In particular the portion with the smallest size can have an impact on health. The disintegration of pellets into smaller particles also increases their number and impacts. The sections below clearly state when the discussed impacts pertain to pellets or microplastics more generally.

While certain categories of impacts (environment, climate and economy) are well documented and relatively well known, the impacts on human health are still poorly understood, despite their extensive presence in the human body. Nevertheless, as concluded by the General Scientific Advisers of the Commission and the European Chemicals Agency, this gap in understanding should not prevent action from being taken as it is likely that they pose a risk to human health. The precautionary principle should therefore be applied. Research efforts are ongoing, in part thanks to EU support under LIFE and Horizon2020, to further elucidate these risks and impacts. Global trends suggest that microplastic emissions will continue to increase. We would generally expect that the adverse impacts of pellets will be proportional to their part in the total microplastic emissions (see Annex 7).

Impacts on the environment

International Pellet Watch, initiated in 2005 by Hideshige Takada[62] and The Great Nurdle Hunt[63], organised by UK charity FIDRA, both relied on pellet samples collected by citizens to demonstrate that pellet pollution is a global issue. Indeed, they are highly mobile and have been found thousands of kilometres from the nearest pellet production or conversion facility[64] in areas including important Natura 2000 areas[65]. Once in the environment, pellets are known to be eaten by a range of organisms and animals and to cause harm to biodiversity and habitats[66,67]. As pellets are mainly composed of either polyethylene or polypropylene, once in the aquatic environment[68], they normally float. If a

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62 edge://newtab (pelletwatch.org)

63 The Great Nurdle Hunt, Reducing plastic pellet pollution at sea.

64 Corcoran P. L. et al., A comprehensive investigation of industrial plastic pellets on beaches across the Laurentian Great Lakes and the factors governing their distribution, Science of the Total Environment, 747:141227, 2020.

65 The unaccountability case of plastic pellet pollution - ScienceDirect

66 Cole, M., Lindeque, P., Halsband, C. and Galloway, T. S., 'Microplastics as contaminants in the marine environment: A review', Marine Pollution Bulletin, Vol. 62, 2011, pp. 2588-2597.

67 Koelmans, A. A. et al., Risk assessment of microplastic particles, Nature Reviews Materials, 7:138–152, 2022.

68 The persistence of a pellet in the aquatic environment may be measured over decades or more, depending on the resin type, the types and amounts of additives, and the reactions of the resins and additives to environmental processes (e.g. weathering, sunlight, wave action). P. L. Corcoran, Degradation of Microplastics in the Environment, Handbook of

biofilm starts to form on the pellets, which may change the buoyancy of the particle. Harm is caused by pellets when they float or are in the water column, where they can be eaten by organisms and marine animals either intentionally because they are mistaken for food or unintentionally when filter feeding animals take in seawater.[69] Several documented accounts describe pellet and other plastic ingestion by wildlife, most notably seabirds and sea turtles.[70,71,72] Seabirds, like fulmars, ingest pellets more frequently than any other animal, as they capture prey from the sea surface, and approximately one-quarter of all seabird species are known to ingest pellets.[73] The ingestion of pellets, as with any microplastic, can cause physical harm such as internal injuries and impair the ability to breathe, swallow, digest food properly, or lead to death.[74] In certain cases, microparticles cannot pass through the digestive system, leading to malnutrition or starvation by creating a false feeling of fullness.[75]

Pellets' and microplastics' potential to act as a carrier for pathogenic microorganisms and their potential toxicity are other integral parts of the problem. There is an emerging concern that microplastics can act as a carrier for pathogenic microorganisms, including species of bacteria, resulting in an increase in the occurrence of non-indigenous species.[76,77,78] Although microplastics do not pose acute fatal effects on living organisms, they can cause chronic toxicity over the longer term. Due to their physical and chemical properties, microplastics can absorb and transport numerous organic contaminants. Microplastics can also contain a complex mixture of chemicals, which may subsequently be released into the environment and constitute new routes of exposure for organisms.

Impacts on climate

Microplastics represent a non-climatic pressure on ecosystems as carbon and nutrient cycling processes in soil can be greatly affected by the presence of microplastics and their further decomposition[79] (and might therefore lead to a decreased capacity for GHG absorption). In addition, plastics and microplastics are a source of GHG emissions, putting additional pressure on the climate. GHGs are emitted throughout the plastic life cycle, because all related activities (extraction, refining,

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Microplastics in the Environment, 2022, 531–542. N. Kalogerakis et al., Microplastics Generation: Onset of Fragmentation of Polyethylene Films in Marine Environment Mesocosms, 2017, doi.org/10.3389/fmars.2017.00084

69 Werner S; Budziak A; Van Franeker J; Galgani F; Hanke G; Maes T; Matiddi M; Nilsson P; Oosterbaan L; Priestland E; Thompson R; Veiga J; Vlachogianni T. Harm caused by Marine Litter. EUR 28317 EN. Luxembourg (Luxembourg): Publications Office of the European Union; 2016. JRC104308

70 Lacroix C. et Huvet A., https://enviroplast2019.sciencesconf.org/data/TR1_1_PPT_journe_es_plastiques_et_environnement_Lacroix_Huvet.pdf [Roundtable n°1 : Outlook and management in ports and coastal environments – scientific introduction : the characterisation of pollution and associated risks], June 2019.

71 Ryan, P. G., 'Seabirds indicate changes in the composition of plastic litter in the Atlantic and south-western Indian Oceans', *Marine Pollution Bulletin*, Vol. 56, no. 8, 2008, pp. 1406-1409.

72 Sheavly, S.B. and Register, K.M., 'Marine Debris & Plastics: Environmental Concerns, Sources, Impacts and Solutions', *Journal of Polymers and the Environment*, Vol. 15, 2007, pp. 301-305.

73 Plastic particles in fulmars | OSPAR Commission

74 Group of Chief Scientific Advisors, 'Scientific opinion on the Environmental and Health risks of microplastics pollution', Aprile 2019.

75 The Convention for the Protection of the Marine Environment of the North- East Atlantic (OSPAR) Commission, OSPAR Background document on pre-production plastic pellets, 2018.

76 Sources, fate and effects of Microplastics in the marine environment: a global assessement

77 Cole, M., Lindeque, P., Halsband, C. and Galloway, T. S., 'Microplastics as contaminants in the marine environment: A review', *Marine Pollution Bulletin*, Vol. 62, 2011, pp. 2588-2597.

78 Khalid, N. et al., Linking effects of microplastics to ecological impacts in marine environments, Chemosphere, 264: 128541, 2021.

79 Rilling M. C. et al., Microplastic effects on carbon cycling processes in soils, Plos Biology, 2021, https://doi.org/10.1371/journal.pbio.3001130

manufacturing and end of life management) are carbon intensive. Conventional plastics (based on fossil fuels) produced in 2015 accounted for 3.8% of total global CO_2 emissions, and their share could reach 15% by 2050[80]. A more recent study estimates even higher CO_2 emissions from plastic production (1.96 Gt of CO_2e)[81].

Microplastics are widely found in aquatic environments.[82] Their presence may cause more greenhouse gas emissions as they can negatively affect multiple factors, such as phytoplankton photosynthesis, which contribute to carbon sequestration.[83]

Impacts on human health

Humans are exposed to microplastics via food consumption[84] and inhalation. The annual intake of microplastics by humans has been estimated to range from 70 000 to over 120 000 particles a year, depending on age, gender, region, and consumption, including ~70 000 particles inhaled in air and ~50 000 particles ingested in food and drink. Seafood is one of the main concerns for humans[85]; however, microplastics can also enter the food chain through plants.[86] Microplastics have been found in human stool,[87] and some studies suggest that they may be present in pregnant women's placenta,[88] and more recently, in human blood.[89]

Although there is still no scientific consensus on their impacts**,** microplastics may be of concern to human health mainly due to their small size, mobility and extensive presence in different environments, increasing chances of exposure.[90] High levels of exposure to microplastics are believed to induce inflammatory reactions and toxicity, possibly due to the additives used to produce the plastic.[91] In addition to being toxic, there is evidence to suggest that additives such as dyes or plasticisers could be carcinogenic and mutagenic.[92,93] Pellets are likely to carry toxic chemicals as well since persistent organic pollutants (POPs) such as polychlorinated biphenyls (PCBs), dichloro-diphenyltrichloroethane (DDT), hexachlorocyclohexanes (HCHs), and polycyclic aromatic

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80 IPCC Working Group III Report: Mitigation of Climate Change (2022) https://www.ipcc.ch/report/sixth-assessment-report-working-group-3/

81 Cabernard, L., Pfister, S., Oberschelp, C. et al. Growing environmental footprint of plastics driven by coal combustion. Nat Sustain 5, 139–148 (2022).

82 Phytoplankton response to polystyrene microplastics: Perspective from an entire growth period - ScienceDirect

83 Can microplastics pose a threat to ocean carbon sequestration? - ScienceDirect

84 Sciencealert.com, Study shows how microplastics can easily climb the food chain. Should we be worried?, 2022.

85 Cox, K. D. et al., 'Human consumption of microplastics', *Environmental Science and Technology*, Vol. 53, No 12, 2019, pp. 7068–7074.

86 Sciencealert.com, 'Study shows how microplastics can easily clim the food chain. Should we be worried?', 2022 (https://www.sciencealert.com/study-shows-how-microplastics-can-easily-climb-the-food-chain-should-we-be-worried).

87 Schwabl, P. et al., 'Detection of various microplastics in human stool', *Annals of Internal Medicine*, Vol. 171, No 7, 2019, pp. 453–457, American College of Physicians.

88 Ragusa, A. et al., 'Plasticenta: First evidence of microplastics in human placenta', *Environment International*, Vol. 146, 2021, Elsevier BV.

89 Leslie, H. A. et al., 'Discovery and quantification of plastic particle pollution in human blood', *Environment International*, Vol. 163, 2022, Elsevier BV.

90 Marine microplastic debris: An emerging issue for food security, food safety and human health - ScienceDirect

91 Potential Health Impact of Environmentally Released Micro- and Nanoplastics in the Human Food Production Chain: Experiences from Nanotoxicology | Environmental Science & Technology (acs.org)

92 Gasperi, J., et al., Microplastics in Air: Are We Breathing It In?, Current Opinion in Environmental Science & Health, 1–5. 2018. https://doi.org/10.1016/J.COESH.2017.10.002

93 Blackburn, K., Green, D., The potential effects of microplastics on human health: What is known and what is unknown, Springer, Ambio, 51:518–530, 2021.

hydrocarbons (PAHs) can be easily adsorbed to their surface and then released over time.[94] The health impacts of POPs are not immediate but result rather from chronic, cumulative and long-term exposure.[95] In addition, microplastics could potentially act as vectors for pathogens and microbes.[96]

Impacts on the economy

Generally, the growing evidence on microplastics' presence in seafood, salt, honey, fruits, vegetables and drinking water could undermine consumer confidence and bear economic consequences.

There are potential negative economic impacts on activities such as commercial fishing and agriculture (e.g. reduced fishing due to impacts of microplastics on marine eco-systems and fauna, which eats it) as well as tourism and recreation (e.g. reduced attractiveness due to impacts of microplastics on beaches and vulnerable areas like national parks, rivers and lakes[97]). Clean-up operations are challenging and, according to OSPAR, often costly, as clean-up off-site and in the environment requires time and specialist equipment. Operations are usually the responsibility of local communities with a negative impact on their budgets. Clean-up costs are often unknown. However, beach clean-ups are estimated to cost the city of Marseille (France) EUR 1 000 000 per year.[98] KIMO Netherlands reported that the clean-up costs of the 2019 pellet spill of the MSC Zoe in the Wadden Sea would be approximately EUR 100 000 annually.[99] Monitoring costs of pellet ingestion by species are also often unknown. However, la Rochelle Aquarium's monitoring of microplastic ingestion by loggerhead sea turtles cost a total of EUR 50 000 over four years. Another relevant example is the monitoring of microplastic ingestion by fulmars provided by ornithological groups, which costs EUR 33 300 for one winter season.

The cost of pellets lost to the environment is equivalent to an economic loss for the businesses owing them of EUR 52 – 184 million, coming from about 52 140 – 184 290 tonnes of lost pellets (with around 1000 EUR/t).

2.4 What are the problem drivers?

There are several market and regulatory failures, which are summarised below and explained in more detail in Annex 8.

2.4.1 Market failures

Prices do not reflect negative externalities: The activities of economic operators do not integrate the negative externalities caused by pellets finding their way into the environment, leading to a

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[94] Corcoran P. L. et al., A comprehensive investigation of industrial plastic pellets on beaches across the Laurentian Great Lakes and the factors governing their distribution, *Science of the Total Environment*, 747:141227, 2020.

[95] Nadal, M. et al., Climate change and environmental concentrations of POPs: A review, *Environmental Research*, 143: 177-185, 2015.

[96] Microplastics from textiles: towards a circular economy for textiles in Europe — European Environment Agency (europa.eu)

[97] Plastic Giants polluting through the backdoor; Silent Pollution – Who is contaminating Puglia's coastline with plastic pellets?; Plastic pellets spill pollutes Danish, Norwegian, Swedish coastlines; Microplastic pollution in the surface waters of Italian Subalpine Lakes; Granulés plastiques industriels sur le littoral français

[98] OSPAR Background document on pre-production Plastic Pellets 2018. SOS Mal de Seine Association highlighted the lack of capacity of public authorities to deal with large- scale pollution of pellets on beaches (e.g. caused by lost containers). As a matter of fact, clean- up operations are complex to undertake because these particles are difficult to see due to their size or vegetation which may hide them, and they should be carried out within an hour of an incident to prevent widespread pollution by wind, rain, and/or tides.

[99] Fishing for Litter fleet cleans up after MSC Zoe but who pays the costs? – KIMO (kimointernational.org)

suboptimal market outcome. On one side, due to their small size, pellets are easy to spill; on the other side, it is relatively costly to prevent spills or to clean up after spills as good handling practices require measures to be taken, such as training of staff. The cost of lost pellets, incurred by economic operators involved in the production, use and transport of pellets, is not sufficiently high to motivate a change in behaviour. In addition, once spilled, pellets are considered contaminated and therefore become waste.[100] There are no other incentives for economic operators to integrate the negative externalities caused by pellets finding their way into the environment.

Imperfect information: Economic operators do not have sufficient information to be fully aware of the pellets that are unintentionally lost from their operations (and of consequential impacts). As no systematic reporting is in place, they are not aware of quantities released, and because there is no or insufficient awareness raising about the impacts, they are not aware of the negative externalities. Furthermore, as information on available preventive and mitigating measures by responsible companies is not sufficiently promoted throughout the supply chain, they are not aware of possible actions to be taken. Under these circumstances, it is difficult for economic operators to make sustainable choices when investing in the equipment, determining their internal procedure or choosing partners along the supply chain.

As such, no sufficient information about quantities, impacts, actions etc., is routinely sought or promoted throughout the supply chain and economic operators do not sufficiently integrate concerns about pellet losses in their operations. This problem of insufficient information is particularly acute among the smaller companies, mostly on the conversion and logistic side.

Lack of specific support and attention for the smaller companies present in the pellet supply chain, to which the measures to implement would be costly, also explains a suboptimal market outcome.

2.4.2 Regulatory failures

Existing EU legislation does not address pellets sufficiently: The absence of specific requirements to implement best handling practices is arguably the most significant of the problem drivers. While existing EU regulatory frameworks could be relevant (governing chemicals, marine litter, water, industrial emissions, waste, packaging and transport activities), they do not specifically address the issue of pellet losses and their responsible handling to prevent and reduce losses to the environment. In particular, pellets are only very partially covered by the REACH restriction on microplastics intentionally added to products[101] as: 1) the requirements i.e. instructions for use and disposal and reporting on estimates on quantities released on an annual basis, are generally defined and 2) they do not help as such to effectively reduce pellet losses or prevent them (e.g. they are not a requirement on their handling). No methodology is foreseen to measure pellet losses (it was left to the industry to develop a methodology).

At the national level, France is the only Member State who has adopted legislation specifically to prevent pellet losses. This is described in detail in Section 5.1.2. Generally, the very large majority of facilities involved in the pellet conversion or the pellet logistic are too small to attract any public attention and routine visits from the environmental regulators.

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[100] Hann, S., Sherrington, C., Jamieson, O., Hickmann, M., Kershaw, P., Bapasola, A., Cole, G. (2018). Investigating options for reducing releases in the aquatic environment of microplastics emitted by (but not intentionally added in) products, Eunomia.

[101] Commission Regulation (EU) …/… amending Annex XVII to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles.

The absence of specific requirements in EU legislation to implement best handling practices is explained in detail in Annex 8.

2.5 How likely is the problem to persist?

It is likely that without EU action, the problems related to plastic pellets would worsen.

Table 2: Assumptions on whether / how the identified problems will persists

Problem	Assumptions on whether / how this problem persists
(I) Market failure - economic operators do not integrate negative externalities of pellet pollution	• In the absence of external factors (economic crisis, pandemic etc.), the demand and consumption of plastic products is expected to increase. Pellets losses are also expected to continue in the coming years, as without EU action, there are no incentives for economic operators to act, particularly for some actors in the supply chain (e.g. actors with a low public profile). • Recently adopted voluntary initiatives and regulatory actions at Member State level (i.e. France; other MS are mostly relying on industry efforts or waiting for EU action) are expected to lead to some reduction in pellet losses. However, the effectiveness of these initiatives and actions is also likely to remain limited considering current enforcement issues and the lack of enforcement mechanisms in the new initiatives and actions, particularly for some actors in the supply chain (e.g. actors with a low public profile).
(II) Market failure – economic operators do not have sufficient information and awareness as to pellet losses (and consequential impacts)	• As scientific understanding of environmental and human health impacts of pellet pollution is further updated, new risks may be identified and pressure to take action may increase. • Recently adopted voluntary initiatives and regulatory actions are also expected to increase the availability of information. • However, the level and quality of information are likely to remain limited. In particular, competencies, training and awareness of staff for all actors in the supply chain may not improve substantially in the absence of proper and mandatory training requirements. Similarly, accessibility of information may not improve substantially in the absence of proper and mandatory transparency mechanisms.
(III) Regulatory failure, even if some aspects of this can be addressed by ongoing initiatives (REACH reporting obligation)	• The REACH reporting obligation may increase information on pellet losses and improve the quality of the information collected to assess future risks. • However, the obligation is not specific to pellets but generic to all 'derogated uses', and it does not reduce pellet losses or prevent them (e.g. it is not a requirement on their handling). Moreover, in the absence of a harmonised methodology for measuring pellet losses, there will be inconsistencies in estimates reported, and comparing data will be difficult.

3 WHY SHOULD THE EU ACT?

3.1 Legal basis

This initiative is based on Article 192(1) of the Treaty on the Functioning of the European Union (TFEU).

3.2 Subsidiarity: Necessity of EU action

Transboundary nature of the problem

This is the most important aggravating factor and reason to act. Microplastic pollution is readily transported from one geographical place to another by atmosphere and surface waters and seas, and can be found in the most remote places on the planet. National action alone cannot address the problem of transboundary pellet pollution. As an example of this, 60% of European river basin districts are international (either shared between EU Member States or between an EU Member State and a third country), and the Water Framework Directive made cooperation between countries sharing a basin within the EU mandatory. As an answer to this transboundary pollution, the Regional Seas Conventions for the protection of the marine and coastal environment around Europe (for the Mediterranean, Baltic, Northeast Atlantic and the Black Sea) have regional plans against marine litter, including microplastics, and recommend actions to reduce them. In particular, the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) has adopted a non-binding Recommendation[102] containing guidelines to reduce the loss of plastic pellets into the marine environment.

3.3 Subsidiarity: Added value of EU action

There is a clear benefit in taking action at the EU level on pellet losses, as this can efficiently ensure a high level of environmental protection throughout the EU territory, and a harmonised and well-functioning internal market across all Member States (same requirements for pellet pollution prevention and reduction, reduced costs of harmonised approaches). Fragmented approaches, such as national actions on one aspect only of pellet pollution (e.g. measuring), actions not covering the entire pellet supply chain (e.g. producers and converters but not transporters) or actions limited to one or a few Member States, would not bring efficiency gains as they are less effective in reducing transboundary pellet pollution and overall more costly in achieving wider policy goals on reducing releases of microplastics.

Furthermore, the size of the internal market provides a critical mass enabling the EU to promote handling practices that release fewer pellets that could influence the pellet supply chain worldwide. It will also guide EU actions at the global level in the context of the negotiations on a Global Plastic Agreement and at the level of Regional Seas Conventions.

The principle of proportionality requires EU action to be limited in its content and form to what is necessary to achieve the objectives of the Treaties it intends to implement. The application of this principle is linked to the principle of subsidiarity and the need to match the nature and intensity of a given measure to the identified problem. The principle of proportionality is considered throughout the impact assessment and, in particular, in Annex 11 where the costs of the regulatory option for SMEs are assessed.

4 OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1 General objectives

The general objective of this initiative is to contribute to the reduction of microplastic-related pollution by preventing and reducing pellet losses to the environment that are due to current handling

[102] OSPAR Recommendation 2021/06 on the reduction of plastic pellet loss into the marine environment.

pellet practices at all stages of the supply chain within the EU, thus reducing the adverse environmental, economic and potential human health consequences of pellet pollution.

4.2 Specific objectives

Accordingly, the above general objective translates into three specific objectives:

- To reduce and prevent pellet losses in an economically proportionate manner to a level consistent with the Commission's 2030 target of a 30% reduction in both intentional and unintentional microplastic releases (compared to 2016 levels);
- To improve information on the magnitude of pellet losses throughout the pellet supply chain, in particular the accuracy of loss estimates, and to raise awareness among relevant actors; and
- To ensure the appropriate mitigation of impacts on SMEs involved in the pellet supply chain.

5 WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1 What is the baseline from which options are assessed?

The baseline has been developed using 2019 as the base year and the following data sources and assumptions.

- 2019 is taken as the base year, as 2020 is an outlier because of COVID, and we are seeing positive growth trends again from 2021.
- For virgin pellets, the projections are made from 2019 figures[103]; a growth rate of 0.9% per year is assumed till 2030.[104]
- Source for recycled pellets production data (2019-2021) is Plastic Recyclers Europe; a growth rate of 5.6% per year is assumed.[105]
- Source for bio-based pellets production data (2019-2021) is Plastics Europe; for growth rate a CAGR of 14% for 2022-2027[106], and the same trend is assumed to continue till 2030.
- Pellets imports and exports figures for virgin pellets are from Eurostat, a growth rate of 0.9% is assumed till 2030.

Using these assumptions, the total EU pellet production is expected to reach about 80 million tonnes in 2030. If we take into account imports and exports, the net volume of pellets used in the EU would be around 76 million tonnes in 2030. The total figures estimated here are within a 1% range of to the estimates from the recent OECD scenario[107] that used a modelling approach.

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[103] Plastics Europe changed the calculation method in 2021, excluding adhesives, paints and coatings, thus not used to be coherent with previous year estimates and also with import/export figures

[104] Plastics Europe and SystemIQ

[105] K 2022 - Trend Report Europe https://www.k-online.com/en/Media_News/Press/Technical_article/K_2022_-_Trend_Report_Europe

[106] Nova Institute (2023) Bio-based Building Blocks and Polymers Global Capacities, Production and Trends 2022–2027 https://renewable-carbon.eu/publications/product/bio-based-building-blocks-and-polymers-global-capacities-production-and-trends-2022-2027-short-version-pdf/

[107] OECD (2022) Global Plastics Outlook: Policy Scenarios to 2060. https://www.oecd.org/publications/global-plastics-outlook-aa1edf33-en.htm

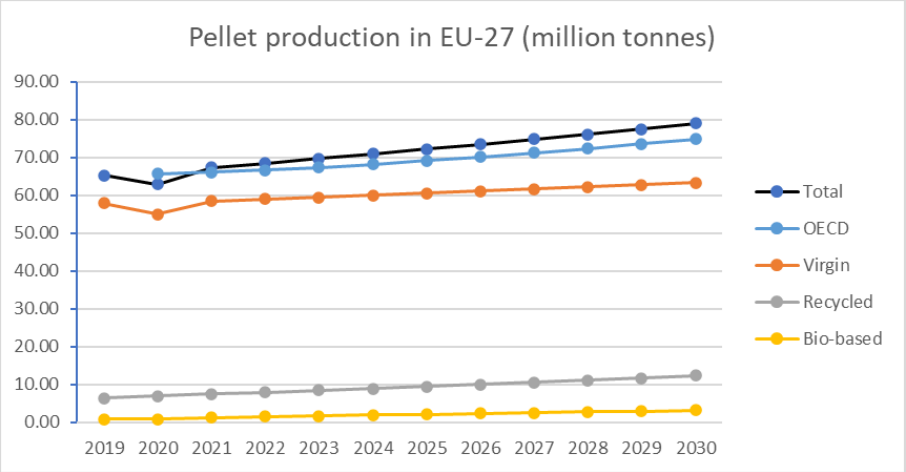


***Figure 5*: Pellet production volumes in EU-27 and projections until 2030**

To define the projected development of total pellet losses by 2030, consideration was given to the following: Existing and forthcoming EU legislation; National and international initiatives; Industry initiatives. These legislation and initiatives are presented below.

5.1.1 Existing and forthcoming EU legislation

The requirement to report estimates of pellet losses under the REACH restriction on microplastics intentionally added to products[108] aims to increase information on pellet losses and improve the quality of the information collected to assess the risks deriving from these microplastics in the future. The reported information aims to allow uses with high releases to be identified and prioritised for further regulatory risk management. However, the requirement does not help as such to effectively reduce pellet losses or prevent them (e.g. it is not a requirement on their handling), and is lacking a methodology to measure pellet losses (it was left to the industry to develop a methodology).

The Marine Strategy Framework Directive (MSFD) addresses the monitoring and assessment of the impacts of microlitter, including microplastics, in coastal and marine environments in a way that they can be linked to point-sources.[109] An update of the first MSFD guidance[110] on monitoring marine litter guidance document is under development in view of harmonised methodologies, including the monitoring of the presence and distribution of plastic pellets along the coastline. However, this does not include specific requirements concerning the prevention or reduction of pellet losses at the source.

The revised Urban Wastewater Treatment Directive (UWWTD)[111] and the evaluation of the Sewage Sludge Directive (SSD)[112] are not explicitly considered in the baseline as (1) the analysis was done

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[108] Commission Regulation (EU) …/… amending Annex XVII to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles.

[109] Directive 2008/56/EC establishing a framework for community action in the field of marine environmental policy: "…micro-litter shall be monitored in the surface layer of the water column and in the seabed sediment and may additionally be monitored on the coastline. Micro-litter shall be monitored in a manner that can be related to point-sources for inputs (such as harbours, marinas, waste-water treatment plants, storm-water effluents), where feasible."

[110] Guidance on Monitoring of Marine Litter in European Seas (europa.eu)

[111] COM/2022/541 final, 2022.

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

at the same time, and (2) more importantly, the measures under consideration for the UWWTD are limited in scope and impact (mainly monitoring and in larger plants, additional treatment to remove microplastics, which would go to sludge). As for the SSD, which is currently being evaluated, it is not clear yet which measures would be proposed in a potential future revision. More information on the links between water legislation and pellet losses is presented in Annex 6.

The Industrial Emissions Directive (IED)[113] regulating the prevention and management of pollution arising from industrial activities in large industrial installations, is only partially suited to address pellet losses as a form of pollution occurring along the entire supply chain. While activities like the production of polymeric materials on an industrial scale fall under the scope of the IED, other activities like the conversion, storage or transport of pellets, usually operated by small and medium enterprises, are not covered. Moreover, the BAT (Best Available Technique) Reference Document (BREF) for the production of polymers was adopted in 2007 and does not address the specific issue of pellet losses.[114]

Waste legislation such as the Waste Framework Directive (WFD)[115] and Packaging and Packaging Waste Directive[116] does not specifically address the pellet loss issue as they do not regulate emissions during the production of products or packaging. The WFD imposes Member States a generic obligation to take waste preventive measures addressing the industrial generation of waste as pellets can be.

Therefore, there is no comprehensive EU legislation addressing pellets to reduce their losses and their environmental and potential health impacts, with a full supply chain approach.

5.1.2 National and international initiatives

A few Member States have already started to introduce measures to tackle pellet losses. These measures are summarised in Table 3 and presented in detail in Annex 6.

Table 3: Member State actions targeting pellet losses

Country	Actions
Austria	• Law adopted addressing "filterable substances" to which pellets belong
Belgium (Flanders)	• Introducing environmental permit system / Best Available Techniques • Examining an environmental management system with possible certification
Denmark	• Monitoring • Waiting for OCS certification scheme implementation and Commission's proposal
France	• Law adopted providing minimum obligations to prevent pellet losses for all actors in the supply chain along with mandatory external auditing
The Netherlands	• Monitoring • Waiting for OCS certification scheme implementation
Spain	• Promoting OCS certification scheme implementation

[113] Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) (recast)
[114] https://eippcb.jrc.ec.europa.eu/reference/production-polymers
[115] Directive 2008/98/EC on waste and repealing certain Directives.
[116] Directive 94/62/EC on packaging and packaging waste.

Sweden	• Revising current guidelines to make them more comprehensive and include more actors across the supply chain

France is the only Member State who has adopted legislation specifically to prevent pellet losses. This legislation covers businesses making and handling pellets in quantities higher than 5 tonnes including logistic platforms but not transporters. The threshold has been reduced from what initially proposed, i.e. 10 tonnes following public consultation. Businesses are subject to equipment and procedural obligations to prevent the loss and leakage of pellets, and are required to be regularly audited by independent and accredited certification bodies.[117] Obligations remain of a relatively generic nature. For instance, a business must identify areas where pellets are more likely to spill, check that the packaging used is designed to minimise the risk of spills and train and raise awareness among staff. As a unique transparency measure, the company must make the summary of the auditing report available on its website. The Decree entered into force on January 1, 2022 for new sites, while for existing sites, it will enter into force in 2023, at the same time as equipment obligations.

In 2021, the British Standards Institution published the Publicly Available Specification PAS 510:2021.[118] This PAS is for use by any organization of any size in any part of the supply chain that handles pellets. It builds on the industry-led Operation Clean Sweep® (OCS) programme by creating a standardized and consistent approach to risk management and containment of pellets.[119] The PAS can be considered for further development as a British standard or constitute part of the UK input into the development of a European or International standard on pellets.

In 2021, the parties to the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) adopted the non-binding Recommendation 2021/06[120] to reduce the loss of plastic pellets in the marine environment by promoting the timely development and implementation of effective and consistent pellet loss prevention standards and certification schemes for the entire plastic supply chain. The Recommendation was accompanied by supporting guidelines which set out essential requirements for standards and certification schemes. The first full implementation report is due in January 2025. However, an interim report on the progress made will be published in 2024. A preliminary interim report was informally shared by OSPAR in February and the actions reported by the Member States that are parties to the OSPAR Convention are presented in the above Table 3.

In the International Maritime Organization (IMO), a Correspondence Group on Marine Plastic Litter from Ships looked at measures that could be relevant in reducing the environmental risk associated with the maritime transport of plastic pellets. While three primary measures including packaging were identified as particularly relevant to reduce the environmental risks associated with the maritime

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[117] Décret no 2021-461 du 16 avril 2021 relatif à la prévention des pertes de granulés de plastiques industriels dans l'environnement [Decree n. 2021-461 of 16 April 2021 related to the prevention of the leakage of industrial plastic pellets into the environment], Journal official "Lois et Décrets" no. 0092 du 18 avril 2021 [JORF] [Official journal "Laws and Decrees" no. 0092 of 18 April 2021], 18 April 2021, Fr.

[118] BSI Knowledge, 'Plastic pellets, flakes and powders. Handling and management throughout the supply chain to prevent their leakage to the environment. Specification - PAS 510:2021101', 2021.

[119] The PAS provides requirements in the following areas: a) Organizational responsibilities; b) Leadership and commitment; c) Competence, training and awareness; d) Risk assessment of pellet loss to the environment; e) Operational controls, i.e. prevention, containment and clean-up, procurement and suppliers; f) Internal and external communication; g) Performance evaluation, i.e. monitoring and documentation, auditing and verification of conformity; h) Improvement, i.e. internal and external non-conformity and corrective action, and continual improvement.

[120] www.ospar.org/convention/strategy

transport of plastic pellets (and a voluntary circular to this effect was drafted), the Group was not in a position to conclude on the most appropriate instrument for mandatory measures.[121] The Group noted that experience gained from the implementation of the voluntary measures could be useful in the further consideration of the most appropriate instrument for mandatory measures.

A similar international initiative is ongoing on containers lost at sea, and discussions are held on the possibility of making the information on containers lost at sea available publicly (to date, sufficient information is reported only to insurance companies). If retained, this measure would allow for a better understanding of the scale and magnitude of pellets lost at sea and would facilitate liability identification and compensation arrangements in line with the polluter pays principle.

5.1.3 Industry initiatives

In 1991, the industry-led Operation Clean Sweep (OCS) initiative was created by SPI (the US Plastics Industry Trade Association, now known as the Plastics Industry Association), with companies voluntarily signing a pledge to work towards zero plastic pellet loss.

Since 2015, the European plastic manufacturing industry has progressively adopted the Operation Clean Sweep® programme (OCS)[122] as a voluntary pledge. Under this programme, each company making or handling pellets recognises the importance of making zero pellet losses by:

1) improving worksite set-up to prevent and address spills;
2) creating and publishing internal procedures to achieve zero pellet losses;
3) providing employee training and accountability for spill prevention, containment, clean-up and disposal;
4) auditing performance regularly;
5) complying with all applicable local and national regulations governing industrial pellet containment;
6) encouraging partners to pursue the same objectives.

Recommendations on how to deliver on each of these six actions are given in the form of a manual.

While best practices are generally well understood by OCS signatories they have not been comprehensively implemented. As of September 2023, 2790 companies have committed to OCS[123]. This figure includes all PlasticsEurope's members (these are producers; adherence to OCS is mandatory for the members of this association). Only around 2% of EuPC's members (converters) have committed to OCS (around 1 000 converters out of 48 000); and only around 500 transport companies. As no precise reporting has been made available within OCS, it is not possible to say whether those who have committed have also effectively or fully implemented the programme, with

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[121] The three primary measures identified as relevant are: Packaging provisions for plastic pellets carried at sea; Provisions for notifying the carrier so that containers containing plastic pellets can be identified; Stowage provisions for freight containers containing plastic pellets. Among the options for mandatory measures, the Group considered the three following options/instruments: Assignment of an individual UN Number (class 9) for plastic pellets transported at sea in freight containers (UN Number); Amendment to Appendix I of MARPOL Annex III that would recognize plastic pellets as a "harmful substance" (Harmful substance); A new chapter to MARPOL Annex III that would prescribe requirements for the transport of plastic pellets in freight containers without classifying the cargo as a harmful substance/dangerous goods.

[122] www.opcleansweep.eu

[123] www.opcleansweep.eu

evidence showing the opposite. Both acute and chronic pellet incidents have been reported to continue over the last years, including at sites that are OCS signatories.[124]

The launch of the OCS Certification Scheme (OCS CS) aims to address these issues. Recognising the low uptake of OCS by the industry, in 2019, European plastic manufacturers (PlasticsEurope) and converters (EuPC) announced plans to develop a voluntary certification scheme building on OCS and including requirements, third-party, independent auditing, certification and some level of transparency (all aspects not foreseen under the current OCS programme). In January 2023, the new scheme was officially launched by its promoters following preparatory work by a Supervisory Board gathering producers, converters, representatives of some governments (Scotland, Germany and Spain), one NGO (Fauna & Flora International), some certification bodies (Aenor and Tuv-Nord) as well as one European Institution (the European Parliament). Representatives of the European Commission, the European Chemical Transport Association (ECTA) and Cefic took part in the discussions as observers.

Under the new scheme, companies are invited to comply with requirements from the following broad categories:

- Commit to making zero loss of pellets, flakes, and powder a priority;
- Improve worksite set to prevent and address spills, meaning site risk assessments;
- Create and publish internal procedures to achieve zero pellet loss goals meaning documented procedures, including, for instance, description of roles and responsibilities, but also recording, investigation and follow-up of incidents and effectiveness of procedures, equipment and instructions in place;
- Provide employee training, including theory and practical hands-on exercises and accountability for spill prevention, containment, clean-up and disposal;
- Audit performance regularly, meaning internal audits;
- Comply with all applicable local and national regulations governing pellet containment;
- Encourage partners to pursue the same objectives to be monitored, for instance, via the % of contracts containing an OCS clause.

Compliance will be verified at site level by third-party independent auditors. Once successfully audited, companies will be certified compliant and will have the name of the company and the site location listed in a public register. The certification will be valid for 3 years after the date of the first audit, subject to an annual follow-up control audit. First audits started in June 2023.

While it goes in the right direction, the new scheme does not encompass the whole supply chain and is, therefore, only a partial attempt to pursue zero pellet pollution effectively. First of all, while the requirements are in principle applicable to all companies handling pellets, and all companies can get audited and certified, the new scheme does not apply to the whole supply chain in the same way: it is mandatory for members of PlasticsEurope (adherence to the existing OCS programme is already mandatory for them) but is for the moment voluntary for key players in the pellet supply chain such as converters, transporters, warehousing operators and recyclers.

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[124] Regarding chronic pellet losses in the Netherlands, Belgium and Spain, see https://www.plasticsoupfoundation.org/wp-content/uploads/2022/03/Westerschelde-plastic-nurdles-versie-definitief-21-11-2021-2.pdf; https://surfrider.eu/en/learn/news/ecaussinnes-belgium-surfrider-foundation-tackles-industrial-plastic-granules-1211028228325.html; https://goodkarmaprojects.org/2020/11/20/new-report-out-exposes-alarming-impacts-of-plastic-pellets-across-europe/?lang=en.

EuPC found it difficult to make adherence to the new scheme mandatory for their members (to date, adherence of converters to the existing OCS programme is very low). Members of EuPC are European and national associations representing close to 48 000 individual companies, out of which 66% are micro-companies. It is estimated that while the certification process is carried out over a relatively short period of time for producers (PlasticsEurope expect all their members to be certified by the end of 2024, some producers reporting however a longer period before certifying all their sites), this process will likely take much longer for converters, with no assurance that it would cover a major part of converters at all.

Transporters, warehousing operators and clean tankers are observers of the new OCS certification scheme and will be assessed (not certified) under the chemical industry's Safety and Quality Assessment for Sustainability (SQAS) system, which contains revised requirements to tackle pellet losses since March 2023[125]. Full alignment between the new OCS certification scheme and the SQAS system is still pending. In particular, there are no plans currently to oblige OCS-certified companies to work exclusively with SQAS-assessed transport, warehousing and cleaning companies. To date, there are approximately 3 000 transport companies which are SQAS-assessed and even more transport companies which are not SQAS-assessed. According to the sector, SQAS-assessed transport companies cover about 80% of the total pellet transport of virgin pellet producers in Europe. Cleaning stations are mostly SQAS assessed, while among warehousing operators, only a part is SQAS assessed.

To test the new scheme, nine pilot audits covering producers, converters and transporters were held in 2021 in five countries: Belgium, Netherlands, Portugal, Spain and France. The audits are conducted by well-known boddies like Aenor, Bureau Veritas, SGS, etc. All audited companies failed to pass.

At the end of 2021, Fauna and Flora International (FFI) decided to resign from the Supervisory Board of the new OCS certification scheme arguing that it does not fully align with the OSPAR Recommendation and citing issues with the governance of the scheme, the level of transparency, the lack of a formal standard from a recognised standardisation body, the fact that the whole supply chain is not captured adequately and that timelines for compliance have not been set. Instead, FFI called for the introduction of effective legislation applicable to all pellet handling companies and based on a supply chain approach to fully eliminate this source of pollution[126].

Recyclers are neither promoters nor observers of the new scheme and have their own certification scheme in place (RecyClass), which has a section on pellet losses requiring the implementation of a procedure to prevent leakages within the premises of and surrounding the recycling plant and the training of staff. To go a step further, recyclers are conducting a study on potential areas in the recycling processes where microplastics can be generated and released and on preventive measures. The recommendations of this study would be used to complete the RecyClass certification scheme on the pellet losses/microplastics requirements.

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[125] SQAS questionnaires. A first addition to the SQAS assessment questionnaire was made in January 2022.

[126] FFI call for the introduction of effective legislation that will require all pellet (flake and powder) handling companies across the whole supply chain to provide independent verification that pellet loss prevention measures have been implemented, maintained and monitored for effectiveness towards the goal of zero pellet loss to the environment, prior to materials being placed on the market. They also call for tighter restrictions on the packaging and labelling of pellets being prepared for transport to reduce the risk of loss and improve communication. Finally, EU legislation should complement international maritime legislation for pellets currently being considered by IMO to reduce the risk of catastrophic pellet pollution at sea.

5.1.4 The baseline

All in all, the above national and international initiatives are expected to contribute to a limited change in pellet loss reduction by 2030. The only national legislation adopted to prevent pellet losses via legal obligations (i.e. France) is relatively generic and does not cover transporters. An assumed reduction is considered for France. Both the BSI PAS and the OSPAR Recommendation provide are reference documents in the field as they provide a comprehensive but non-binding set of guidelines. However, in both cases, it is up to the companies or parties to implement such measures, and it was not possible, at the moment of the impact assessment, to evaluate their precise implementation. The IMO work on pellets focuses on one aspect only i.e. shipping of pellets, and has resulted so far in voluntary measures only, with very limited effects up to date.

Once fully in place, the new industry-led OCS certification scheme is expected to contribute to some reduction in pellet losses by 2030. However, the new scheme does not adopt a full supply chain approach and uncertainties persist about its enforceability. In particular, it is difficult to estimate the take-up of the new scheme by the industry, and therefore its effectiveness, and this counts equally for the schemes by the recyclers and logistic companies (respectively, RecyClass and SQAS). It is generally expected that smaller firms will implement voluntary schemes to a lesser degree than larger ones. This results in different assumptions for the producers (larger firms) compared to converters and logistics (smaller firms).

Therefore, for the baseline, it has been assumed that by 2030:

1) 90% of the total virgin pellet volume produced (by the members of Plastics Europe) and 5% for the non-Plastics Europe members will be certified compliant against OCS new rules and will be effectively implementing such rules with a success rate ranging from 60% to 80%;

2) 20% of the total recycled pellet volume will be certified compliant against RecyClass pellet provisions and will be effectively implementing the new provisions with a success rate ranging from 40% to 60%;

3) 30% of the total volume processed will be certified compliant against OCS' new rules and will be effectively implementing such rules with a success rate ranging from 40% to 60%;

4) 40% of the total volume handled by logistics companies will be SQAS assessed and will be effectively implementing such a scheme with a success rate ranging from 40% to 60%.

5) The French legislation will cover about 85% of the French pellet volume (about 10% of the EU volume), leading to a 60-80% pellet loss reduction in 2030.

Based on these assumptions, there will still be pellets lost in the range of 42 050 – 170 266 tonnes per year by 2030.

5.2 Description of policy options assessed in this impact assessment

This impact assessment considers four policy options addressing the general and specific objectives defined under Section 4. These options were selected based on literature review and input from stakeholders, either bilateral or in six stakeholder workshops, and a seventh workshop organised in December 2022 to specifically address pellets, the related baseline and preferred option. Information provided in response to the Inception Impact Assessment and the Public Consultation was also taken into account along with the findings of a survey carried out between January and February 2023 specifically targeting SMEs active in the pellet supply chain as requirements would affect them more

than larger companies. Each selected option has been screened from a longer list of potential options developed with experts and stakeholders that are presented in detail in Annex 10. As the IA focussed on measures with direct impact and in alignment with the Commission's overall 30% reduction target by 2030, research actions were screened out at an early stage. However, they might still be needed to foster further innovation in actions that could have an impact in the longer term. It was also estimated that a full value chain approach should be privileged in order to assure that all parts would implement pellet reduction measures.

5.2.1 Option 1: Mandatory standardised methodology to measure pellet losses

Focus: Develop a mandatory standardised methodology to measure pellet losses.

Description: under this option, the Commission initiates the development of a mandatory standardised methodology to measure pellet losses from the range of relevant pellet-related industrial activities (i.e. production, conversion, recycling, transport and other logistic operations), to be used for the reporting on estimates of quantities released on an annual basis, as obliged under the REACH restriction. Reporting is needed to increase information on pellet losses and improve the quality of the information collected to assess the risks deriving from these microplastics in the future. This methodology would need to be coherent with the requirements of the restriction. The new standard will improve the quality of the reporting on the quantities released (one methodology for all instead of several, different ones) improving the information on the magnitude of pellet losses throughout the pellet supply chain, while also raising awareness among relevant actors as they can measure pellet spills and losses and assess their evolution over time.

This option would be developed via the European Standards Organisation (CEN), which typically takes 3-4 years to complete. The umbrella association of European converters (EuPC) is developing for the OCS certification scheme signatories a methodology for measuring pellet losses, named the Bow-tie model, and this work can serve as the basis of the mandatory harmonised methodology.

This option addresses mainly the problem drivers of market (imperfect information), but also of regulatory failures and support to SMEs. It would address the information failure problem and allow for the effective implementation of the other options. Indeed, a standard methodology is essential to monitor the implementation of Option 2 and the evolution of pellet losses. It would facilitate the comparison of different packaging solutions for pellets, under Option 3. It would also be necessary to set up an EU target under Option 4. It is therefore the best and fastest option to address information failure on pellets and monitor the possible success of the options.

5.2.2 Option 2: Mandatory requirements to prevent and reduce pellet losses in a new EU law

Focus: Impose mandatory requirements on proper handling of plastic pellets combined with mandatory certification.

Description: under this option, mandatory requirements are defined and imposed on the entire pellet supply chain thus maximising the opportunities of preventing and reducing pellet losses. The requirements to comply with at the site level are based on those already identified by stakeholders in the framework of the BSI PAS and OSPAR recommendation and the industry-led OCS certification scheme. Firms will need to provide evidence of the following:

1. The creation and publication of internal procedures such as defining organisational responsibilities, a pellet loss prevention policy with pellet loss prevention objectives, a regular risk mapping exercise and corresponding risk management assessment at site level;

2. Competence, training and awareness of staff to prevent, contain and clean up spills including maintaining a record of spills;
3. Operational controls including preventive, mitigating and clean up measures and equipment;
4. Communication of implemented policies, measures and objectives both within the organisation and externally, as well as of improvement as reaction to non-conformity.

A risk mapping exercise needs to be performed to identify the leakage potential of all necessary, handling steps in all high-risk areas and pathways to the external environment. Once this is done, there needs to be a risk management assessment performed to determine where actions are required for equipment, best practice handling, mitigation and remediation.

Knowing that the first step should be to avoid all unnecessary handling of pellets, preventive barriers include "Avoidance of unnecessary handling" (as the possibility of minimising the number of transfer points in the supply chain is the starting point for reducing spill opportunities) and "Best practice handling". The latter can take the form of collection and retention trays. Mitigation and clean-up measures can take the form of filters, vacuum systems to remove accumulated pellets, and tools for immediate cleaning (shovel, broom, brush, vacuum cleaner).

To demonstrate compliance with the defined mandatory requirements, all pellet handling companies including transporters and logistic platforms must be externally audited and certified at the site level by independent certifying bodies selected among accredited organisms, as a condition to operate. This implementation approach is consistent with the OSPAR Recommendation, adopted by OSPAR contracting parties including the EU and 11 Member States, which promotes certification schemes for the entire supply chain. It is fully in line with the polluter pays principle as companies are required to bear the compliance costs referring to the needed measures. It allows for a harmonised implementation across the EU as a whole, ensuring a level playing field among operators in the single market. Certification obligations will be imposed in a phased manner. Once externally audited, companies or the auditors must notify the public authority about the outcome of the external audit (i.e. whether the site was successfully certified as compliant or not, following the external audit). In the case of non-compliance, the public authorities in the Member States are responsible for imposing corrective measures and, where relevant, penalties.

This option does not include reduction targets and it is assumed that over a period of time the certification process will deliver results. Once the measure under Option 1 is in place, the reduction targets could possibly be defined. The measure under Option 1 would enable measuring its possible success rate.

In light of concerns raised during a targeted SME consultation, **three sub-options were assessed** in the form of:

- lighter requirements for the micro companies (sub-Option 2a);
- lighter requirements for the micro and the small companies (sub-Option 2b); and
- lighter requirements for the micro, the small and the medium companies in the pellet supply chain (sub-Option 2c)

The possibility of lighter requirements was only considered for micro-, small and medium companies because large operators (mainly producers) did not raise concerns about the economic burden of complying with mandatory requirements during stakeholder consultations and bilateral meetings. Instead, they indicated that as long as these requirements would build on existing industry best practices (e.g. Operation Clean Sweep) then they would be relatively straightforward and quick to implement. In addition, the relative cost of these requirements is low for large entreprises.

This option addresses the problem drivers of market and regulatory failures, as well as support to SMEs.

5.2.3 Option 3: Improved packaging for pellet logistics

Focus: Impose packaging provisions for pellet logistics.

Description: this option imposes the use of specific types of bags and containers for transport, intermediate storage and handling during these operations. It aims to ensure that all bags and containers used for pellet logistics (transport, intermediate storage) are environmentally sealed, airtight and puncture-resistant to prevent damage and tears, which could lead to pellet losses. It can be set up as an independent legislation or can be implemented as part of the legal proposal in Option 2.

This option addresses the problem drivers of market and regulatory failures.

5.2.4 Option 4: EU target to reduce pellet losses

Focus: Introduce EU target to reduce pellet losses

Description: this option is to establish an EU emission reduction target for pellet losses in line with the Commission's overall microplastic releases reduction target of 30% by 2030. Companies must introduce the same preventive, mitigation and clean up measures as in Option 2. Each Member State must introduce the necessary transposing legislation and measures to ensure delivery, including compliance assurance, reporting by economic operators to track progress against the target, and enforcement. Periodic reporting by national public authorities to the Commission would also be necessary to ensure delivery and appropriate remedial action in case of shortfall in reducing pellet losses.

This first requires the establishment of a mandatory standardised methodology to measure pellet losses (Option 1). Without it, it would be challenging to establish a baseline and measure the achievement/non-achievement of the established target.

This option addresses the problem driver of regulatory failure.

5.3 Options discarded at an early stage

Overall, 173 ideas were identified during desk research and in stakeholder workshops. The main discarded ideas are presented below.

Voluntary commitments like the one under the industry-driven OCS and in particular its new certification scheme were considered as suitable options to address the identified problem driver 'Market failure (prices do not reflect negative externalities)'. It was discarded as the new scheme was in the meantime launched by its promoters. Therefore, this impact assessment considers such commitment as part of the baseline. In Annex 6, the actions of industry are detailed.

The option of developing voluntary verification of best practices using well-designed standards and certification schemes is ongoing under the work of the Commission of the regional convention for the protection of the Marine Environment of the North-East Atlantic (OSPAR) and in the framework of the above mentioned industry efforts. Therefore, this impact assessment considers such development as part of the baseline. Also, certification is an essential part of Option 2.

Information/awareness raising on the handling of pellets throughout the pellet supply chain, and the development of a universal information leaflet and labelling for packaging of plastic pellets for their transport, were not considered as suitable options as they are already partially covered by OCS, they would not trigger sufficient change, and where appropriate, they would be better taken up by the mandatory requirements in Option 2.

Training obligations (with regular updates) for all actors in the pellet supply chain are not sufficient as stand-alone measure, but would be better taken up by the mandatory requirements in Option 2. Indeed, training is an essential part of this option.

The possibility of using the Industrial Emissions Directive[127] to address pellet losses at relevant installations was discarded on the ground of effectiveness, efficiency and relevance. The IED is not suited to address pellet losses as a form of pollution occurring along the entire supply chain. While activities like the production of polymeric materials on an industrial scale fall under the scope of the IED, other activities like the conversion, transport or storage of pellets, usually operated by small and medium enterprises, are not covered. Moreover, the BAT Reference Document (BREF) for the production of polymers was adopted in 2007 and does not address the specific issue of pellet losses.

Supporting SMEs, including via financial incentives, is integrated in Option 2 as a way to mitigate the regulatory burden on SMEs.

The possibility of setting extended producer responsibility schemes and environmental damage remediation funds, financed by industry, were discarded on the ground of technical feasibility and relevance. EPR targets a product, while for pellets, we have different types of "producers", those who manufacture the pellets, those who transform them into a product etc. Also, EPR aims to tackle the end-of-life, i.e. when the product becomes waste, while for pellets, it is a diffused pollution issue along the entire supply chain.

An initiative on classifying pellets as a "harmful substance" in the International Maritime Law is currently already ongoing in the International Maritime Organization with the support of the European Union. At the same time, the Ship Source Pollution Directive[128] is under revision, and one of the options could be to extend the scope of this Directive to cover this provision. Therefore, while addressing the maritime transport of pellets by means of more stringent packaging or stowing provisions may help reduce pellet losses at sea, this impact assessment considers such initiatives as part of the baseline. The same applies to developing a mandatory reporting system for containers lost at sea in international waters.

5.4 The intervention logic

The diagram below illustrates the logical connection between the problem, its drivers and the specific objectives and policy options, which are assessed in Section 6.

[127] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (recast).

[128] Directive 2005/35/EC of the European Parliament and of the Council of 7 September 2005 on ship-source pollution and on the introduction of penalties, including criminal penalties, for pollution offences.

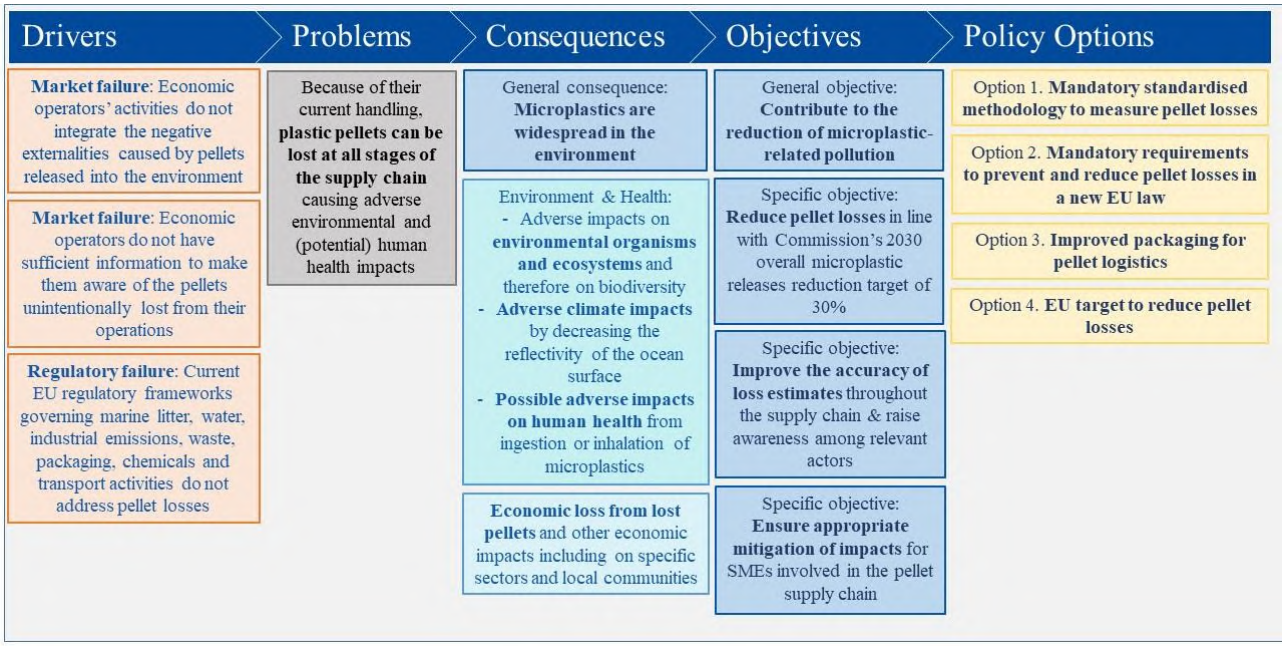


Figure 6: The intervention logic

6 WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

Each policy option is assessed as regards its expected environmental, economic and social consequences, as well as the costs and administrative burden it is likely to cause. This is based on a qualitative and, where possible, quantitative assessment. All calculations are made in relation to the baseline for 2030.

This assessment places particular focus on the pellet loss reduction that is possible under each policy option as a contribution to the Commission's 30% reduction target on microplastic releases to the environment (compared to releases in 2016).

Environmental consequences mainly refer to the specific objective of reducing 'pellet losses to a level consistent with the Commission's 30% reduction target'. A degree of uncertainty remains around the impact of the policy options on pellet losses as the baseline pellet loss data is based on incomplete data, as highlighted and addressed by the use of ranges to present pellet losses. Assumptions, including on the impact of policy options on pellet loss rates, are explained in Annex 4. Monetising benefits on the environment (e.g. benefits on ecosystems and biodiversity) is difficult due to the lack of available data. That is why a qualitative analysis is added.

Economic consequences refer to both the direct and indirect economic costs and benefits that are generated from taking measures to reduce pellet losses. Taking measures to reduce pellet losses will have positive knock-on economic effects on the pellet industry such as reduced waste, modernised equipment, improved reputation, a level playing field among operators and the economic gain of fewer pellets lost. These effects also include the positive knock-on economic effects on activities that are affected by pellet losses (i.e. commercial fishing, agriculture as well as recreation and tourism in affected areas). Taking measures will, however, generate direct compliance costs for the sector (both adjustment and administrative costs), especially for SMEs.

Social consequences mainly refer to whether the policy option increases or decreases the creation of jobs.

The administrative cost / burden on public authorities depends on the degree to which public authorities are involved in the design, implementation or enforcement of the policy option.

The benefit to cost assessments are relative to the other options to allow for more effective comparison of the different options. These impacts are presented in detail in Annex 11, along with the stakeholder groups affected. The following coding is used to present the likely impacts.

Table 4: Coding used to present likely impacts (relative scale)*

Score	Description
+++	Very significant direct positive impact or benefit
++	Significant direct positive impact or benefit
+	Small direct positive impact or benefit
(+)	Indirect positive impact or benefit
+/-	Both direct positive and negative impacts, and balance depends on how implemented
0	No impact or only very indirect impacts
(-)	Indirect negative impact or cost
-	Small direct negative impact or cost
--	Significant direct negative impact or cost
---	Very significant direct negative impact or cost
High	High benefits significantly outweigh costs of measure
Medium	Medium benefits on balance outweigh costs of measure
Low	Low benefits close to or even below costs of measure
Uncertain	Potential high benefits, but significant questions as to whether the measure can deliver outcome

(*): The benefit to cost comparison is done in a relative scale, not in absolute values. Indications of "high/medium/low" reflect therefor the comparison with the other option. E.g., "high" means that the benefit to cost ration of the option is higher than for the option that has "medium".

6.1 Option 1: Mandatory standardised methodology to measure pellet losses

Table 5: Summary of impacts of Option 1

Consequences/Impacts				**Assessment and considerations**	**Benefit to cost**
Environmental	Economic	Social	Cost		
(+)	(+)	0	(+)	A mandatory standardised methodology benefits all the other options by replying to the information failure. While it can imply some (development and testing) costs for the sector (but these might be taken up by the Commission), it will still result in cost savings as only one method needs to be developed and applied, also leading to lower verification costs. The benefit to cost ratio is considered to be high because the multiple benefits outlined above outweigh the costs of developing this methodology.	**High**

Under this option, there are **no direct reductions of pellet losses, but a mandatory standardised methodology to measure such losses.** Such a methodology will enable relevant actors to tackle pellet losses, thus reducing the impacts on the environment. One methodology for all will be used, instead of several, different ones that otherwise might be developed. The common standard will simplify the reporting on the quantities released improving also the information on the magnitude and evolution of pellet losses throughout the pellet supply chain, and raising awareness among

relevant actors. Setting reporting obligation is a necessary step to measure any reduction measure's success rate.

This option benefits all other options as the magnitude of pellet losses is a critical knowledge gap which requires a standardised measurement methodology. In addition, it will contribute to their effective implementation and monitoring their success rate.

No significant social impacts are expected.

This option entails **both costs and cost savings**. The cost of developing (and testing) the methodology is one-off and depends on the time required to develop the methodology. The European Standards Organisation (CEN) typically takes 3-4 years to complete the process. Either the industry could bear this cost, or the Commission could provide support through a dedicated study. The latter approach is more likely if the standard has to be taken up in legislation.

When developing the common standard, CEN could take into account the methodology that is being developed under the OCS certification scheme.

This assessment has estimated the cost of developing the common standard to be between EUR 558 087 (12 months development) and EUR 1 674 263 (36 months development). The testing at one facility costs about EUR 700-1500 per test, depending on the installation size. Assuming that about 1 000 installations test the standard during the development phase, the testing therefore costs between EUR 700 000 and EUR 1 500 000. The total costs would thus be between EUR 1 258 000 and EUR 3 174 000 (rounded figures). As the common standard would be based on developments under the OSC certifications scheme, it is estimated that the lower end of the cost estimation is more likely.

The implementation costs incurred to use the common standard, once this is developed and tested, are already considered under the REACH restriction (as part of the reporting costs) and do not need to be taken into account here as the scope of companies is basically the same as it is in the REACH restriction and its requirement to report pellet losses (the REACH restriction encompasses all uses, while the upcoming pellet proposal would be limited to uses above 5 tonnes). These costs would consist of the costs for the companies to set up specific reporting systems and for the public authority to set up verification and evaluation systems[129].

At the same time, imposing a standardised methodology to measure pellet losses has the potential to save costs on different levels:

- The plastic industry is developing a methodology, however, it is not clear how much such a method would be accepted by the whole value chain. Some parts of the value chain and Member States might also develop a methodology on their own. Under Option 1, there is only one cost for developing the methodology, and not several;
- More importantly, businesses have to apply only one methodology in the different parts of the supply chain and in different countries; and
- The verification and evaluation of the reporting by the public authority is simplified.

[129] For the Committee for Socio-economic Analysis (SEAC), established under REACH, the total costs of reporting could be substantial as the number of companies affected is likely to be large. SEAC considers that there are different options to reduce such costs, e.g. by excluding certain actors (small or micro-sized companies) from the requirement or by setting a threshold for microplastics volumes used or released to be reported. However, SEAC did not draw a firm conclusion on how these different options would compromise the value of information obtained and hence the benefits of reporting in terms of facilitating better risk management.

While it is difficult to do an exact cost-benefit assessment, the cost savings would be higher than the development costs of the standard. These cost savings are fully in line with the Communication COM(2021) 219 final on joining forces to make better laws[130].

Stakeholder views: Stakeholders generally agree on this option. In the targeted SMEs consultation conducted early 2023, a standardised methodology to measure pellet spills and losses was mentioned by 51% of respondents as a support measure that could best help them to take action to reduce pellet losses. The testing costs for one facility would be around EUR 700 per test, which means a proportionally greater cost for small compared to large companies. However, these costs are already covered under the REACH restriction.

Summary: This is the basis for setting up the framework to measure pellet losses and thus fundamental for monitoring pellet losses and their evolution in the future. This option will therefore be instrumental to achieving the objective of improving the availability of data on pellet losses. It will facilitate and improve the quality of the reporting on pellet losses required by the REACH restriction on intentionally added microplastics. Coherence with the REACH restriction will need to be assured. It will also raise awareness among relevant actors as they can measure pellet spills and losses and assess their evolution over time. While an exact cost-benefit assessment could not be made, the cost savings are expected to be higher than the development costs of the standard.The measures in this option are considered to be proportional to the objectives it aims to achieve.

[130] COM(2021) 219 final of 29 April 2021 on joining forces ro make better laws.

6.2 Option 2: Mandatory requirements to prevent and reduce pellet losses in a new EU law

Table 6: Summary of impacts of Option 2 and suboptions

	Impacts				Assessment and considerations	Benefit - cost
	Env	Eco	Soc	Cost		
2	+++	+	+	---	Mandatory requirements & certification have the highest reduction in pellet losses, and highest direct compliance costs for the sector. This option was awarded a medium benefit to cost ratio because while there are costs associated with these requirements for both authorities and industry, the benefits to the environment, human health and affected communities still outweigh these costs. However, relative to option 2b it scores a bit less good.	**Medium**
2a	+++	+	+	--	The reduction of pellet losses is still very high, but costs are lower than under 2 thanks to lighter requirements for micro-enterprises. This sub-option has a medium benefit to cost ratio because the benefits outweigh the associated costs, but a bit less good then 2b.	**Medium**
2b	+++	+	+	-	Reduction of pellet losses is still very high; costs are lower than under 2a thanks to lighter requirements for micro- & small enterprises. This sub-option has a high benefit to cost ratio because the economic operators for whom associated costs would be the most burdensome, are subject to lighter requirements, which reduces costs. The benefits are still high and therefore significantly outweigh the costs compared to the other options.	**High**
2c	++	+	+	-	The reduction of pellet losses is lower than under the other sub-options, and costs are only slightly lower than under Option 2b due to lighter requirements for micro-, small, and medium enterprises. This sub-option has a medium benefit to cost ratio because while the costs to industry have been significantly lowered, the resulting benefits have also lowered due to more companies being eligible for the lighter requirements. The lower costs for medium enterprises are less important than for micro- and small ones.	**Medium**

In this option, imposing mandatory requirements and certification for all pellet handling companies is the EU's responsibility, while the sector bears the costs of the measures to implement and of the audits, and the public authorities in the Member States are responsible, in the case of non-compliance, for imposing corrective measures and, where relevant, penalties.

As it is a mandatory approach covering the full supply chain with explicit requirements, a certification obligation and checks and enforcement activities by public authorities in the case of non-compliance, we estimate that the sector will have a high degree of compliance (95% of the total virgin pellet volume handled) and will be effectively implementing such rules with a success rate ranging from 80 to 95% (meaning that pellet losses would reduce with these percentages).

The economic impacts are primarily related to the direct compliance costs for the sector of implementing the measures. **Lighter requirements are assessed for SMEs in sub-options**. The environmental impacts are primarily related to the environmental benefits associated with the reductions in pellet losses. **A derogation for companies making and handling pellets in quantities**

lower than 5 tonnes also applies (as done in the existing French legislation[131] - this limit was decided as a consequence of a public consultation in France), which avoids requiring costly investments with very limited environmental benefits in terms of pellet loss reduction.

Environmental impacts

As this option requires that all actors of the supply chain comply with mandatory requirements and certification (with the only exception of companies making and handling pellets in quantities lower than 5 tonnes), the main expected environmental impact from this option is **a significant reduction of pellet losses** that are likely to be harmful to ecosystems and biodiversity and may affect human health.

Under this option, the reduction of pellet losses is expected to be between 27 128 tonnes/year (low emission scenario) and 148 879 tonnes/year (high emission scenario), representing respectively a 65% and 87% reduction overall, compared to the baseline. This also leads to a saving of 106 to 583 $ktCO_2e$, representing 11 – 58 M€/year in savings[132].

When providing for lighter requirements for the micro-enterprises, the reduction of pellet losses ranges from 26 730 tonnes/year to 147 227 tonnes/year (105 – 576 $ktCO_2e$). With lighter requirements for the micro- and small enterprises, the reduction of pellet losses ranges from 25 142 tonnes/year to 140 621 tonnes/year (98 – 551 $ktCO_2e$). Similarly, with lighter requirements for micro-, small and medium-enterprises, the reduction of pellet losses ranges from 21 569 tonnes/year to 125 757 tonnes/year (84 – 492 $ktCO_2e$).

Economic impacts

This option will entail **both economic benefits and costs**. These are presented below with the indication of the stakeholder group affected.

Direct compliance costs for the sector

There is limited direct information available regarding the costs to companies of taking measures to adhere with best practice handling over the value chain. Discussions with stakeholders in the course of this IA suggest that the costs of implementing Option 2 would be limited for some parts of the plastics industry, as these actors (producers and some converters and logistic companies) are already moving towards measures and a system of external auditing and certification based on OCS. At the same time, costs of this option vary significantly according to the types of companies. For example, micro and small companies (which constitute 89% of all converters in numbers, but only 20% in terms of turnover) would be significantly affected by the costs incurred by the upgrade of their facilities, the introduction of procedures including internal and external audit and the training of their personnel. There is also a significant number of transport companies handling pellets.

Stakeholder views: the NGOs active in the field have strongly supported harmonised minimum requirements for pellet handling to be established at the EU level, along with a comprehensive and transparent certification scheme requiring a secure chain of custody. The umbrella association of European manufacturers, PlasticsEurope, has agreed that the most effective approach to tackling

[131] Décret no 2021-461 du 16 avril 2021 relatif à la prévention des pertes de granulés de plastiques industriels dans l'environnement [Decree n. 2021-461 of 16 April 2021 related to the prevention of the leakage of industrial plastic pellets into the environment], Journal official "Lois et Décrets" no. 0092 du 18 avril 2021 [JORF] [Official journal "Laws and Decrees" no. 0092 of 18 April 2021], 18 April 2021, Fr.

[132] 1 tonne of CO^2 estimated value is 100 €/t.

pellet losses is mandatory external auditing and certification building on OCS and applied to all actors throughout the supply chain. Producers therefore consider a legislative proposal requiring certification of an OCS-like pellet loss prevention management system would be very quickly implementable throughout the whole supply chain because it would benefit from the existing industry initiative and would reinforce it. The umbrella association of European converters, EuPC, has pointed to limited resources as a barrier to implementing voluntary measures under the industry-driven OCS programme. The umbrella association of European recyclers, PRE, favour an EU-wide legally binding instrument to enable a level-playing field in the single market among all actors in the supply chain and across all Member States.

A second consultation targeting all SMEs handling pellets was conducted from January to February 2023 in all EU languages (Annex 12). Based on the 330 replies received, it emerges that a majority of respondents prefers a lighter version of requirements. Specifically, they reported that the requirement on the training of staff should be made mandatory in the same way for all companies, but the obligation of being externally audited and certified should not be imposed on SMEs. The survey also indicates that the direct economic impacts of this option would be too high to be sustainable for micro and small companies, as well as companies with capacities below 1000 t. Among the various best handling practices, the mandatory use of specific equipment and of specific packaging (i.e. airtight, puncture-resistant and environmentally sealed) is identified as the most expensive measure. Generally, the cost per tonne of the measures to be implemented would become insignificant for companies with capacities above 5000 t. Finally, financial support and standardised methodology to measure pellet losses are identified as the support that would best help respondents.

Costs of Option 2 are presented in Annex 11. They were calculated using industry estimates, where available, on one hand, for producers (including recyclers) and converters and, on the other hand, for logistic operators (transporters and storage/warehouse operators). As the industry has already started implementing some of the proposed measures through their voluntary commitments (i.e. OCS CS, RecyClass and SQAS), some of these costs are already incurred under the baseline.

The costs were calculated for micro, small, medium and large plastic enterprises. The upfront investment costs and costs per tonne of pellets handled are relatively more important for SMEs, especially for micro-and small enterprises than for other enterprises. It was therefore estimated that lighter requirements would be needed to alleviate a part of these costs to mitigate concerns from SMEs (e.g. lack of staff/time, lack of information on risks and solutions and lack of financial resources). This is also consistent with the replies and requests received throughout the stakeholder consultations. In light of the above, **three sub-options were assessed** in the form of:

- lighter requirements for the micro companies (sub-Option 2a);
- lighter requirements for the micro and the small companies (sub-Option 2b); and
- lighter requirements for the micro, the small and the medium companies present in the pellet supply chain (sub-Option 2c).

These lighter requirements include, for example, additional time before entry into force of the requirements and for renewal of the certificate and no costly investments (in particular into sewage treatment system). It is estimated that this lighter regime will help reduce the costs of compliance by 10% (e.g. due to less paperwork).

The costs of applying lighter requirements for micro, small and medium sized companies for typical plant capacities are presented in Annex 11. With these reduced requirements, we assume that the pellet losses will be 35% higher from converters and 20% higher from logistics providers than under the main scenario. This assumption means that the remaining requirements are still the most important ones to reduce pellet losses, but that there is already a significant increase in pellet loss.

Overall, the cost of implementing Option 2 would be 742 and that of sub-options 2a, 2b, and 2c would be 615, 516 and 479 million EUR/year respectively.

In particular for the converters, the lighter requirements reduced the cost per tonne to about half of the ones under Option 2. For medium enterprises, this difference is smaller. Option 2 represented already less than 0,5% of their turnover. An important reasons for the relatively high cost of converters compared to the producers is that it is assumed that producers would already subscribe to the OCS CS, while only a limited number of converters would do so.

The cost-effectiveness of the options ranges from 2 672 EUR/tonne avoided per year to 26 342 EUR/tonne avoided per year, depending on the sub-option and the lower/higher estimation of losses.

What would the costs be for the public authorities?

The costs will depend on its implementation in Member States, which may vary significantly. The focus is on administrative costs, including monitoring, delays, complaint-handling mechanism, and access to justice. Further costs for competent authorities can be related to the setting up and maintaining of the system, including enforcement of the regulation. However, it may be covered by existing systems through other legislation. In addition, the public authorities in the Member States could be required to hold a public register of certified companies to ensure full transparency and traceability of the supply chain and compliance with the requirements. This registry could be set up in pre-existing systems to lower the costs. There might also be minor reporting costs (188 000 € per year) for the economic operators (to notify the outcome of the certification), as reporting already exists under REACH (see option 1).

The processing and enforcement costs for the public authorities in the Member States would be EUR 313 000 for the first year and EUR 125 000 per year for the whole EU (see Annex 11). These cost will vary across Member States as they would be higher for larger ones and lower for smaller ones.

What would the benefits be for the sector?

For businesses owning the pellets, this option could prevent the estimated economic loss of EUR 42 to 170 million associated with about 42 050 to 170 266 tonnes of pellets being lost per year (1000 EUR/t)[133].

For SMEs implementing similar requirements under the international initiative of the BSI PAS, the following benefits were reported:

- modernised equipment thanks to grants they secured;
- less legacy pellet pollution, which had previously been extensive around the sites;
- reduced waste (and lower waste management costs);
- improved staff awareness and training;
- reduced fire risk because proper and regular site assessments revealed build-up of dust in areas previously unchecked;
- involvement of suppliers/customers – all site visitors are required to read and accept rules relating to proper pellet management; and
- improved reputation.

[133] Prices of plastics are fluctuating and depend on the exact polymer type and the stage of processing.

What would the benefits be for the economy at large and society?

Under this option, reducing pellet losses may have positive knock-on economic impacts on sectors such as commercial fishing, agriculture, tourism and recreation, in areas where these activities are affected by the releases with significant harm to ecosystems and biodiversity. In particular, there would be fewer pellets lost to the marine environment and, thus, fewer perturbations to all marine organisms, including economically important organisms such as oyster and seabass[134]. Considering that the ecosystem services provided by the oceans are estimated to be worth over USD 24 trillion, the regulation of microplastics to help the protection of marine ecosystems and organisms seem to be of significant importance[135]. Similarly, there would be fewer pellets lost in the installations' wastewater and in the sludge resulting from their treatment. Consequently, there will be less pellets lost to the soil after the application of sludge on agricultural land.

Benefits would also include avoided costs to society such as those related to clean up and remediation activities by local communities that are affected by the releases, that are normally challenging to these communities in terms of technological, human and financial resources.

Social impacts

This measure requires additional staff to prevent pellet losses and for training. With the same assumptions made on the share of the volume between micro, small, medium and large factories, implementing the measure would need from 3 772 to 4 103 FTE personnel.

Since this option may increase the cost of plastic raw materials, the general public may be impacted by an increase in the cost of plastic goods. Since plastic is used everywhere, any increase in its cost is felt in society. However, the cost increase is likely to be limited as the cost of the measure is small compared to the turnover of the sector. For large companies, in particular, it is possible that the manufacturer would absorb such a slight increase in its production costs and that consumers would be unaffected.

Summary: The introduction of mandatory requirements and certification would result in significant reductions of pellet losses and plug a clear regulatory gap. This option would therefore be critical to achieving the overall objective of this initiative of preventing and reducing pellet losses, while mitigating its impacts on SMEs through its sub-options. The more losses are avoided, the greater the positive impacts are for the environment and for economic activities like commercial fishing, agriculture, tourism and recreation. The costs incurred by the sector under Option 2 and its sub-options (without micro/without micro and small /without micro, small and medium companies) may increase the cost of plastic goods produced and/or converted in the EU.

This option has less risks as to the probability of reaching the objectives and massively reduces the number of free riders that exist in the voluntary approach. The system is set up in a way to limit public costs as it involves third party auditing and certification. The possibility of a public register of certified companies at national level would further increase the transparency and traceability of the supply chain, with limited processing costs for the public authorities in the Member States. The measures in this Option are therefore considered proportional to its objective.

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[134] Zhu, X. et al. (2020) 'Bioaccumulation of microplastics and its in vivo interactions with trace metals in edible oysters', Marine Pollution Bulletin, 154, 111079. doi: https://doi.org/10.1016/j.marpolbul.2020.111079 83 Barboza, L.G.A et al. (2018) 'Microplastics cause neurotoxicity, oxidative damage and energy-related changes and interact with the bioaccumulation of mercury in the European seabass, Dicentrarchus labrax (Linnaeus, 1758)', Aquatic Toxicology, 195, pp. 49-57. doi: https://doi.org/10.1016/j.aquatox.2017.12.008.

[135] WWF Report 2015; Reviving the ocean economy

Although the net costs of sub-option 2c are only slightly lower than sub-option 2b, the reduction in pellet losses is also lower so sub-option 2c's effectiveness and efficiency are slightly lower than 2b's. In addition, the reductions in costs are much more significant for micro- and small companies (under option 2b) than medium companies (option 2c). Indeed, the costs to comply with requirements represent less than 0.5% of medium companies' turnover. Therefore, option 2c alleviates costs which are less significant for medium enterprises, while significantly reducing the reduction of pellets lost to the environment. In contrast, option 2b significantly alleviates the burden of the costs for micro- and small enterprises, while nevertheless achieving a relatively high reduction in pellet losses.

The comparison of different options 2 and its sub-options 2a-c needs to take into account what the ranges consist of (lower and higher figures under each option). The ranges are determined by the uncertainty around pellet loss. Therefor, when comparing these ranges, one should always keep in mind to compare either a low pellet loss scenario, a high pellet loss scenario or any intermediate one. Therefore, the lower end figure of the costs of option 2 is linked with a lower end figure of the costs of the other options 2a, 2b or 2c as these are all linked with the scenario of lower pellets losses. Higher costs within the range of a specific option should be compared with the higher costs within a range of another option, as they are linked to higher pellet reductions.

Table 7: Summary of impacts in 2030 of Option 2 and sub-options 2a, 2b and 2c

	Option 2	**Option 2a: Lighter requirements for micro-enterprises**	**Option 2b: Lighter requirements for micro-and small enterprises**	**Option 2c: Lighter requirements for micro-, small and medium-enterprises**
Environmental impacts (reduced pellet losses) (tonnes)	27 128 – 148 879	26 730 – 147 227	25 142 – 140 621	21 569 – 125 757
Environmental impact (Savings of GHG emission) (tonnes of CO^2 eq)	106 210 – 582 890	104 655 – 576 424	98 437 – 550 560	84 446 – 492 366
Reduction in trucks (number, of 25 t microplastics)	1085 – 5595	1069 – 5889	1006 – 5625	863 – 5030
Economic impacts				
Cost of the measure (MEUR/y)	742	615	516	479
Savings from the pellet losses (MEUR/y)	27 – 149	27 – 147	25 – 141	22 – 126
Net cost to businesses (MEUR/y)*	593 – 715	468 – 588	376 – 491	353 – 457
Cost-effectiveness (EUR/tonne/y)	3 982 – 26 342	3 177 – 22 005	2 672 – 19 536	2 805 – 21 186

	Option 2	Option 2a: Lighter requirements for micro-enterprises	Option 2b: Lighter requirements for micro-and small enterprises	Option 2c: Lighter requirements for micro-, small and medium-enterprises
Savings from GHG emission (MEUR/y)	11 – 58	10 – 58	10 – 55	8 – 49
Other economic impacts	**Public Administrations**: increased costs for data collection (i.e. public register) and overall monitoring of the implementation, intervention in case of non-compliance (i.e. enforcement of the sanctions) **Citizens**: limited increase of the cost of plastics goods **Tourism and recreation:** increased attractivity through the reduction of pellets in coastal areas and other vulnerable areas **Fisheries:** fewer pellets released in water and improved ecosystem services due to fewer pellets absorbed by marine organisms and animals in areas affected **Agriculture:** fewer pellets released on soils and improved ecosystem services due to fewer pellets affecting soil properties in areas affected **Society**: fewer costs related to clean up and remediation activities by local communities in affected areas			
Social impacts (jobs in FTE)	4 103	4 004	3 858	3 772

*Net cost: cost – savings. In every option there are 2 scenarios of the projection of the pellet losses. Therefore, higher pellet loss reduction refers to lower costs and vice versa.

6.3 Option 3: Improved packaging for logistics of pellets

Table 8: Summary of impacts of Option 3

Consequences/Impacts				Assessment and considerations	Benefit to cost
Env	Eco	Soc	Cost		
+	-	0	--	Improved packaging reduces pellet losses throughout the supply chain (not quantified), but generates more GHG emissions (subject to the packaging type), while entailing potentially quite high investment costs for the sector. This option's benefit to cost ratio is considered medium to low because while it could significantly reduce pellet losses, its costs could be high for industry.	**Medium to Low**

This option specifically targets the producers of plastic pellets and logistics operators to prevent and reduce pellet losses from transport (in case of re-packaging), intermediate storage and handling during these operations. It could also be included in the mandatory requirements under Option 2.

Current packaging materials used to transport pellets are:

- plastic bags (up to 25kg of pellets) stacked on pallets;
- octabins (cardboard containers containing between 0.5 and 1.3 tonnes of pellets);
- big bags, containing from 0.5 to 1 tonne of pellets;
- containers, containing up to 25 tonnes of pellets; and
- silo trucks, containing up to 35 tonnes of pellets.

These different packaging materials do not present the same pellet loss risks, with plastic bags holding the most risks for pellet losses and silo trucks the least. However, the plastic bags also hold several advantages over rigid HDPE barrels and intermediate bulk containers (IBC) because they allow for more flexibility in the size of shipments and prevent dust contamination. They also allow for more volume to be transported per unit of transport, thus reducing GHG emissions and transport costs. Silo trucks have airtight suction mechanisms and the loading and unloading of these trucks leave little room for pellet spills, but if they are spilled, then they are collected for disposal.

Plastic bags are the packaging material which would be targeted first because of their poor resistance to tears during operations. OSPAR[136] mentions that plastic bags and octabins could be replaced with reusable rigid HDPE barrels or with IBC (Intermediate bulk containers). Replacing existing machinery and processes might also generate extra costs. Another approach could be to propose thicker plastics bags which are more resistant to tears. The IMO Correspondence Group on Marine Plastic Litter from Ships considered packaging provisions for plastic pellets carried at sea as primary measures to take forward for further assessment.

The proposal for a packaging and packaging waste regulation[137] includes a provision that requires transport packaging to be reusable. The impact of this proposal was not examined as the focus of this option is on the increased resistance of packaging.

Environmental impacts

This option could **potentially significantly reduce pellet losses** during logistics operations (transport, intermediate storage and handling during these operations) thus bringing potentially significant environmental benefits. However, there is not data available to quantify the losses due to torn plastic bags or octabins. Also, replacing plastic bags with alternatives would increase GHG emissions. Indeed, rigid HDPE barrels and IBC do not offer the same flexibility as plastic bags. When not entirely filled up with material, they increase storage volume for a given quantity of material, increasing the GHG emissions incurred by the storage. If thicker bags would be chosen, there would only be a minor increase of GHG emissions (due to more use of plastics).

Economic impacts

What would the costs of this option be for the sector?

This option could **potentially entail quite high costs**, especially for producers, who may have to change their production lines since plastic bags are automatically filled on-site through their own manufacturing chain, and for SMEs. Similarly, logistics operators would have to adapt their transport and storage approaches depending on the type of packaging. However, due to important data gaps, it was not possible to quantify the direct compliance costs (mainly investment costs) for the sector deriving from this option.

The cost per tonne of pellet losses avoided is expected to be higher than with Option 2 because it would force the industry to overhaul their production lines to effectively remove the bagging lines and replace for instance plastic bags with reusable and resistant rigid HDPE barrels or IBC. Imposing thicker more resistant plastic bags could lower such costs. However, as all these solutions mainly represent an investment cost, smaller enterprises would be affected more than bigger ones respective to their size.

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[136] OSPAR Commission, Background document on pre-production plastic pellets, 2018, https://www.ospar.org/documents?v=39764. Accessed 12 Apr 2022.

[137] COM(2022) 677 final. Proposal Packaging and Packaging Waste (europa.eu)

Social impacts

There are no social impacts foreseen for this measure. However, moving towards more automated solutions like silo trucks could reduce the number of jobs (more workforce is needed for manual loading and unloading of pellet containers/bags).

Stakeholder views: NGOs often emphasise the importance of improving packaging to reduce pellet losses, while industry is less convinced, especially in light of the expected high costs of improved packaging. Plastics Europe, representing producers, considers that addressing packaging does not address the root cause of the problem. From the second consultation conducted early 2023 targeting all SMEs handling pellets, it emerged that while two-thirds of respondents consider the use of specific packaging effective to reduce pellet losses, only 54% do it always or often (and a third never does it or has no opinion). Views on whether this should become a mandatory requirement are mixed: 33% in favour, 20% in favour if lighter requirements for SMEs, and 27% against, while the use of specific packaging is estimated as the most costly measure both in terms of person/days and euros/tonne/year. Financial support was identified as the support that would best help respondents along with a standardised methodology to measure pellet losses.

Summary: The use of more resistant packaging materials and spill-proof packaging options would reduce pellet losses throughout the supply chain. However, the impacts differ according to the type of improved packaging chosen. While switching out plastic bags for barrels would likely present a greater reduction in losses, it would also increase the GHG emissions and costs of transport, in addition to require greater investment costs (as infrastructure will need to be replaced). Opting for thicker more resistant plastic bags would avoid these investment costs and allow for greater volumes to be transported per unit of transport. This option could be incorporated into a more comprehensive set of requirements, such as those laid out in Option 2. Therefore, while this option would help contribute to a reduction in pellet losses at certain stages of the value chain (eg. transport), it is considered to be less effective than the more comprehensive Option 2. Due to the high associated investment costs and the impact on pellet losses being limited to transport, the measures in this Option were not considered proportional to the overall objectives of this initiative.

6.4 Option 4: EU target to reduce pellet losses

Table 9: Summary of impacts of Option 4

Consequences/Impacts				**Assessment and considerations**	**Bene fit to cost**
Env	Eco	Soc	Cost		
++	+	+	---	An EU emission target has potentially a high reduction of pellet losses, as operators have to adopt preventive, mitigation and clean-up measures, but the enforcement might be challenging. Its costs are comparable / slightly higher than those of Option 2 and higher than those under sub-options 2a-c. As it depends on Option 1, it can only be implemented afterwards, leading to a delay in implementation time. This option is considered to have a low benefit to cost ratio because while its costs are similar to option 2, its benefits would be delayed and will likely not be as high due to the challenges linked to its enforcement.	**Low**

An EU emission reduction target for pellet losses is set in this option. This option can only be achieved in the medium to long term as it first requires the establishment of a mandatory standardised methodology to measure pellet losses (Option 1) (including its testing in various sites of different

sizes over a significant period of minimum 12 months). Further to that, knowledge should be gathered on quantities released, through the REACH reporting requirement, before implementing this option. Once developed, the standard would need to be applied over 12 to 36 months to generate a statistically strong database including prevention, mitigation and clean-up measures. The target could be defined as the result of this observation phase.

The target could be set either for the whole plastics industry, or at sector level. In the latter case, there could be differentiated targets depending on the place in the supply chain. These approaches are presented in Annex 11.

This measure could be implemented by including the emission threshold in legislation. It is a medium to long-term measure, as time is necessary for the data to become available and for identifying the relevant threshold. Once the threshold is defined, it could be possible to include it in legislation.

Environmental impacts

The reductions of pellet losses are expected to be in the same order of magnitude as in Option 2. However, **implementation and enforcement by Member States seem more challenging in this option than in Option 2, which might lead to less reduction of pellet losses**.

Economic impacts

The costs of this option are expected to be comparable to those in Option 2 as similar prevention, mitigation and clean-up measures would be implemented. The cost of setting the target would depend on the mandatory standardised methodology developed under Option 1.

However, other considerations seem equally important, **possibly increasing costs of this option compared to those of Option 2**. First, accurate monitoring following the standardised methodology developed under Option 1 would be needed to ensure that the target is respected (not included in Option 2 which focuses on mandatory requirements and certification). Further, each Member State must introduce the necessary transposing legislation and measures to ensure delivery, including compliance assurance, reporting by economic operators to track progress against the target and enforcement. Periodic reporting by national public authorities to the Commission would also be necessary to ensure delivery and appropriate remedial action in case of shortfall in reducing pellet losses. Similarly to Option 2, lighter requirements would be needed for SMEs, especially for micro- and small firms, as achieving the same reduction objective would be more costly for smaller than larger firms.

Social impacts

The main social impact is additional job creation mainly for the industry (for reducing pellet losses and reporting) and some for competent authorities (for enforcement) – these are relatively similar to Option 2.

Stakeholder views: This option was not discussed by stakeholders in detail. It was however mentioned that setting up a performance monitoring system would be costly.

Summary: Defining an EU emission reduction target for pellet losses, once a mandatory standardised methodology has been developed, tested and applied, can significantly reduce pellet losses as it requires preventive, mitigation and clean-up measures to be taken. Both implementation and enforcement are the tasks of the Member States, which are required to introduce transposing legislation and measures to ensure delivery. However, this option only looks at the objective, and not at the means to achieve it. It requires setting up a new system, instead of fully benefiting from the existing good practices in industry, such as under OCS. Implementing a reduction target will also take considerably more time. For these reasons, this Option is considered to be as efficient as Option

2 but less effective. It leaves it up to Member States to design their own regimes so this Option is nevertheless considered proportional to the objectives of the initiative.

7 HOW DO THE OPTIONS COMPARE?

The qualitative analysis and comparison of the different options is done in a relative scale as there is few evidence on absolute values. Also, using ranges for the estimation of the costs in options is linked to the respective pellet loss. Option 1 has the potential to benefit all options by improving information on and accuracy of pellet losses, thus ensuring the identified information failure is tackled. It also presents synergies with the REACH reporting requirement on estimates of quantities released. It is therefore considered that all options should build upon option 1 to ensure all identified problems are addressed in the preferred option. Option 2 significantly contributes to the Commission's 2030 overall microplastic releases reduction target, as proposed in the Zero Pollution Action Plan, increasing policy coherence, and its sub-options 2a-c respond to the need to limit EU action to what is necessary and proportional by building on industry commitments and by providing lighter requirements for smaller businesses. While there was not enough data to calculate the exact costs of Option 3, this option would entail quite high investment costs for the sector, and it was estimated that the cost effectiveness of this option would be lower than for Option 2. Option 4 requires a performance monitoring system first, which would take time, its implementation seems more challenging and its costs would be slightly higher than under Option 2 (because of Member State involvement) and its sub-options 2a-c. This option is not favoured in the short term.

Although the exact impact of each option cannot be assessed in detailed way, the relative scale to compare different options will show which option would be relatively the best option and therefor the preferred option. The estimation of costs is linked to the pellet volume that would be lost (in case of higher costs there would be lower pellet losses and in case of lower costs there would be higher pellet losses). The net costs per tonne avoided microplastic emission of the preferred policy option are 3-4 times lower than costs under the REACH restriction[138] on microplastics intentionally added to products. The net costs of the options can also be compared to those calculated in the Impact Assessment for single-use plastics (SUP), for the relevant Directive[139] (see section 8.2.1).

There are some data gaps and uncertainties in the comparison of different options. The principal uncertainty comes from the pellet loss rates used for production, recycling, processing and logistics phases. There are uncertainties regarding the potential success of existing and upcoming measures on the reduction of pellet loss. There are data gaps on the structure of the sector (except for converters and producers), as well as on the exact costs and benefits that should be attributed under the different options, leading to some uncertainties. Therefore, assumptions are used (more detail can be found in Annex 4). Table 10 gives an overview of how the assessed policy options compare.

[138] Commission Regulation (EU) …/… amending Annex XVII to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles.

[139] SWD(2018) 254 final (EUR-Lex - 52018SC0254 - EN - EUR-Lex (europa.eu))

Table 10: Summary of impacts of all options (and sub-options)

	Impacts				**Assessment and considerations**	**Benefit - cost**[140]
Option	Env	Eco	Soc	Cost		
1	**(+)**	**(+)**	**0**	**(+)**	A mandatory standardised methodology benefits all other options as it targets the information failure. While it can imply costs (development and testing) for the sector (or the Commission can take this up), it will result in cost savings as only one method needs to be developed and applied, also leading to lower verification costs.	**High**
2	+++	+	+	---	Mandatory requirements and certification have the highest reduction in pellet losses, with the highest direct compliance costs for the sector.	**Medium**
2a	+++	+	+	--	The reduction of pellet losses is still very high, but costs are lower than under Option 2 thanks to lighter requirements for micro-enterprises.	**Medium**
2b	+++	+	+	-	The reduction of pellet losses is still very high, and costs are lower than under Option 2a thanks to lighter requirements for micro- and small enterprises. This has the highest cost-effectiveness of the (sub)options 2, 2a-c.	**High**
2c	++	+	+	-	The reduction of pellet losses is lower than under the other sub-options, and costs are only slightly lower than under Option 2b due to lighter requirements for micro-, small, and medium enterprises.	**Medium**
3	+	-	**0**	--	Improved packaging reduces pellet losses throughout the supply chain (not quantified) but generates more GHG emissions (subject to the packaging type), while entailing potentially quite high investment costs for the sector.	**Medium - Low**
4	++	+	+	---	An EU emission target has potentially a high reduction of pellet losses, as operators have to adopt preventive, mitigation and clean-up measures, but the implementation and enforcement might be challenging. Its costs are comparable / slightly higher than those of Option 2 and higher than those under suboptions 2a-c. As it depends on Option 1, it can only be implemented afterwards, leading to a delay in implementation time.	**Low**

Table 11 provides an overview of the relative effectiveness, efficiency, coherence and proportionality of the options assessed in this initiative.

A simple relative scoring system has been used to assess each option along the dimensions of effectiveness, efficiency, coherence and proportionality ranging from "+" to "++++" with "+" being the lowest score and "++++" the highest. Brackets "(+)" indicate a half-point. Effectiveness considers how successful each option would be in achieving or progressing towards the objectives of this initiative. Efficiency considers the resources used by each option to achieve the desired changed.

[140] The benefit to cost comparison is done in a relative scale, not in absolute values. Indications of "high/medium/low" reflect therefor the comparison with the other option.

Coherence considers how each option fits with existing or forthcoming EU legislation. Proportionality considers whether the means required by each option are suitable and necessary to achieve the desired end. These assessments are based on each option's relative costs, economic, environmental and social impacts, laid out in Section 6.

Table 11: Comparison of options according to effectiveness, efficiency, coherence and proportionality

Option	Effectiveness	Efficiency	Coherence	Proportionality
1	++	++++	+++	++++
2	+++	++	++++	++
2a	+++	+++	++++	++
2b	+++	++++	++++	+++
2c	++(+)	+++(+)	++++	+++
3	++	+	++++	++
4	++	+++	++++	+++

Explanation of the scores (relative scale, based on impacts described in Table 7 and Table 10):

- Effectiveness: No option got score "++++" as each option would need other option(s) to be most effective. Options 2 and sub-Options 2a and 2b scored "+++" as being most effective options to achieve the objectives outlined in section 4 (better information and reduce pellet loss). Sub-Option 2c has slightly lower effectiveness with less pellet loss reduced than previous options, scored "++(+). Options 1, 3 and 4 have scored "++" as having lower effectiveness than Options 2 and sub-Options 2a-2c with less clear evidence on achieving the objectives.

- Efficiency: Options 1 and sub-Option 2b scored "++++" with Option 1 requiring low costs and sub-Option 2b being the most cost-efficient. Sub-Options 2c, 2a and Option 2 have a decreasing degree of pellet loss versus costs. Option 4 scored "+++" having high costs, but also high impacts. Option 3, with high costs and limited reduction in pellet losses, scored "+".

- Coherence: All options, besides Option 1, got the highest score as being coherent with existing or forthcoming EU legislation. Option 1 got lower score "+++" due its linkages to REACH legislation where coherence is slightly less (but it can be managed).

- Proportionality: Option 1 got highest score "++++" as being the basis of achieving the objectives. Sub-Options 2b, 2c and Option 4 got scored "+++" as being proportional regarding the costs and impacts they would achieve, but lower than Option 1. Options 2 and sub-Option 2a got scored "++" considering the costs and impacts they would entail. Option 3 got scored "++" due to the high associated investment costs and the impact on pellet loss reduction being limited to transport.

8 PREFERRED OPTION

8.1 Elements of the preferred option

Following the analysis of the different policy options, a preferred option has been constructed with a view to addressing the problem identified in section 2 and achieving the specific objectives outlined in section 4, in particular contributing to the Commission's 2030 overall reduction target.

The preferred policy option is a combination of Option 1 (Mandatory standardised methodology to measure pellet losses) and sub-Option 2b (Mandatory requirements in a new EU law with lighter requirements for micro and small companies). The identified problem is about the mishandling of pellets by businesses and consequential impacts, so public intervention is warranted.

Option 1 is needed to address the specific objective "To improve information on the magnitude of pellet losses throughout the pellet supply chain, in particular the accuracy of loss estimates". This will be done through the REACH reporting requirement, which would be applied to all companies. In that context, it could also be decided to exclude companies handling less than 5 tonnes per year.

Sub-Option 2b is needed to address the specific objective "To reduce and prevent pellet losses in an economically proportionate manner to a level consistent with the Commission's overall microplastic releases reduction target of 30% by 2030" and the specific objective "To ensure the appropriate mitigation of impacts on SMEs involved in the pellet supply chain". This assessment shows that **sub-Option 2b has the highest benefit-to-cost ratio**. It also aligns with the results of the targeted SME survey where micro- and small companies expressed the main concerns about the burden of complying with mandatory requirements. It will have a strongly positive environmental impact in terms of reduced pellet losses compared to the baseline, reducing microplastic pollution, preserving ecosystems and biodiversity and decreasing potential health impacts. Indeed, it could reduce pellet releases into the environment by 60% to 83% compared to the baseline. The reduction potential is expressed using a range due to a lack of reliable and comparable data creating uncertainty around the baseline figure for pellet losses. However, the comparison of the different options is relatively more certain as it shows how options rank as a relative scale is used to compare different options (see Table 10). This sub-option should represent on average a 7%[141] reduction of the total amount of microplastic releases. It is estimated that this initiative will contribute to around 1/4th of the Commission's 30% reduction target for microplastics.

Sub-Option 2b will have positive knock-on economic impacts on sectors such as commercial fishing, wastewater management, agriculture, recreation and tourism. It will also increase transparency and significantly reduce the number of free riders. Costs for business (65 000 companies are expected to be impacted of which 7 700 are medium or large companies) are expected to be higher in the beginning as some initial investments are needed to be done. There will also be a learning curve which will reduce process costs later on. However, costs are mitigated for micro and small companies, and kept within acceptable limits for the other companies, ensuring a level playing field in the single market (reinforcing the position of companies applying reduction measures vis-à-vis companies not applying such measures). Those companies could also benefit from phased implementation, financial and non-financial support (see examples in Annex 13). In light of the impacts of microplastics (including pellets) on the environment and possibly health, it was judged that the benefits of significantly reducing microplastic releases (by 1/4th) would outweigh the additional cost for industry. In addition, the existing industry scheme OCS has been mainly taken up by larger companies who produce pellets, meaning that most of the pellets value chain does not abide

[141] Based on 2018 data.

by these best practices. It is also difficult to assess the successful implementation of OCS and therefore whether it is significantly reducing pellet losses. Option 2 addresses these issues by ensuring all actors in the supply chain are subject to these requirements (thus preventing free riders and levelling the playing field), and enforcing implementation of the requirements (thus reducing pellet losses to the environment).

There is a balance to be sought between the magnitude of cost effects, in particular on SMEs, and reducing pellet losses. It is observed that the preferred policy option reaches the appropriate balance, but should the college want to go further, additional lighter requirements (not foreseen in sub-Option 2b) are described, mainly for micro- and small companies. These additional lighter requirements would help reduce further administrative costs for micro-, small and medium companies, along with carriers transporting pellets, but are assumed to increase pellet losses. Box 4 captures all requirements for all operators, including additional lighter requirements conceived to mitigate further burden on SMEs. As carriers do not have permanent facilities, they also warrant a differentiated approach.

Box 4: Overview of all requirements for all operators, including additional lighter requirements conceived for SMEs (the latter <u>not</u> yet foreseen in sub-Option 2b)

A standard to measure pellet losses will be requested to help tackle the market and regulatory failure and facilitate companies' reporting on pellet losses, as required by the REACH restriction.

Large companies (Operators with 250 or more employees) with a capacity of over 1000t/year will be subject to the following regime:

(1) Set up, implement and keep up-to-date a risk assessment;
(2) Train their staff;
(3) Monitor and keep records of relevant implementation actions and of estimates of losses;
(4) Internal assessment to monitor compliance with the pellet handling requirements, plus some other additional requirements (i.e. formal management meetings reviewing compliance and awareness and training programme);
(5) External audit by certifiers, based on data from internal assessment, to monitor compliance; and
(6) Certification, using the results of the external audit, to certify compliance and be listed in a public register set up by public authorities in Member States.

Medium companies (operators with 50 to 249 employees) with a capacity of over 1000t/year will be subject to the following regime:

(1) Set up, implement and regularly review a risk assessment;
(2) Train their staff;
(3) Monitor and keep records of relevant implementation actions and of estimates of losses;
(4) Internal assessment to monitor compliance with the pellet handling requirements, plus some other additional requirements (i.e. formal management meetings reviewing compliance and awareness and training programme);
(5) External audit by certifiers, based on data from internal assessment, to monitor compliance; and
(6) Certification, using the results of the external audit, to certify compliance and be listed in a public register set up by Member States, with a longer transitional period before first certification (36 months instead of 24) and longer validity of the certificate (four years instead of three).

Micro- and small companies (operators with fewer than 50 employees) and companies with a capacity of less than 1000t/year will be subject to the following regime:

(1) Set up, implement and keep up-to-date a risk assessment; the risk assessment is sent to public authorities in Member States alongside the self-declaration (below) and made available to them on demand at all times;
(2) Train their staff;
(3) Monitor and keep records of relevant implementation actions and of estimates of losses;

(4) No obligation of independent, third-party certification but self-declaration of compliance, as well as a longer validity of their assessment (five years);
(5) No obligation to carry out internal assessments;
(6) No obligation to review compliance assessments at formal management meetings; and
(7) No obligation to establish an awareness and training programme and schedule.

Carriers providing transport of pellets will be subject to the following regime:

(1) Implement actions to prevent, contain and clean up losses;
(2) Train their staff;
(3) Monitor and keep records of relevant implementation actions and of estimates of losses;
(4) No obligation to carry out internal assessments;
(5) No obligation to obtain certification, or third-party environmental audit;
(6) No obligation to acquire certain equipment;
(7) No obligation to review compliance assessments at formal management meetings; and
(8) No obligation to establish an awareness and training programme and schedule;

Stakeholder feedback: In the OPC responses (Annex 2), stakeholders agree that there is improper handling of pellets. There is also awareness that the measures undertaken so far are voluntary, at the industry level, which needs more control to ensure compliance. The NGOs active in the field as well as a group of Member States have strongly supported a regulatory approach at the EU level as the only way to tackle pellet losses effectively. Converters have pointed to high costs and limited resources as a barrier to implementing mandatory requirements, especially for SMEs. Producers have considered a legislative proposal requiring certification of an OCS-like pellet loss prevention management system as quickly implementable throughout the whole supply chain because it would benefit from the existing industry initiative and would reinforce it.

This assessment showed that the preferred policy option does not go beyond what is necessary to achieve the objectives of the initiative. It aligns with what the industry had indicated would be appropriate to effectively reduce pellet losses, and includes lighter requirements for micro and small companies, who had indicated the necessity of this.

Table 12: Preferred policy option gives an overview of the preferred policy option, based on the comparison of options and the analysis of synergies and complementarities across options.

Table 12: Preferred policy option

Preferred option	Benefit to cost[142]
Mandatory standardised methodology (Option 1)	**High**
Mandatory requirements (sub-Option 2.b lighter requirements for micro- and small companies)	**High**

[142] The benefit to cost comparison is done in a relative scale, not in absolute values. Indications of "high/medium/low" reflect therefor the comparison with the other option.

Table 13 summarises the policy options that are not retained to their full extent (these may be still addressed partially, also due to positive spill-over effects from the preferred policy option).

Table 13: Discarded policy options

Options discarded	Benefit to cost
Mandatory requirements (Option 2)	**Medium**
Mandatory requirements (sub-Option 2.a lighter requirements for micro-companies)	**Medium**
Mandatory requirements (sub-Option 2.c lighter requirements for micro-, small and medium companies)	**Medium**
Improved packaging for pellets logistics (Option 3)	**Medium - Low**
EU target to reduce pellet losses (Option 4)	**Low**

8.2 Impacts of the preferred policy option

8.2.1 Costs and benefits

The following table sets out the different types of costs and benefits of the preferred option – more information is available on this in Annex 3.

Table 14: Overview of the preferred policy option's benefits and costs

Benefits	
Direct	The preferred option will reduce pellet losses to the environment by 2030 with 25 142 to 140 621 tonnes (saving 98 – 551ktCO_2e). This will benefit the environment and society thanks to higher environmental quality. There will be positive knock-on economic benefits including job creation.
	The measurement standard will help improve understanding around pellet loss quantities, pathways and impacts by increasing the quality and availability of data on pellet losses. This will allow industry to adapt their operations to reduce pellet losses, and enable public authorities to monitor more effectively reduction measures.
	The measurement standard will also make it easier for industry to measure their pellet losses and for authorities to collect and verify data related to pellet losses, leading to cost savings.
	The preferred option will help the level playing field in the single market across the supply chain in the EU and improve the global reputation of the EU industry around environmental protection.
Indirect	It will decrease possible risks to human health. It is a precautionary measure.
	It will increase employee safety by reducing injury risks, due to fewer pellet spills to the work floor.
	It will result in healthier soil and water due to less pellets directly lost or indirectly through the use of sewage sludge, improving ecosystem services and benefiting agriculture and fisheries.
	It will reduce the quantities of pellets in affected areas, thus benefiting tourism and recreation.
	It will prevent local populations from having to finance clean-up operations following losses.

Costs					
Citizens/consumers		Businesses		Administrations	
One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
None	Possible minor increase in the price of plastic products.	Developing a measurement standard will entail adjustment costs of EUR 1.3 to 3.2 million, but compensated by recurrent savings in reporting.	Applying the new requirements will cost an additional EUR 376 – 491 million (including administrative costs). Businesses could absorb these or pass them on to consumers.	Costs if the EU directly supports the development of the measurement standard.	There will be minor costs for Member States associated with the processing of the certification and enforcement of the regulation EUR 125 000 per year for the whole EU).
		Operators need to adapt their administrative procedures to the new requirements, entailing one off costs (EUR 0.1 million)[143].	Businesses will face administrative costs for internal assessments, external auditing and certification of about EUR 43.9 million): - internal assessment – EUR 30.8 million - external audit and/or certificate – EUR 12.9 million - filling forms and tables – EUR 0.2 million (for notifying public authorities of the certification).	Costs to set up at national level a public register of certified companies (EUR 36 700[144] per year for the whole EU).	

There is a balance to be sought between the magnitude of cost effects, in particular on SMEs, and reducing pellet losses. It is observed that the preferred policy option reaches the appropriate balance, but should the college want to got further, additional lighter requirements (not foreseen in sub-option 2b) are assessed. These additional lighter requirements would help reduce further administrative costs for micro-, small and medium companies, along with carriers transporting pellets, but are assumed to increase pellet losses. The overall measures and procedures are described in Box 4. Possible further reductions in administrative costs are quantified in Box 5 and they are different from other figures in the Impact Assessment.

Box 5: Possible further reductions in administrative costs due to additional lighter requirements conceived for SMEs (<u>not</u> yet foreseen in sub-Option 2b)

Possible **<u>additional</u>** lighter requirements for SMEs and transport providers would further reduce costs for internal assessments, external audit and/or certification and notification by EUR 24.6 million (from EUR 44 million down to EUR 19.4 million) compared to sub-option 2b. These include:

- For micro- and small companies and for transport providers: a EUR 12.7 million additional reduction in costs due to carry out risk assessments only instead of the obligation to carry out risk assessments and internal assessments (foreseen in sub-option 2b[145]) and 9.2 million additional reduction in costs due to no obligation to obtain external audit and/or certification (foreseen in sub-option 2b);

[143] Total initial costs are EUR 0.5 million for businesses, which have been annualised over a 5 year period using a discount rate of 3% (0.5 hour for medium and large businesses and 0.25 hour for small and micro businesses and using EU average wages (29 €/hour)). It is estimated that the internal assessment is already covering most of the related cost.

[144] Total initial costs are EUR 313 000 million for public authorities, which have been annualised over a 10 year period using a discount rate of 3% (50 person days in average for each Member State using EU average wages (29 €/hour)).

[145] Although micro and small companies and the transport providers do not need to carry out *internal* assessment, it is still estimated that 50% of the related cost needed to carry out *risk* assessments and compile the self-declaration.

- For medium companies: EUR 1.9 million additional reduction due to a reduced frequency of certification (every 4 years instead of every year as foreseen in sub-option 2b);
- For large companies: EUR 0.8 million additional reduction due to a reduced frequency of certification (every 3 years instead of every year as foreseen in sub-option 2b).

In addition to the reduction of EUR 24.6 million described above, it can be assumed that these measures would also lead to an additional 10% reduction in personnel costs (related to pellet reduction measures) for micro- and small enterprises and for all transport providers (in addition to the 10% reduction already foreseen in sub-option 2b). This would translate to an additional cost reduction of EUR 16.9 million.

The sum of the possible additional reduction of costs of EUR 41.5 million would be around 8-11% of the total net cost as calculated for sub-option 2b. For micro and small enterprises, the additional reduction is equivalent to almost 15% of the net cost.

It is difficult to estimate the consequence of these additional lighter requirements on the reduction of pellet losses; there is no data available. It is probable that additional lighter requirements lead to an increase in pellet losses.

If assumed that pellet losses would increase with 10%, then these additional lighter requirements would lower the reduction in pellet losses by about 2 500 to 14 000 t/year compared to sub-option 2b.

The net costs of the preferred policy option can be compared to those calculated for the REACH restriction on microplastics intentionally added to products[146]. The REACH restriction would result in a cumulative emission reduction of approximately 500 000 tonnes of microplastics (central scenario) over the 20-year period following its entry into force (including an 8-year transitional period for fragrance encapsulates); the corresponding total restriction costs would be EUR 9.3 billion (between EUR 2.1 billion and EUR 20.6 billion)[147]. While the costs calculated for the preferred option 2b would be similar the ones in REACH, the preferred option 2b would reduce significantly more microplastics (83 000 tonnes per year) than under the REACH restriction (an average of 25 000 tonnes per year). Therefor the preferred policy option 2b is about 3 to 4 times more efficient than the REACH restriction.

The net costs of the preferred policy option can also be compared to the Impact Assessment for single-use plastics (SUP), for the relevant Directive[148]. It was estimated that the SUPD would save around 9 000 tonnes of SUP, for a loss of business turnover of around 3.8 billion EUR and additional costs of 2.8 billion on information, compliance and waste management. While the methodologies used in both IA are clearly different, the cost efficiency ratio on pellets is clearly higher than for the SUPD, as this analysis estimates a minimum reduction in pellet losses to the environment of 25 000 tonnes for net costs of 491 million EUR per year.

The proposal will also make a significant contribution to the EU reduction target for microplastic releases, as outlined in Box 6.

[146] Commission Regulation (EU) …/… amending Annex XVII to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles.

[147] Compiled opinion of the Committee for Risk Assessment (RAC) and of the Committee for Socio-economic Analysis (SEAC)

[148] SWD(2018) 254 final (Circabc (europa.eu))

Box 6: Contribution of the preferred option to Zero Pollution Action Plan target

This Impact Assessment concludes that the preferred option could contribute to achieving ¼ of the Zero Pollution Action Plan target for a 30% reduction in releases by 2030. This is a relatively high contribution compared to its contribution to microplastic releases (7-10%) and suggests that this course of action should be pursued.

8.2.2 SMEs

A consultation targeting specifically SMEs handling pellets was conducted from January to February 2023 in all EU languages (Annex 12). For a majority of the 330 replies received, only a lighter version of requirements could be imposed. Specifically, they reported that the requirement on the training of staff should be made mandatory for all companies, but that the obligation of being externally audited and certified should not be imposed at all on SMEs. The survey also indicated that the direct economic impacts of all the requirements would be proportionally more significant for micro and small companies, considering their limited staff compared to medium and large companies. They also appeared to be too burdensome for companies with a capacity below 1 000 tonnes per year. Among the various best handling practices, the mandatory use of specific equipment and of specific packaging (i.e. airtight, puncture-resistant and environmentally sealed) was identified as the most expensive measure. Generally, the cost per tonne of the measures to be implemented would become insignificant for companies with capacities above 5000t. Finally, financial support and a measurement standard for pellet losses were identified as the support that would best help respondents.

In order to reply to the survey and minimise burden, sub-Options were assessed, and sub-Option 2b with lighter requirements for micro- and small enterprises chosen. Medium companies are not included in the lighter regime as the costs are significantly less burdensome to them, as emerged both during the targeted survey and our cost analysis. Further mitigating measures can be envisaged, such as a delayed phasing-in of the requirements, longer validity periods for the auditing results, differences in obligations (external audit or certification) and financial and non-financial support to tackle concerns raised by SMEs (lack of staff/time, lack of information on risks and solutions and lack of financial resources, see Box 5 and Annex 12). In addition, SMEs can benefit from various EU programmes and support mechanism to help them implement this initiative (COSME, Enterprise Europe, InvestEU, Horizon), along with national support through Cohesion policy and NEXTGEN EU.

The Commission and Member States could provide some non-financial support. For example, a project could be supported by the Commission which would:

1 develop SME-specific guidance and training materials and tools to help compliance with the new legal requirements and certification;
2 deliver advisory services; and
3 establish a help desk/expert pool to assist first-level advisers and deal with more difficult questions or issues.

Such support can be open potentially to larger companies. This non-financial support would incur costs for the competent authorities and/or the Commission (with a budget of around EUR 1 million).

8.2.3 Competitiveness

According to EUPC, the turnover of the plastics sector in the EU27 in 2021 was EUR 405 billion. Therefore, the additional estimated cost of option 2b would represent about 0.13% of the EU plastics sector turnover. The additional costs are likely to have a very minor negative impact on the competitiveness of the EU pellet producers, as their competitors outside the EU will not be subject to the requirements (logistical operators importing pellets will have to comply within the EU). Annex 5 further details the preferred option's impact on the competitiveness of the sector and of SMEs.

8.3 REFIT & administrative costs

There are no administrative costs for citizens.

There are administrative costs of EUR 44 million for businesses:

- One-off costs (EUR 0.1 million[149]) of setting up systems in businesses for administrative procedures to report pellet losses;
- Reccurent costs (EUR 43.9 million) for internal assessments, external auditing and certification:
    - internal assessment – EUR 30.8 million;
    - external audit and/or certificate – EUR 12.9 million;
    - filling forms and tables – EUR 0.2 million (for notifying public authorities of the certification).

These costs are calculated for the preferred option 2b; they do not take into account the additional reductions described in Box 5.

8.4 Policy instrument

A Regulation would be best suited to delivering the mandatory requirements foreseen under the preferred option, as it will ensure pellet-handling companies will only have to comply with one set of requirements across the Union that will be directly applicable ensuring equal implementation in the Member States. The entire pellet supply chain will be subject to these requirements, and Member States will be responsible for enforcement.

9 HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

Whilst the existing data is sufficient to underpin a policy response, more monitoring is needed to further understand the dimension and impacts of the problem, inform further policy developments and track the possible success of the proposed actions. Therefore, Option 1 was proposed under the preferred options. In order to track performance against the 30% microplastic emission reduction target (by 2030), an estimate of total pellet losses is required. An initial estimate has been compiled for this IA, but further work should continually improve and expand this into the coming years. Based on the results of the monitoring in 2030, a review of this initiative will take place.

[149] Total initial cost are EUR 0.5 million for businesses, which have been annualised over a 5 year period using a discount rate of 3% (0.5 hour for medium and large businesses and 0.25 hour for small and micro businesses and using EU average wages (29 €/hour)). It is estimated that the internal assessment is already covering most of the related cost.

In the OPC, apart from business associations who somewhat agree, all other stakeholders completely agree with a system to monitor and report microplastic releases throughout the life-cycle.

The following monitoring of microplastics could be helpful:

- The proposed monitoring of microplastics at the inlet and outlet of UWWTPs, as well as in the sludge, included in the proposal for the revision of the UWWTD.
- The obligation to monitor and assess microplastics (including pellets) in coastal and marine environments, in the framework of the MSFD. Regulatory thresholds for the concentration of microlitter, including microplastics, are under preparation.
- The preparatory work for the revision of the list of polluting substances under the EQSD, the GWD and the Water Framework Directive, including the setting of a methodology to monitor microplastics in the aquatic environment as well as in the Drinking Water Directive.

In addition, standardised measurement measures could be developed for the unintentional releases of microplastics from the other five main sources. These could be pursued through Research and Innovation Programmes by relevant research projects or under the Standardisation Regulation.[150]

The information will need to be reported at Member State level and collated at EU level in order to create synergies and consistency between policies. This could also help identify new sources of microplastics that would need to be addressed by specific measures in the future

[150] Regulation (EU) No 1025/2012 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 and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC.